July 31, 2018

VIA ELECTRONIC TRANSMISSION

Alex Azar, Secretary of Health and Human Services
Attention: Family Planning
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 716G
200 Independence Avenue SW
Washington, DC 20201

Valerie Huber, Senior Policy Advisor, Assistant Secretary for Health
Attention: Family Planning
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 716G
200 Independence Avenue SW
Washington, DC 20201

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

RE: RIN 0937-ZA00, Compliance With Statutory Program Integrity Requirements

Dear Secretary Azar, Senior Advisor Huber, and Deputy Assistant Secretary Foley:

The Federal AIDS Policy Partnership (FAPP) submits these comments and recommendations in response to the proposed rule by the Department of Health and Human Services (HHS), entitled "Compliance with Statutory Program Integrity Requirements," published in the Federal Register on June 1, 2018.[1] The proposed rule would significantly and detrimentally alter the Title X Family Planning Program (Title X)—the only federal program dedicated to providing vital sexual and reproductive health services to people across the country, primarily those low-income and under-served, for more than 40 years. Each year, Title X provides services to about four million clients nationwide.[2]

FAPP is a coalition comprised of more than 120 local, regional, and national organizations advocating for federal funding, legislation and policy to end the Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) epidemics in the United States. These organizations represent people living with HIV and HCV, and those most affected, including communities of color, gay men, women, and transgender people. Our partners include HIV medical, housing, food, and employment providers, as well as HIV/AIDS service and prevention organizations, state and bonusuri pariuri sportive local HIV health department programs, and legal advocates from across the U.S. and its territories.

Executive Summary:

As a coalition that serves populations in need of family planning and related preventive health services provided by Title X-funded clinics, we are uniquely qualified to speak to harmful impact of the proposed rule, including on individuals at higher risk for HIV. Title X delivery sites are integral providers of HIV and other STD prevention services for low income and uninsured individuals Title X sites provide HIV prevention and testing to more than 5 million low-income or uninsured people each year.[3] Moreover, at a minimum, all Title X-funded sites are required to provide HIV prevention education and testing, either on-site or by referral,[4] in addition to cancer and sexually transmitted infection (STI) screenings, a range of contraceptives, pregnancy testing, well-woman exams, and other relevant counseling and referrals. Title X was envisioned to provide "educational, comprehensive medical, and social services necessary to aid individuals to freely determine the number and spacing of their children."[5] This language is inclusive of *all* individuals, regardless of their financial or social background and access to

[1] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. 25502 (proposed Jun. 1, 2018) (to be codified at 42 C.F.R. pt. 59).
[2] Kiersten Gillette-Pierce and Jamila Taylor, *The Threat to Title X Family Planning,* CTR. AM. PROG. (Feb. 9, 2017), https://www.americanprogress.org/issues/women/reports/2017/02/09/414773/the-threat-to-title-x-family-planning/; *Title X Family Planning Annual Report 2016 Summary,* U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, https://www.hhs.gov/opa/title-x-family-planning/fp-annual-report/fpar-2016/index-text-only.html
[3] Vanessa White and Christine Brazell, *Family Planning Providers Key in Fight Against HIV,* HIV.GOV, https://www.hiv.gov/blog/family-planning-providers-key-in-fight-against-hiv.
[4] Vanessa White and Christine Brazell, *Family Planning Providers Key in Fight Against HIV,* HIV.GOV, https://www.hiv.gov/blog/family-planning-providers-key-in-fight-against-hiv.
[5] 42 C.F.R. § 59.1

health insurance, and inclusive of *all* services. The proposed rule, however, would restrict access to these critical services, including prevention and treatment for HIV and other STDs.

Contrary to Title X's mission to increase and diversify quality reproductive health and family planning services for the protection of health, welfare, and life, we are concerned that the proposed rule will lead to worse outcomes for women of color and other populations who disproportionately rely on these clinics for services, including individuals who are LGBTQ. In addition, the rule is likely to raise overall costs to the health care system due to delayed access to preventive and other healthcare services. Our comments focus on the following detriments of the rule:

The proposed rule would:

- Interfere with the provider-patient relationship and deny patients receiving services at Title X funded clinics from receiving complete and accurate medical information.
- Compromise the health and well-being of low-income and uninsured patients by restricting providers' financial, physical, and geographical capacity to deliver critical services, including treatment for HIV and STDs.
- Restrict access to family planning and reproductive health services for low-income and uninsured adults and adolescents.
- Underestimate significantly the costs imposed on patients, providers, the nation's health care system, and, therefore, taxpayers.

We strongly urge withdrawal of this rule due to the harms it will cause to low income and uninsured individuals, particularly women of color and individuals who are LGBTQ, and due its significant economic impact. Our justification along with additional recommendations follows.

