July 31, 2018

VIA ELECTRONIC SUBMISSION

The Honorable Alex Azar, Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: Notice of Proposed Rulemaking: Compliance With Statutory Program Integrity Requirements

Dear Secretary Azar:

The National Health Law Program ("NHeLP") appreciates the opportunity to comment on the proposed changes to the regulations governing the Title X program, published in the Federal Register on June 1, 2018.[1] The National Health Law Program (NHeLP) is a public interest law firm working to protect and advance the health rights of low-income and underserved individuals. Founded in 1969, NHeLP advocates, litigates, and educates at the federal and state levels. Consistent with its mission, NHeLP works to ensure that all people in the United States have access to the full range of reproductive health services and methods.

NHeLP strongly opposes the proposed changes to Title X. Title X is the only federal program in the country dedicated solely to providing family planning and related preventive services. In 2016, Title X sites provided high quality family planning services to more than four million patients.[2] The program is a critical source of health care for low-income and underserved individuals and communities. In 2016, 64 percent of Title X patients had family incomes at or below the federal poverty level (FPL), and 24

[1] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. 25502 (June 1, 2018) (to be codified at 42 CFR Part 59).
[2] Dep't of Health & Human Servs., Off. of Population Affairs, *Title X Family Planning Annual Report: 2016 National Summary* (2017), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf [hereinafter "*Title X Annual Report*"].

percent had incomes between 101 percent and 250 percent of the FPL.[3] Nearly one-third of patients self-identified as nonwhite, one-third as Hispanic or Latino, and 13 percent were limited English proficient.[4] In addition, 18 percent of patients were under age 20.[5]

The proposed changes would severely undermine the effectiveness of the Title X program.[6] By reconfiguring who receives Title X funding, as well as the scope of family planning methods and services that those providers offer, the proposed regulations would make it more difficult for low-income individuals to obtain the quality family planning services that they need and have historically received.

I. The proposed rule would reduce low-income individuals' access to the full range of contraceptive methods and services

To have true control over their bodies and their health, individuals need access to the full range of contraceptive methods and services. In addition, evidence indicates that access to all available contraceptive methods leads to better health outcomes.[7] Women who are able to use the method of their choice are more likely to use contraception consistently and effectively.[8] When women use contraception consistently and correctly, their risk of unintended pregnancy drops significantly.[9]

Consistent with this evidence, the Department of Health and Human Services (HHS) has taken steps to ensure that individuals have access to all FDA-approved contraceptive methods. For example, the Affordable Care Act requires most private plans to cover women's preventive health services with no cost sharing and directs the

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[3] *Id*. at 21.
[4] *Id*. at 12, 24.
[5] *Id*. at 9.
[6] *See* Dep't of Health & Human Servs., *Announcement of Anticipated Availability of Funds for Family Planning Services Grants* (2018), https://www.hhs.gov/opa/sites/default/files/FY18-Title-X-Services-FOA-Final-Signed.pdf.
[7] *See* Adam Sonfield, *Why Family Planning Policy and Practice Must Guarantee a True Choice of Contraceptive Methods*, 20 GUTTMACHER POLICY REVIEW 103 (2017), https://www.guttmacher.org/sites/default/files/article_files/gpr2010317.pdf.
[8] *See* Caroline Moreau et al., *Social, Demographic and Situational Characteristics Associated with Inconsistent Use of Oral Contraceptives: Evidence from France*, 38(4) PERSPECTIVES ON SEXUAL & REPRODUCTIVE HEALTH 190 (2006), https://www.guttmacher.org/sites/default/files/article_files/3819006.pdf; Joanne Noone, *Finding the Best Fit: A Grounded Theory of Contraceptive Decision Making in Women*, 39(4) NURSING FORUM 13 (2004); Loretta Gavin et al., Ctrs. for Disease Control and Prevention & U.S. Off. of Population Affairs, Providing Qualify Family Planning Services: Recommendations of CDC and the U.S. Off. of Population Affairs, MORBIDITY & MORTALITY WEEKLY REP. at 37 (April 25, 2014), http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf [hereinafter "QFP"].
[9] *See* Adam Sonfield et al., Guttmacher Inst., *Moving Forward: Family Planning in the Era of Health Reform* at 8, 9 (2014), https://www.guttmacher.org/sites/default/files/report_pdf/family-planning-and-health-reform.pdf.

Health Resources & Services Administration (HRSA) to define those services.[10] Upon the recommendation of the independent Institute of Medicine, in 2011 HRSA defined women's preventive health services to include all female-controlled FDA-approved contraceptive methods. HRSA reaffirmed its position in 2016.[11] In addition, as part of its Healthy People 2020 campaign, the Office of Disease Prevention and Health Promotion established a goal of increasing the proportion of publicly funded family planning clinics that offer the full range of FDA-approved contraceptive methods onsite.[12] Similarly, in 2014 the Office of Population Affairs and the Centers for Disease Control and Prevention (CDC) issued joint recommendations for providing quality family planning services.[13] The evidence-based recommendations support offering a full range of FDA-approved contraceptive methods.[14]

The NPRM represents a stunning and dangerous shift from this position. Instead of continuing to promote evidence-based and patient-centered standards of care, the proposed regulations promote HHS's ideological preferences for particular methods and services, namely natural family planning (abstinence) to prevent pregnancy and adoption to "manage" infertility.

Changes to Title X Services (§§ 59.2, 59.5)

First, HHS seeks to transform the meaning of family planning, proposing a definition of the term that emphasizes non-medical services, such as abstinence, natural family planning, and adoption as a way to manage infertility.[15] HHS's emphasis on non-medical services is misplaced, as Congress designed Title X to provide health care services to people who did not have the means to access the most effective methods to prevent pregnancy.[16] Significantly, data shows that fertility awareness methods are among the least effective family planning methods.[17] In fact, the FDA has warned that

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[10] 42 U.S.C. § 300gg-13(a)(4).
[11] Health Resources & Servs. Admin., *Women's Preventive Services Guidelines* (last updated Oct. 2017), https://www.hrsa.gov/womens-guidelines-2016/index.html.
[12] Off. of Disease Prevention and Health Promotion, Healthy People 2020 Topics & Objectives, Family Planning https://www.healthypeople.gov/2020/topics-objectives/topic/family-planning/objectives.
[13] QFP*, supra* note 8.
[14] QFP, *supra* note 8, at 2, 7. In addition, prior administrations have required applicants who do not intend to offer all FDA-approved contraceptive methods within their project to provide a justification for excluding a particular method. *See* OPA, *Announcement of Anticipated Availability of Funds for Family Planning Services Grants* (FY 2017), https://www.hhs.gov/opa/sites/default/files/FY-17-Title-X-FOA-New-Competitions.pdf.
[15] 83 Fed Reg. at 25529 (§ 59.2).
[16] S. Rep. No. 91-1004, at 9 (1970).
[17] QFP, *supra* note 8, at 47.

these methods are not reliable forms of contraception.[18] This is likely one of the reasons why very few women choose to use natural family planning to prevent pregnancy.[19]

Second, in keeping with its emphasis on abstinence, fertility awareness methods, and adoption, HHS proposes several changes to section 59.5(a), which sets forth the basic requirements for Title X projects. The current provision requires each Title X project to "[p]rovide 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)."[20] HHS seeks to delete the term "medically approved" and instead add fertility awareness methods of family planning. In the preamble, HHS emphasizes that fertility awareness methods, many of which do not require FDA approval because they do not involve drugs or medical devices, qualify as acceptable and effective family planning methods. The agency cites the fact that HRSA added fertility awareness methods to the women's preventive health services guidelines in 2016. [21] Notably, HHS refrains from fully quoting the guidelines, which indicate that fertility awareness methods are "less effective," but "should be provided for women desiring an alternative method."[22]

Even more strikingly, proposed section 59.5(a)(1) would explicitly state that Title X projects need not provide every acceptable and effective family planning method or service, as long as they offer a "broad range" of family planning methods and services. However, the preamble indicates that a "broad range" does not mean all FDA-approved methods.[23] This represents a marked shift in position, as HHS has required Title X sites to follow the Quality Family Planning Guidelines, which since 2014 have recommended providing all FDA-approved contraceptive methods.[24] In explaining its rationale for the shift, HHS claims that it is difficult and expensive for projects to offer all acceptable and effective family planning methods. However, HHS cites no evidence indicating that entire projects have been unable to offer the full range of contraceptive methods or services, or that HHS has denied Title X funding to such projects in the past. Instead, HHS highlights providers who object to some or all forms of contraception and focuses on the need for more Title X sites that only offer natural family planning services.[25] It is

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[18] *See* FDA, iPledge Program FAQs 9 (2006), https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm094313.pdf.