I. Proposed 42 C.F.R. § 59.14 would interfere with the provider-patient relationship, undermine medical ethics, and deny Title X patients the complete information they require to make the best decisions for themselves and their families.

§ 59.14(a): Prohibition on Referral for Abortion

Proposed § 59.14(a)[6] would eliminate the existing requirement in 42 C.F.R. § 59.5(a)(5) that patients be provided with abortion referrals upon request, as part of the full range of health care options for pregnant women, including referrals for prenatal care and delivery, infant care, foster care, and adoption.[7] Specifically, the proposed rule would "expressly prohibit Title X projects from performing, promoting, referring for, or supporting, abortion as a method of family planning."[8] This rule mirrors the provisions of the Protecting Life in Global Health Assistance rule, which restricts providers globally from freely speaking with and fully informing their patients.[9] Further, proposed § 59.14(a) reinstates a similar rule introduced by President Reagan's

[6] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25518.
[7] 42 C.F.R. § 59.5(a)(5).
[8] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25518.
[9] *Factsheet: The Global Gag Rule and Human Rights,* CTR. FOR REPROD. RIGHTS, https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/GLP-GGR-FS-0118-Web.pdf.

Administration in 1988, which did not reach full implementation due to its concerning effects on access to care.[10]

Ethical Implications

This provision would interfere with the provider-patient relationship by effectively putting the government in the exam room. It undermines core medical and ethical standards and constitutional human rights to life, health and welfare, full information, autonomy, and privacy. Requiring health care providers to knowingly withhold information from patients violates the Hippocratic Oath upholding preventive measures,[11] informed consent protocols, and individual health care entity and association regulations.

The American Medical Association (AMA),[12] the American Nurses Association,[13] the American College of Physicians,[14] and other professional provider organizations[15] have publicly outlined their opposition to this rule and its resulting harm to patient care. The AMA states in its Code of Medical Ethics that providers should "present relevant information accurately and sensitively, in keeping with the *patient's* preferences for receiving medical information."[16] Withholding information without the patient's knowledge or consent is ethically unacceptable and disrespects patient autonomy.[17]

§ 59.14(b)-(d): Nondirective Counseling Ambiguity

Moreover, proposed § 59.14 not only prohibits referrals for abortion, but would also eliminate existing guarantees that pregnant Title X patients receive complete counseling.[18] Presently, all counseling must be neutral, factual, and nondirective.[19] But the proposed rule would go so far to require that all pregnant women be referred outside of a Title X facility or project for prenatal

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[10] Susannah Luthi, *Trump could ban Title X funding for Planned Parenthood,* MODERN HEALTHCARE (Apr. 26, 2018), http://www.modernhealthcare.com/article/20180426/NEWS/180429923; Kinsey Hasstedt, *Trump Administration Looks to Impose "Domestic Gag Rule," Continuing its Assault on Reproductive Health and Rights,* GUTTMACHER INST., https://www.guttmacher.org/article/2018/06/trump-administration-looks-impose-domestic-gag-rule-continuing-its-assault.

[11] Peter Tyson, *The Hippocratic Oath Today,* PBS (Mar. 27, 2001), http://www.pbs.org/wgbh/nova/body/hippocratic-oath-today.html.

[12] David O. Barbe, *AMA Response to Administration's Attack on Family Planning Services,* AMERICAN MED. ASSOC. (May 23, 2018), https://www.ama-assn.org/ama-response-administrations-attack-family-planning-services.

[13] *ANA Condemns Title X Funding Cuts Proposed by the Trump Administration,* AMERICAN NURSES ASSOC. (May 22, 2018), https://www.nursingworld.org/news/news-releases/2018/ANA-condemns-title-x-funding-cuts--proposed-by-the-trump-administration/.

[14] Ana Maria Lopez, *Internists Concerned Changes to Title X Will Restrict Access to Health Care for Vulnerable Populations, Undermine Patient-Physician Relationship,* AMERICAN COLLEGE OF PHYSICIANS (May 23, 2018), https://www.acponline.org/acp-newsroom/internists-concerned-changes-to-title-x-will-restrict-access-to-health-care-for-vulnerable.

[15] *America's Women's Health Providers Oppose Efforts to Exclude Qualified Providers from Federally-Funded Programs,* AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (May 23, 2018), https://www.acog.org/About-ACOG/News-Room/Statements/2018/Health-Providers-Oppose-Efforts-to-Exclude-Qualified-Providers-from-Federally-Funded-Programs.

[16] *Informed Consent,* AMERICAN MED. ASSOC., https://www.ama-assn.org/delivering-care/informed-consent.