[19] Megan L. Kavanaugh & Jenna Herman, *Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014*, 97 CONTRACEPTION 14 (2018), https://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf (finding that 2 percent of women who use a contraceptive method use natural family planning).

[20] 42 C.F.R. § 59.5(a)(1).

[21] 83 Fed Reg. at 25515.

[22] *Women's Preventive Services Guidelines*, *supra* note 11.

[23] 83 Fed. Reg. at 25516.

[24] *See, e.g.*, OPA, *Announcement of Anticipated Availability of Funds for Family Planning Services Grants* (FY 2017), https://www.hhs.gov/opa/sites/default/files/FY-17-Title-X-FOA-New-Competitions.pdf.

[25] 83 Fed. Reg. at 25516.

clear that HHS designed the proposed rules to cater to providers who refuse to provide the quality family planning services that Title X patients need.

Taken together, these changes could reduce low-income individuals' access to the full range of contraceptive methods and services. Due at least in part to current program requirements, Title X providers are more likely than many other providers to offer comprehensive family planning services. For example, 72 percent of publicly funded family planning centers that participate in Title X offer all FDA-approved methods onsite, compared with 49 percent of publicly funded centers that do not participate in Title X.[26] Similarly, Title X clinics are more likely than non-Title X clinics to use protocols designed to facilitate initiation and continuation of contraception.[27]

A recent survey of community health centers further confirms the relationship between receiving Title X funding and providing quality family planning services.[28] Title X-funded community health centers consistently offer a larger range of contraceptive methods onsite. When compared to sites that do not receive Title X funding, "Title-X funded sites also consistently show greater incorporation of evidence-based best practice methods . . . are more likely to follow best practices related to screening and counseling . . . [and] are also far more likely – 43 percent compared to 16 percent – to have health counselors or educators providing family planning counseling."[29]

If finalized, the proposed rule would likely reverse the progress Title X providers have made in offering quality family planning services, making it more difficult for Title X patients to access their preferred contraceptive method. With fewer Title X sites offering the full range of contraceptive services and methods, low-income individuals could be forced to settle for a method that is not right for them or to forgo contraception altogether.

Changes to the criteria for reviewing applications (§59.7)

Other proposed changes further reflect HHS's desire to fund providers that only offer natural family planning services. For example, HHS proposes to alter the criteria it uses to decide which applicants receive Title X funding. The statute requires HHS to consider four factors: the number of patients to be served; the extent to which family planning services are needed locally; the relative need of the applicant; and its capacity to make

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[26] Mia R. Zolna & Jennifer J. Frost, Guttmacher Inst., *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols* at 30, 35 (2016), https://www.guttmacher.org/sites/default/files/report_pdf/publicly-funded-family-planning-clinic-survey-2015_1.pdf.
[27] *Id*. at 19, 21.
[28] *See* Susan F. Wood et al., George Washington Univ. & Kaiser Family Found, *Community Health Centers and Family Planning in an Era of Policy Uncertainty* (2018), http://files.kff.org/attachment/Report-Community-Health-Centers-and-Family-Planning-in-an-Era-of-Policy-Uncertainty.
[29] *Id*. at 2.

rapid and effective use of such assistance.[30] Since 1971, HHS has considered these four factors, as well as three others: the adequacy of the applicant's facilities and staff; the relative availability of non-federal resources within the community and the degree to which those resources are committed to the project; and the degree to which the project plan adequately provides for the requirements set forth in the Title X regulations.[31] In the name of increasing "competition and rigor among applicants," HHS intends to change these criteria.[32] In particular, HHS proposes to emphasize whether or not an applicant has "a broad range of partners and diverse subrecipients and referral individuals and organizations, including non-traditional partnering organizations." Likewise, HHS seeks to consider whether or not the applicant proposes "innovative" methods for serving unserved or underserved patients.[33]

Here, HHS is using words such as "diverse" and "non-traditional" as code for faith-based providers that oppose abortion and some or all forms of contraception. In fact, HHS is quite clear that it intends to increase the number of Title X providers serving "patients who seek providers who share their religious or moral convictions."[34] This effort to shift the Title X network away from experienced Title X providers that deliver evidence-based, comprehensive family planning services further threatens the ability of low-income individuals to receive high quality health care, including all FDA-approved contraceptive methods and services.