[17] *Withholding Information from Patients,* AMERICAN MED. ASSOC., https://www.ama-assn.org/delivering-care/withholding-information-patients.

[18] 42 C.F.R. § 59.5(a)(5).

[19] 42 C.F.R. § 59.5(a)(5).

care and other related medical and social services related to pregnancy.[20] This measure would leave Title X clients without access to care if they do not have the physical and financial resources or paid time off from employment to seek care elsewhere.

Further, the rule's language leaves much room for ambiguity regarding the definition for "nondirective counseling" and how providers should act in accordance. Additionally, it does not address whether clients will be informed, at the very least, that they are not receiving complete information because their providers are bound by religious or moral restrictions.[21] Therefore, clients are neither truly able to provide informed consent to Title X providers concerning their health care options and treatments, nor are they even aware of whether they are receiving complete information in order to know to seek care elsewhere.

A related ambiguity lies in reading proposed § 59.14 and § 59.5(b)(1) together, which would still allow Title X programs to provide pregnant clients with a list of licensed health care providers for prenatal care and delivery services, some of which also provide abortion.[22] Although it is stated that doctors "providing such a list would be permitted only in cases where a program client who is currently pregnant clearly states that she has already decided to have an abortion" and that "such nondirective counseling would not be considered encouragement, promotion, or advocacy of abortion," it is unstated what protections may exist for doctors that do provide such a list.[23] Moreover, staff would be barred from distinguishing sites on the list that do offer abortion from those that do not, leaving patients—less technically educated, of low-literacy levels, and often without paid time off—to determine that on their own.[24]

Furthermore, while imparting medically necessary information assessing the risks and benefits of different contraceptive methods is deemed permissible and outside of the subpart's prohibitions, proposed § 59.14(d) does not clarify what else the scope of "medically necessary" entails.[25] Such ambiguities in key terminology lead to confusion among Title X programs as to what information they may provide, and to whom and in which cases they may provide it.

A prime example is that the rule does not explicitly protect or allow for abortion referrals in cases where there is a danger to the life of the pregnant client or the fetus. As mentioned, providers' ability to counsel patients on all risks, whether "non-direct" or due to "medically necessary" reasons, is ambiguous. In a mere footnote, the rule states that in case of rape and/or incest, only, it would not violate the proposed prohibition on referrals for abortion if a patient is referred to a licensed, qualified, comprehensive health service provider who also provides abortion, "provided that the Title X provider has complied with all state and/or local laws requiring reporting to, or notification of, law enforcement or other authorities and such reporting or notification is documented in the patient's record."[26] The bottom line, however, is that the rule would give providers the option to refuse referring patients for abortions, against even the

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[20] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25518.
[21] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25506, 25518.
[22] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25518.
[23] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25518.
[24] Kinsey Hasstedt, *A Domestic Gag rule and More: The Administration's Proposed Changes to Title X,* GUTTMACHER INST., https://www.guttmacher.org/article/2018/06/domestic-gag-rule-and-more-administrations-proposed-changes-title-x.
[25] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25531.
[26] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25518, n. 54.

patient's request, and withhold neutral and factual information on abortion, against medical ethics, to the ultimate detriment of the client's life and safety.

While the proposed rule intends to protect federal health care conscience statutes—embodied in the Church, Coats-Snowe, and Weldon Amendments—it does not protect the ethical standards that medical providers must abide by or patients' rights.[27] An ethical doctor-patient relationship is especially vital for vulnerable populations living with HIV, HCV, and other chronic health conditions who historically have experienced discrimination by health care providers and health care systems. Patients with HIV and HCV rely on trusted providers to ensure comfort in discussing personal health concerns and long-term and follow-up care for disease management. Without open and honest communications, people living with HIV and HCV may not receive adequate medical information to combat faced physical and social stigmas, exacerbating disease conditions.[28]

The prohibition on abortion referrals directly conflicts with medical ethics, renders providers unable to provide the best level of care or risk being unable to participate in Title X altogether. Restricting access to Title X funding will severely limit the number of clinics able to serve individuals who are low income and uninsured at a time when STD rates are at a historic high and rates of HCV and HIV care increasing due to the opioid epidemic in some cases.

Recommendations

As a model medical landscape for global trainees, the U.S. must be a leader in sexual and reproductive health care. Thus, in light of medical ethical violations, the rule's ambiguous application, and its indisputable negative outcomes on patients' health, we urge HHS to withdrawal the proposed § 59.14(a) prohibiting referrals for abortion.