II. The proposed rule would impose onerous separation requirements on Title X providers, upending the Title X network and leaving low-income individuals without access to adequate care and services

For several decades, HHS has interpreted the Title X statute to require projects to maintain financial separation between Title X activities and abortion services. Now, in a complete reinterpretation of the statute, HHS contends that the statute requires providers to establish a "wall of separation" between Title X activities and a specific list of prohibited activities.[35] The proposed rule requires that providers must maintain separate accounting records, facilities (including treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites), personnel, health care records, and signs and other forms of identification.[36] Imposing these onerous conditions on providers is unwarranted and guaranteed to interrupt patient care.

The change targets Title X clinics that use separate, non-federal funding to offer abortion services. Contrary to HHS's assertions, these clinics would simply be unable to

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[30] 42 U.S.C. § 300(b).
[31] *See* 42 C.F.R. § 59.7(a).
[32] 83 Fed. Reg. at 25511.
[33] *Id*. at 25530 (§ 59.7).
[34] *Id*. at 25526.
[35] *Id*. at 25506.
[36] *Id*. at 25532 (§ 59.15).

meet the proposed separation requirements. In addition, the change could affect Title X providers who do not offer abortion services, as the list of prohibited activities that require complete separation is both broad and vague.[37] As a result, the change would eliminate a large number of specialized family planning providers from the Title X network. For example, in 2015 Planned Parenthood health centers alone represented 13 percent of Title X-funded clinics and served more than 40 percent of all contraceptive clients.[38]

Past experience proves that eliminating these providers from the Title X network would have devastating consequences for low-income individuals in need of family planning services. In 2013, Texas excluded providers who offer abortion services or affiliate with providers who do so from its state program that provides family planning services to low-income women. A large body of research shows the harmful effect of this decision on access to family planning services. Between 2011 and 2015, the number of women who received family planning services dropped by nearly 15 percent.[39] Further, 26 percent of women enrolled in the program in 2016 had never received health services through the program, up from 10 percent in 2011.[40] Similarly, utilization of contraception among women enrolled in the program dropped significantly. Between 2011 and 2015, claims or prescriptions filled for all contraceptive methods dropped 41 percent, including dramatic decreases in women obtaining injectable contraceptives, oral contraceptives, condoms, and the contraceptive patch and ring.[41] In addition, according to research published in the *New England Journal of Medicine*, claims for long-acting reversible contraceptives (LARCs) – the most effective reversible contraceptive method – fell by

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[37] *Id*. (§ 59.15 (requiring separation for activities prohibited under §§ 59.13, 59.14, and 59.16).
[38] Jennifer J. Frost et al., Guttmacher Inst., *Publicly Funded Contraceptive Services at U.S. Clinics, 2015* (2017), https://www.guttmacher.org/sites/default/files/report_pdf/publicly_funded_contraceptive_services_2015_3.pdf.
[39] Kinsey Hasstedt & Adam Sonfield, Guttmacher Inst., *At It Again: Texas Continues to Undercut Access to Reproductive Health* (2017), https://www.guttmacher.org/article/2017/07/it-again-texas-continues-undercut-access-reproductive-health-care (citing Tex. Health & Human Servs. Comm'n, *Final Report of the Former Texas Women's Health Program: Fiscal Year 2015 Savings and Performance* (2017), https://hhs.texas.gov/reports/2017/03/former-texas-womens-health-program-fiscal-year-2015-savings-performance).
[40] Ctr. for Pub. Pol'y Priorities, *Excluding Planned Parenthood Has Been Terrible for Texas Women and Texas Still Wants Medicaid to Pay for its Bad Idea* at 7 (2017), https://forabettertexas.org/images/HW_2017_08_PlannedParenthoodExclusion.pdf.
[41] Tex. Health & Human Servs. Comm'n, *Final Report of the Former Texas Women's Health Program: Fiscal Year 2015 Savings and Performance* 8 (2017), https://hhs.texas.gov/reports/2017/03/former-texas-womens-health-program-fiscal-year-2015-savings-performance (reporting a 32 percent decrease in claims for contraceptive injections, 47% decrease for oral contraceptives, and 59 percent decrease for condoms).