Should HHS choose to advance this rule, we recommend that it first consult with the AMA and other professional medical organizations to clarify the ethical standards by which providers must abide. Thereafter, HHS must work alongside these organizations to clarify the scope of activities that would qualify as "nondirective counseling" and "medically necessary," in keeping with proposed 42 C.F.R. § 59.14 and § 59.5(a)(5). While interfering with the provider-patient relationship, altogether, is a harmful facet of HHS' proposed rule, at the very least HHS should incorporate a provision that calls on doctors wishing to refuse providing abortion referrals and related counseling patients to inform patients, in a transparent and overt manner, of their refusal and withholding of information, so that patients are aware of the need to seek care elsewhere. Moreover, protections should be clarified for doctors that do offer nondirective counseling and a comprehensive list of providers to pregnant clients who request abortion services, so that they can steer clear of the actions that may risk losing Title X funding. Overall, we call on HHS to revise this proposal with additional considerations of medical ethical guidelines and their crucial impact on patient health.

Lastly, the rule's language should be revised to explicitly protect or allow for abortion referrals in cases where there is a danger to the life of the pregnant client or the fetus, and HHS should

[27] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25506.
[28] *Trust is the bedrock of effective communication with HIV patients,* MEDICAL ECONOMICS (Dec. 8, 2016), http://www.medicaleconomics.com/medical-economics-blog/trust-bedrock-effective-communication-hiv-patients.

specifically consider other conditions broader than sexual abuse that may present danger to the lives of the mother and child.

II. The rule's mandate for financial and physical separation and revised grant criteria are unjustified reversals of prior Title X standards and restrict providers' capacity to deliver services, compromising access to critical care for the most vulnerable populations.

§ 59.15 and § 59.16(a): Physical and Financial Separation

Sites that provide Title X-funded services have long been permitted to provide abortions and abortion referrals using separate, non-federal funds.[29] Section 1008 of the Public Health Service Act enacted in 1970 still holds: "None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning."[30] However, the Act does not further extend funding prohibitions. Now requiring Title X recipients to physically and financially separate Title X activities from any abortion-related activities, including abortion referrals, ignores the crucial role that specialized providers have played in the Title X program for decades.[31] This rule would directly impact more than 10% of Title X sites, which offer abortions using non-federal funds, including health centers operated by hospitals and independent agencies.[32]

Proposed § 59.16(a) further defines activities that build abortion infrastructure to include a host of lobbying, educational, and legal activities.[33] The precise phrasing prohibiting activities that may "encourage, promote or advocate abortion as a method of family planning" is left intentionally vague and open for greater inclusion. As such, the proposed rule makes it impossible for Title X providers to continue to effectively serve and comprehensively inform patients of their full range of options, by incapacitating them physically, financially, and geographically.

The unfounded assertion that "mere bookkeeping separation of Title X funds from other monies is not sufficient" lends credence to HHS' distrust of Title X providers, assuming that grantees are incapable or incompetent of already ensuring financial separation and decreasing grantees' autonomy in operation. Besides brief statements of Medicaid overbilling among only six individual providers nationwide, HHS provides no other significant evidence of the co-mingling of funds used towards abortion-related expenses.[34] Moreover, although HHS provides a single example of a Title X grantee in Massachusetts having admitted to co-mingling Title X expenses with all other family planning expenses, abortion-related activities is not listed as one such

[29] Kinsey Hasstedt, *Trump Administration Looks to Impose "Domestic Gag Rule," Continuing its Assault on Reproductive Health and Rights,* GUTTMACHER INST., https://www.guttmacher.org/article/2018/06/trump-administration-looks-impose-domestic-gag-rule-continuing-its-assault.
[30] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25502.
[31] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25532.
[32] Kinsey Hasstedt, *A Domestic Gag rule and More: The Administration's Proposed Changes to Title X,* GUTTMACHER INST., https://www.guttmacher.org/article/2018/06/domestic-gag-rule-and-more-administrations-proposed-changes-title-x.
[33] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25532.
[34] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25509.

expense.[35] Thus, HHS has not provided a clear justification for this rule, nor for its sweeping departure from prior agency practice.