nearly 36 percent after Texas removed certain family planning providers from its program.[42]

The evidence from Texas is overwhelmingly clear – eliminating providers who perform or promote abortion services (or affiliate with providers who do so) from a family planning program designed to serve low-income individuals reduces access to health care. Other states that have prevented certain providers from receiving Title X funding have likewise seen a serious reduction in access to services.[43] Given the evidence, HHS's assertion that the proposed rule is likely to increase access to family planning services strains all logic.[44]

III. The proposed restrictions on abortion referrals and counseling would prevent patients from receiving full and accurate information about their pregnancy options

Referral and counseling restrictions

Consistent with ethical and medical standards described below, the current Title X regulations require projects to give pregnant patients the opportunity to receive information and counseling about: prenatal care and delivery; infant care, foster care, or adoption; and abortion. If a patient requests such information and counseling, projects must provide neutral, factual information and nondirective counseling on each of the options, as well as referrals upon request.[45]

HHS proposes several changes, all of which would undermine the provider-patient relationship and cause significant harm to pregnant individuals. First, HHS proposes to eliminate the requirement that Title X projects provide neutral, factual information and nondirective options counseling to pregnant individuals.[46] While HHS states in the preamble that a doctor would be permitted to provide nondirective counseling on abortion, the proposed regulations themselves would prohibit projects from "encouraging," "promoting," or "presenting" abortion.[47] At a minimum, these changes would have a chilling effect on providers, who could fear even mentioning the word abortion while counseling a pregnant patient on their options would violate the Title X

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[42] Amanda Stevenson et al., *Effect of Removal of Planned Parenthood from the Texas Women's Health Program*, 374 NEJM 853 (2016), https://www.nejm.org/doi/full/10.1056/nejmsa1511902.
[43] Compliance With Title X Requirements by Project Recipients in Selecting Subrecipients, 81 Fed. Reg. 91852, 91852-91853 (Dec. 16, 2016) (highlighting that after Kansas prohibited certain providers from receiving Title X funding, the number of patients served declined over 37 percent).
[44] *See* 83 Fed. Reg. 25525.
[45] 42 C.F.R. § 59.5(a)(5).
[46] 83 Fed. Reg. at 25530 (§ 59.5(a)).
[47] *Id*. at 22506; 25531 (§ 59.14).

regulations. Moreover, HHS's use of the word "doctor" in the preamble is problematic, as most providers in the Title X network are mid-level clinicians.

Second, HHS seeks to prohibit Title X projects from providing abortion referrals.[48] Furthermore, the proposed changes seem to encourage projects to provide confusing and even misleading referral information to pregnant individuals. When a pregnant patient clearly states that she has already decided to have an abortion and explicitly requests a referral, a physician (and only a physician) may – but is not required to – 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)."[49] However, neither the physician nor the list may indicate which providers on this list offer abortion services.[50] In essence, the doctor may or may not choose to provide the list, the list may include a long list of providers, which may or may not offer abortion services, and the patient would have to identify on her own which providers – if any – in fact offer abortion services. Moreover, when a pregnant patient does not clearly state that she has already decided to have an abortion, but explicitly requests a referral for an abortion, the patient must be given "a list of licensed, qualified, comprehensive health service providers (including providers of prenatal care) who do not provide abortion as part of their services."[51]

These proposed changes to the regulations would force Title X providers to violate their ethical obligations to their patients. Providers must provide patients with complete, accurate, and unbiased information about their health care options so that they can make voluntary decisions about their care.[52] The American Medical Association describes withholding information from patients as "ethically unacceptable."[53]

Established standards of care for providing treatment to pregnant individuals reflect these principles. Recommendations issued by the Office of Population Affairs and the Centers for Disease Control and Prevention make clear that providers should be respectful of, and responsive to, patients' needs, values, and preferences.[54] The recommendations direct family planning practitioners to provide options counseling to

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[48] 83 Fed. Reg. at 25530 (§ 59.14).
[49] *Id*.
[50] *Id*.
[51] *Id*.
[52] *See* AMA, Informed Consent, Code of Medical Ethics Opinion 2.1.1, https://www.ama-assn.org/delivering-care/informed-consent; ACOG, *Committee Opinion Number 439: Informed Consent* (reaffirmed 2015), https://www.acog.org/-/media/Committee-Opinions/Committee-on-Ethics/co439.pdf?dmc=1&ts=20180710T1746338624
[53] *See* AMA, Withholding Information from Patients, Code of Medicaid Ethics Opinion 2.1.3, https://www.ama-assn.org/delivering-care/withholding-information-patients.
[54] QFP, *supra* note 8, at 13.

pregnant patients "in accordance with recommendations from professional medical associations, such as ACOG and AAP [American Academy of Pediatrics]."[55] According to the AAP, pediatricians should provide nonjudgmental counseling, including a factual and accurate discussion of all options available to the patient, including abortion.[56] Pediatricians should also refer patients who are considering abortion to a trained abortion provider for further information and counseling.[57] Likewise, ACOG recommends that a "pregnant woman who may be ambivalent about her pregnancy should be fully informed in a balanced manner about all options, including raising the child herself, placing the child for adoption, and abortion. . . There is an ethical obligation to provide accurate information that is required for the patient to make a fully informed decision."[58]

The purpose of these clinical guidelines is to protect patients and help ensure that they receive high quality, evidence-based care. If Title X providers are no longer able to follow the established standards of care due to the federal regulations, patients would suffer serious consequences. Some pregnant patients might not know that abortion is an option for them. Even pregnant individuals who are aware of the option could experience a delay in receiving care because they have trouble locating an abortion provider. Notably, time is of the essence for pregnant patients – the longer it takes to access abortion services, the more complicated and costly the procedure would be. Moreover, as more than half of states in the country prohibit abortion procedures after 20 weeks, any delay could force a patient to unwillingly carry a pregnancy to term, possibly jeopardizing her health and well-being.[59]

Tellingly, many Title X providers have already spoken out about the serious ethical concerns raised by the proposed regulations on abortion counseling and referral. The National Association of Community Health Centers denounced the proposed changes, stating that they would impermissibly interfere with the provider-patient relationship and "remove the guarantee that people get full and accurate information about health care

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[55] *Id*.
[56] Laure L. Hornberger, Committee on Adolescence, *Options Counseling for the Pregnant Adolescent Patient, Policy Statement of the American Academy of Pediatrics*, 140 PEDIATRICS e20172273 (2017), http://pediatrics.aappublications.org/content/pediatrics/140/3/e20172274.full.pdf.
[57] *Id*.
[58] ACOG, *College Statement of Policy: Abortion Policy* (revised 2014), https://www.acog.org/-/media/Statements-of-Policy/Public/sop069.pdf?dmc=1&ts=20180710T1333046794.
[59] Kinsey Hasstedt, *Unbiased Information on and Referral for All Pregnancy Options Are Essential to Informed Consent in Reproductive Health Care*, 21 Guttmacher Policy Review 1 (2018), https://www.guttmacher.org/sites/default/files/article_files/gpr2100118.pdf.

from their doctors."[60] The proposed rule could also create medical liability risk for community health centers and conflict with their legal obligations under Section 330.[61] Thus, if the proposed rule is finalized, community health centers could very well decide to drop out of the Title X program, further shrinking the Title X network and causing many individuals to lose critical access to family planning services.[62]

Forced referral for prenatal care

In contrast to the prohibition on referring for abortion, the proposed rule would mandate that all pregnant patients be referred for prenatal and social services, such as infant or foster care, and "be given assistance with setting up a referral" – regardless of their wishes or health status.[63] Again, this requirement conflicts with medical ethics and the established standards of care described above and is harmful to patients. In the long term, patients would no longer trust their providers to provide full and accurate information about their health care. The implications are worse for the population that Title X most serves – low-income women and women of color – who have experienced coercive and other damaging treatment in the context of reproductive health care.