Instead, this rule would grant HHS broad, subjective discretion to evaluate Title X recipients' compliance with physical and financial separation by way of using a "facts and circumstances" test to determine whether a Title X project has achieved "objective integrity and independence" from abortion-related activities.[36] In its analysis, the agency would consider: (1) the existence of separate, accurate accounting records; (2) the degree of separation from facilities (e.g., treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites) in which prohibited activities occur and the extent of such prohibited activities; (3) the existence of separate personnel, electronic or paper-based health care records, and workstations; and (4) the extent to which signs and other forms of identification of the Title X project are present, and signs and material referencing or promoting abortion are absent.[37]

Without reason, these factors reverse HHS' longstanding interpretation that "[i]f a Title X grantee can demonstrate [separation] by its financial records, counseling and service protocols, administrative procedures, and other means…then it is hard to see what additional statutory protection is afforded by the imposition of a requirement for 'physical' separation."[38] In 2000, HHS further issued a notice to clarify that Title X service sites could use common waiting rooms, staff, and filing systems for abortion-related activities and Title X project activities.[39]

In this manner, proposed § 59.15 and § 59.16(a) advance beyond the Reagan Administration's 1988 rule, but it is clear that HHS has not adequately considered the time and monetary costs that Title X providers would have to shoulder to comply with these requirements, nor how such expenditures would detract from providers' ability to continue delivering comprehensive, quality services to clients. Not only would sites have to hire and train additional personnel, but they would also have to acquire additional building space to house separate workstations and activities, purchase and learn separate accounting and e-technology systems, sort through years of administrative records to ensure continued separation, and discard and recreate educational materials. Providers would additionally require time and funds to ensure compliance with proposed § 59.5(13), under which strict monitoring and evaluation methods must be implemented to ensure transparency among sub-recipients and referral agencies, and relevant records must be maintained and submitted to the Office of Population Affairs (OPA) for oversight.

Title X sites that are already underfunded and financially struggling to provide comprehensive services, are busy meeting high client demand, and/or are geographically located in dense areas with no room for workstation expansion will not be able to comply with this rule for total separation. In some cases, this rule would force Title X site closures altogether and, in others, would cause a decrease or dilution in the provision of quality family planning services.

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[35] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25509-10.
[36] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25532.
[37] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25532.
[38] Standards of Compliance for Abortion Related Services in Family Planning Services Projects, 65 Fed. Reg. at 41270, 41276 (Jul. 3, 2000).
[39] Provision of Abortion-Related Services in Family Planning Projects, 65 Fed. Reg. at 41281, 41282 (Jul. 3, 2000).

§ 59.5 and § 59.7: Revised Title X Grant Eligibility and Award Criteria

HHS states that it seeks to better achieve the statutory requirements and goals of Title X and increase competition and rigor, encouraging broader, more diverse, and quality applicants.[40] These changes, however, do not accomplish HHS' goals. Instead, the revised criteria would bar providers that separately provide abortion services outside of Title X funds from participating in the Title X program, ultimately limiting the provision of essential services to communities in need. By pushing comprehensive reproductive health care providers out of the Title X network—such as those that do not provide natural family planning, sexual risk avoidance, and other fertility awareness methods[41]—the revised criteria remakes the network by including and supporting providers that do not focus on evidence-based reproductive health care. Diverse applications providing high quality prevention and care will be discouraged to apply for Title X funds, due to their inability to comply with revised criteria that cost already-limited time and funds in light of pressing family planning needs.

Compromised Care for Vulnerable Populations

The proposed rule disproportionately burdens vulnerable Title X client populations, including women, people of color, those low-income, those with limited English proficiency (LEP), those living with chronic conditions like HIV and HCV, and LGBTQ individuals. Every year, Title X sites serve more than four million individuals with preventive health and family planning methods, through cancer, STI, and HIV screenings; contraceptives; pregnancy testing; well-woman exams; and counseling support and referrals for adoption, prenatal care, and abortion. African Americans make up 21% (840,000) and Hispanic and Latino patients make up 32% (1,280,000) of Title X's patient population.[42] Nearly 66% of patients have incomes at or below the federal poverty level (FPL), of which 43% are uninsured,[43] and about 10% are LEP persons.[44]

Moreover, women make up more than one-half of people living with HIV/AIDS, with young women and adolescent girls primarily comprising new HIV infections.[45] In 2016, nearly 4,000

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[40] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25511.
[41] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25530.
[42] *What is Trump's "Gag Rule?,"* PLANNED PARENTHOOD ACTION FUND, https://www.plannedparenthoodaction.org/blog/what-is-the-domestic-gag-rule; Christina Fowler, et al., *Family Planning Annual Report: 2016 National Summary,* RTI INT. (Aug. 2017), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf.
[43] Sasha Ingber, *Kenyan Clinic Rejects Trump Abortion Policy, Loses $2 Million In U.S. Aid*, NPR (May 2, 2018), https://www.npr.org/sections/goatsandsoda/2018/05/02/604425181/kenyan-clinic-rejects-trump-abortion-policy-loses-2-million-in-u-s-aid.
[44] Kinsey Hasstedt, *A Domestic Gag rule and More: The Administration's Proposed Changes to Title X,* GUTTMACHER INST., https://www.guttmacher.org/article/2018/06/domestic-gag-rule-and-more-administrations-proposed-changes-title-x.
[45] Jamila Tyalor and Jonathan Rucks, *On International Women's Day, Resist Trump's Global Gag Rule,* CTR. FOR AM. PROG. (Mar. 7, 2018), https://www.americanprogress.org/issues/women/news/2018/03/07/447558/international-womens-day-resist-trumps-global-gag-rule/.

Title X centers performed 720,000 pap smears, provided nearly one million women with breast exams, and administered 1.2 million HIV tests, of which 2,824 were found positive.[46] Men at risk for HIV also benefit from Title X centers. In 2016, 5.7 out of every ten HIV tests were conducted for male clients.[47]

The National HIV/AIDS Strategy emphasizes that testing, diagnosis and linkage to care are critical steps toward viral suppression in patients and ending the dual HIV/HCV epidemics.[48] Out-of-pocket, HIV and STI testing could cost hundreds of dollars,[49] a price not feasible for many patients. Moreover, two out of five U.S. adults are not even be able to produce $400 to pay for emergency care costs.[50] But the Title X program goes beyond affordability, as in many communities, a Title X provider is both clients' sole source of care[51] and the only place where preventive services are accessible.[52] For example, closing a Planned Parenthood health center that was the sole source of free HIV testing in its community in 2013 caused an uptick in new HIV infections within the same community.[53]

Studies of the Protecting Life in Global Health Assistance rule's effects have shown that stopping people from seeking abortion services does not limit abortions or reduce the unintended pregnancy rate, but actually causes people to seek unsafe, unregulated procedures that contribute to maternal and child mortality.[54] Contraception is frequently provided after safe abortion services are performed. Thus, eliminating access to abortion by prohibiting abortion referrals and comprehensive provider counseling decreases opportunities for people in need to obtain contraceptives, resulting in higher unintended pregnancies that are at high-risk for complications.[55]

Without Title X's adequate provision of preventive screenings, counseling, comprehensive referrals, as well as pre- and post-conception care, the most vulnerable individuals will be subject to increased unintended pregnancies; HIV and HCV transmission particularly via mother-to-child transmission; STIs; and unsuccessful and unsafe abortions. The proposed rule does not account for these inevitable, damaging impacts on patient health and well-being. As is, uniquely

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[46] Letter to HHS from United States Senators and Congress people, https://www.warren.senate.gov/imo/media/doc/2018.05.14%20Letter%20to%20HHS%20Opposing%20Domestic%20Gag%20on%20Title%20X.pdf.

[47] *Title X Family Planning Annual Report 2016 National Summary,* U.S. DEPT. HEALTH AND HUMAN SERVICES, https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf, 13.

[48] *What is the HIV Care Continuum?,* HIV.GOV, https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-continuum.

[49] *How Much Does STD Testing Cost?,* COST HELPER HEALTH, http://health.costhelper.com/std-testing.html.

[50] Sarah O'Brien, *Fed survey shows 40 percent of adults still can't cover a $400 emergency expense,* CNBC (May 22, 2018), https://www.cnbc.com/2018/05/22/fed-survey-40-percent-of-adults-cant-cover-400-emergency-expense.html.

[51] *Publicly Funded Family Planning Services in the United States,* GUTTMACHER INST., https://www.guttmacher.org/fact-sheet/publicly-funded-family-planning-services-united-states.

[52] *Response to Inquiry Concerning the Availability of Publicly Funded Contraceptive are to U.S. Women,* GUTTMACHER INST., https://www.guttmacher.org/article/2017/05/guttmacher-murray-memo-2017.

[53] Philip Peters, et. al., *HIV Infection Linked to Injection Use of Oxymorphone in Indiana, 2014-2015,* NEW ENGLAND J. MED., (Jul. 21, 2016), https://www.nejm.org/doi/full/10.1056/NEJMoa1515195.

[54] Eran Bendavid, Patrick Avila & Grant Miller, *United States aid policy and induced abortion in sub-Saharan Africa,* WHO Bulletin (Sept. 27, 2011), http://www.who.int/bulletin/volumes/89/12/11-091660/en/.

[55] Eran Bendavid, Patrick Avila & Grant Miller, *United States aid policy and induced abortion in sub-Saharan Africa,* WHO Bulletin (Sept. 27, 2011), http://www.who.int/bulletin/volumes/89/12/11-091660/en/.

vulnerable populations go unconsidered in the family planning agenda. Title X does not merely serve "women, men, and adolescents," as constantly referenced in the rule, and requires greater inclusivity.[56]

Recommendations

Mandating physical and financial separation, and revising Title X grant criteria, would have detrimental effects on providers' ability to continue serving clients in need, especially those communities most vulnerable to chronic conditions and the persistent cycle of poverty. Moreover, physical separation would force providers to stray from the national focus towards comprehensive, integrated health care. Thus, we urge HHS to reconsider requiring physical and financial separation and revising grant criteria altogether.