IV. The proposed rule would deter minors from seeking needed services, putting their health and wellbeing at risk

In 1978, Congress amended Title X to make clear that projects must provide services to adolescents.[64] The current regulations implement that intent, requiring Title X sites to provide services to adolescents on a confidential basis.[65] To ensure that minors are able to receive confidential services, the existing regulations require sites to consider if minors meet the definition of a "low-income family" (and thereby qualify for free family planning services) on the basis of their income alone.[66]

These policies make good sense. HHS has noted that the U.S. has one of the highest adolescent pregnancy rates in the developed world, with more than 700,000 individuals between ages 15 and 19 becoming pregnant each year.[67] In addition, adolescents and young adults are more likely to acquire sexually transmitted infections "for a

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[60] Nat'l Ass'n of Community Health Ctrs, NACHC Statement Regarding the Proposed Rule for Title X Funding (June 5, 2018), http://www.nachc.org/news/new-nachc-statement-regarding-the-proposed-rule-for-title-x-funding/.
[61] Sara Rosenbaum et al., *The Title X Family Planning Proposed Rule: What's at Stake For Community Health Centers?* Health Affairs Blog (June 25, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180621.675764/full/.
[62] *Id*.
[63] 83 Fed. Reg. 25531.
[64] *See* Pub. L. No. 95-613, 92 Stat. 3093 (1978) (codified at 42 U.S.C. § 300(a)).
[65] 42 C.F.R. §§ 59.2, 59.11.
[66] *Id*. § 59.2.
[67] QFP, *supra* note 8, at 1.

combination of behavioral, biological, and cultural reasons." [68] The CDC has noted that "[t]he higher prevalence of STDs among adolescents may also reflect multiple barriers to accessing quality STD prevention and management services, including inability to pay, lack of transportation, long waiting times, conflict between clinic hours and work and school schedules . . . and concerns about confidentiality."[69] In fact, substantial research shows that confidentiality can greatly influence adolescents' willingness to access and use family planning services whenever they need them.[70]

If finalized, the proposed rules could increase several of these barriers, further compromising minors' access to family planning and other critical health services. A number of the proposed changes discussed above would result in fewer Title X providers offering the full range of contraceptive methods, meaning that individuals would likely have longer wait times and/or would have to travel further to access the family planning methods and services that they need. These added burdens would be a particular barrier to adolescents, who often have fewer resources than adults and less freedom to travel.

In addition, the proposed rules would impose requirements on providers that could have a chilling effect on minors' willingness to seek needed services through Title X. Existing law requires Title X grantees to certify that they encourage minors to include their family in their decision to seek family planning services.[71] The proposed rule goes further. Title X sites may only offer free services to a minor if they document in their medical record the specific actions taken to encourage the minor to involve their parent(s) or guardian(s) in their decision to seek family planning services.[72] The proposed provision contains a narrow exception – providers need not document encouragement if they suspect that the minor is the victim of child abuse or incest, and they have reported the situation to the relevant authorities if required or permitted by state or local law.[73] Title X projects would have to meet similar documentation requirements for minor patients who are not seeking free care.[74]

In addition, proposed section 59.17 would require Title X projects to document their compliance with state and local laws requiring notification or reporting of various criminal conduct. As part of that documentation, Title X providers would be required to maintain records indicating the age of each minor patient served, the age of each minor patient's sexual partner(s), if required by law, and each notification or report made to

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[68] Ctrs. for Disease Control and Prevention, *Sexually Transmitted Disease Surveillance 2016* at 43 (2017), https://www.cdc.gov/std/stats16/CDC_2016_STDS_Report-for508WebSep21_2017_1644.pdf.
[69] *Id*.
[70] QFP, *supra* note 8, at 13.
[71] 42 U.S.C. § 300(a); Consolidated Appropriation Act, 2018, Pub. L. No. 115-141, Div. H, § 207, 132 Stat. 348, 736.
[72] 83 Fed. Reg. at 25529-30 (§ 59.2).
[73] *Id*.
[74] *Id*. at 25530 (§ 59.5(a)(14)).

state officials.[75] The same section would require Title X projects to conduct a special screening when any patient under the age of consent in the jurisdiction presents with an STD or pregnancy. The purpose of the screening would be to "rule out victimization of a minor."[76]

While protecting minors from criminal conduct is of critical importance, the proposed changes would not further that goal. Instead, the changes would simply undermine the relationship between Title X providers and their patients and prevent minors who have concerns about confidentiality from seeking needed medical services, putting their health at risk. HHS should focus on promoting policies and practices proven to improve adolescent health, such as providing age-appropriate sex education and ensuring that minors have access to high quality, youth-friendly and confidential family planning services.[77]

V. The proposed definition of "low-income family" is contrary to the text and purpose of Title X

HHS is proposing a change to the definition of "low-income family" that does not comport with the language of the statute or the intention of the Title X program. Under the proposed rule, a "low-income family" would include a woman who has health insurance through an employer, but whose employer refuses to cover contraceptive services because of a "sincerely held religious or moral objection to providing such coverage."[78] The change is completely untethered to the text and history of Title X and subverts the intent of the program.