Should HHS move forward with the rule, however, clearer justifications are firstly needed for the physical separation mandate, as HHS' longstanding perspective has held that financial separation, without physical separation, is sufficient. Title X recipients that provide abortions using non-federal funds and abortion referrals have played a crucial role in the national family planning landscape and progress. Secondly, we urge HHS to provide substantial large-scale examples of the co-mingling of funds across the country to corroborate its stance that the historic financial separation mandate is not operating optimally. Thirdly, we urge HHS to consult a diverse cohort of Title X providers—spanning urban and rural locales, large and small centers, and the varied populations they serve—to calculate, with an evidence-base, the great monetary and time costs providers would have to shoulder to comply with the rule.

Through these consultations, HHS will be able to revise the period of time for provider compliance to reflect a more realistic window that would ensure greater provider compliance and maintain as many current providers as possible in the Title X network. One year for physical separation and 60 days for financial separation, following the publication of the final rule, are not long enough periods of time for provider compliance and appear to be arbitrary determinations.[57] As Title X providers are diversely compromised, HHS should consider instating differing transition requirements for tiers of Title X recipients—determined by resource-level, location, revenue, and client population. These factors would undoubtedly influence the time and monetary costs it would take providers to balance client demand with hiring and training additional personnel, acquiring additional workstation space, learning separate accounting and e-technology systems, sorting through administrative records, recreating educational materials, and monitoring and evaluating sub-recipient compliance. Title X recipients, themselves, are best positioned to suggest appropriate time periods for their required compliance.

III. The rule's family participation requirements, as well as its site exemptions to provide a broad range of medically approved family planning methods, are neither in line with Title X's envisioned purpose nor protect adults and adolescents in need.

§ 59.5(a)(14): *Family Participation Requirement*

[56] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25513.
[57] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25521.

Encouraging and documenting family participation in the decision of minors to seek family planning services by way of proposed § 59.5(a)(14) can render unaccompanied minors or minors without protective parental relations who visit Title X centers unable to seek necessary, immediate assistance. These proposed barriers will cause adolescents to forgo or delay needed care, contributing to greater unintended pregnancies, disease transmission, and unsafe abortions. This rule does not ensure adolescent clients' confidentiality and safety from social stigma, should they have strained relations with parental figures. It further violates the private, trusted provider-patient relationship, which maintains safe, quality, and sustained care, and encourages adolescents to seek care in the first place.

§ 59.2 and § 59.5(a)(1): Undermining Access to Medically Approved Services

Proposed § 59.5(a)(1) makes it explicit that a Title X project is not required to provide a broad range of acceptable and effective family planning methods and services.[58] A participating entity may offer only a single method or a limited number of family planning methods as long as the entire project offers a broad range. This rule allows grantees to exclude contraceptive options due to "staffing limitations, technological capacity, economics (including costs and demand), and conscience concerns."[59] Proposed § 59.2 removes "medically approved" from the definition for family planning, allowing Title X clinics to provide contraceptive and fertility awareness methods (i.e. calendar-based methods relying on abstinence during fertile windows) that have not been regulated, approved, or certified by any particular agency or accreditation body.[60] This proposal threatens Title X's mission to ensure access to a full range of contraceptive methods and dilutes an essential feature of quality family planning by no longer requiring provision of Federal Food and Drug Administration (FDA)-approved contraceptive methods.[61]

The proposed rule, instead, emphasizes that projects are not required to provide "every acceptable and effective family planning method or service," allowing Title X projects to exclude methods of their choosing.[62] To ensure compliance with and enforcement of conscience protections embodied in the Church, Coates-Snow, and Weldon Amendments—designed to uphold non-compliance with originally envisioned Title X provisions based on religious grounds—single-method sites are now permissible.[63]

But it is HHS' mere speculation to stand by the notion that if a family planning method is "acceptable and effective," then "it is likely to be approved by at least some medical sources."[64] This misconception allows doctors and professional organizations to exclude crucial contraceptives, preconception counseling, and other preventive screenings with an evidence-base of success and replace them with non-medically approved fertility awareness and "sexual risk

[58] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25530, 25515.
[59] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25516.
[60] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25515.
[61] The U.S. Office of Population Affairs, which administers Title X, and the Centers for Disease Control and Prevention in their authoritative clinical guidelines for quality care deemed FDA-approved contraceptive methods an essential feature of quality family planning. Department of Health and Human Services and Centers for Disease Control and Prevention, *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs*, 2, (Apr. 2014), available at https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf.
[62] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25515.
[63] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25523.
[64] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25515.