Since its inception, Title X has required projects to give priority to "persons from low-income families" and to provide services to such individuals free of charge.[79] The text of the statute, as well as the legislative history, indicates that Congress intended for Title X to serve individuals who would not otherwise be able to access family planning services on their own. In supporting the program's passage, President Nixon 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."[80] Other congressional materials also illustrate that Congress's central focus was on the "more than 5 million poor and near-poor women who, for the most part, have not been given the opportunity to avail themselves of family planning services in order

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[75] 83 Fed. Reg. at 25520, 25532-33 (§ 59.17).
[76] *Id*.
[77] *See* QFP, *supra* note 8, at 7, 13.
[78] 83 Fed. Reg. at 25530 (§ 59.2).
[79] *See* Fam. Plan. Servs. & Population Res. Act of 1970, Pub. L. No. 91-572, 84 Stat. 1504 (codified at 42 U.S.C. 300a-4(c)).
[80] Richard Nixon, Special Message to the Congress on Problems of Population Growth (July 18, 1969), http://www.presidency.ucsb.edu/ws/?pid=2132.

to exercise their right to determine the size and spacing of their families."[81] In short, Congress intended for "low-income" to refer to people who could not afford to access family planning services in the way that more affluent individuals could. While Title X gives the Secretary authority to define "low-income family," he may not do so in a way that completely disregards the obvious meaning of the term.

The current Title X program reflects Congress's central focus, primarily serving individuals who do not have the financial resources to access family planning and related preventive services. As noted above, of the more than four million patients who received Title X services in 2016, nearly two-thirds had incomes below the FPL, and 88 percent had incomes at or below 250 percent of the FPL.[82]

If finalized, the proposed definition could mean that fewer low-income individuals would receive Title X services. The Title X network does not have the capacity to serve a flurry of new middle-income patients who have insurance coverage through their employer nor the resources to serve those patients at low- or no-cost. Title X providers would be incapable of meeting these sudden and significant demands. The reality of who benefits from the Title X program would change significantly, to the detriment of those who need free to low-cost services the most. Congress did not design Title X to absorb the needs of higher-income, privately insured individuals, and the program would not have the capacity to meet the needs of current patients under the proposed rules. For example, approximately one-quarter of Title X sites are community health centers, and a recent survey indicates that few community health centers have the capacity to absorb a significant number of new patients.[83]

Notably, HHS is proposing this change to support its efforts to exempt any employer or university with a moral or religious objection to some or all contraception from its obligation to offer coverage of all FDA-approved contraceptive methods.[84] In particular, HHS has contended that the expanded exemption would not reduce access to care because women can simply receive services that their employer or university refuses to cover from a Title X provider. However, Congress did not design Title X as a substitute for private coverage. The statute explicitly contemplates that Title X and third-party payers, including employer-sponsored plans, would work together to pay for care, directing Title X-funded agencies to seek payment from such third-party payers.[85]

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[81] S. Rep. No. 91-1004, at 12 (1970).
[82] *See Title X Annual Report*, *supra* note 2.
[83] *See* Wood et al., *supra* note 28.
[84] *See* Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,803 (Oct. 13, 2017); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,838 (Oct. 13, 2017).
[85] 42 U.S.C. § 300a-4(c)(2) (prohibiting charging persons from a "low-income family" for family planning services "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"); 42 CFR § 59.5(a)(7), (9)).

Conclusion

We appreciate your consideration of our comments. We have included numerous citations to supporting research, including direct links to the research. We direct HHS to each of the studies we have cited and made available to through active links, and we request that the full text of each of the studies cited, along with the full text of our comment, be considered part of the formal administrative record on this proposed rule for purposes of the Administrative Procedure Act. If you have questions about these comments, please contact Susan Berke Fogel at fogel@healthlaw.org or at or (310) 736-1658.

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