avoidance" methods,[65] or abstinence-only education, which has been proven ineffective and harmful.[66]

In 1970, Congress stated that Title X's very purpose was to make "*comprehensive* voluntary family planning services readily available to all persons desiring such services."[67] Yet, these changes collectively allow Title X projects to deny patients access to the full range of effective contraception and other family planning methods. HHS does not provide any evidence to support its contentions that the proposed rule will result in "more clients being served, gaps in service being closed, and improved client care that better focuses on the family planning mission of the Title X program."[68] In actuality, with reduced thresholds for quality, this rule may result in providers with little or no experience in providing medically effective sexual and reproductive health care participating in the Title X program.

Among 15-19 year-olds, 75% of pregnancies are unplanned and 45% of the 6.1 million pregnancies each year are unintended.[69] Due in large part to access to affordable and effective contraception, the U.S. has been able to achieve its current 30-year low in unintended pregnancies and all-time low in teen pregnancies. Title X sites continue decreasing the unintended pregnancy rate. In 2015, Title X provision of contraceptive services helped avoid 822,000 unintended pregnancies, which would have resulted in 387,000 unplanned births and 278,000 abortions.[70] The proposed rule thwarts the national progress that has been made.

Recommendations

HHS should reconsider instating the family participation requirement. Confidentiality and trust are key foundations for successful provider-patient relationships and patient uptake of treatment services—especially adolescent patients that should be encouraged to seek care in precise times of need. Additionally, if HHS intends to improve public health and continue the downward trend for unintended pregnancies, unplanned births, and abortions, then HHS must provide a medical evidence-base for what family planning services are approved, contribute to health and success, and are truly preventive of negative health outcomes. Permitting sexual risk avoidance and non-FDA approved methods will instead reverse recent strides in national family planning.

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[65] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25516.
[66] *Abstinence-Only-Until-Marriage Programs are Ineffective and Harmful to Young People, Expert Review Confirms,* GUTTMACHER INST., https://www.guttmacher.org/news-release/2017/abstinence-only-until-marriage-programs-are-ineffective-and-harmful-young-people.
[67] Pub. L. No. 91-572, § 2(1); see S. Rep. No. 91-1004, at 2 (1970).
[68] [68] *See, e.g.,* Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25505 ("If finalized and implemented as proposed, the new regulations would contribute to more clients being served, gaps in service being closed, and improved client care that better focuses on the family planning mission of the Title X program"); 83 Fed. Reg. at 25522 (HHS cites as expected benefits of the proposed rule "Enhanced patient service and care"and also states that the rule "is also expected to increase the number of entities interested in participating in Title X as grantees or subrecipient service provides and, thereby, to increase patient access to family planning services focused on optimal health outcomes for every Title X client").
[69] Geography United States, GUTTMACHER INST., https://www.guttmacher.org/geography/united-states.
[70] Letter to HHS from United States Senators and Congress people, https://www.warren.senate.gov/imo/media/doc/2018.05.14%20Letter%20to%20HHS%20Opposing%20Domestic%20Gag%20on%20Title%20X.pdf.

IV. Contrary to HHS' analysis, outlined in § 59.19, the impacts of Title X providers' transition to compliance with this rule are economically significant and increase costs imposed on patients, providers, and the nation's health care system, likely requiring greater taxpayer contributions.

HHS considerably underestimates the economic impacts of providers' compliance with this rule. In deeming this rule an insignificant regulatory action, HHS effectively finds that the actions Title X providers would have to take to comply with the rule would not affect the economy in excess of $100 million or more in any one year, and would not adversely and materially affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities.[71]

But HHS fails to consider the long-term cyclical impacts of this rule. Restricting patient access and the provision of comprehensive, quality care leads to: (1) the possible closure of Title X centers, (2) patients delaying or forgoing care and developing a range of negative health outcomes as previously discussed, and (3) overburdened state and local health systems facing additional emergency care demands from low-income vulnerable patients. Moreover, because the rule would redefine eligibility for free family planning services to include individuals whose employer-based insurance does not cover contraception without cost sharing, due to the Affordable Care Act's contraceptive coverage exclusion for employers with religious or moral opposition, already-limited Title X funds would be redirected to cover privately-insured patients' costs.[72] Ultimately, increased taxpayer contributions will be required to shoulder Title X and the health system's costs. Currently, $1 invested in Title X saves more than $7 in Medicaid-related costs, thereby saving taxpayer contributions towards Medicaid.[73] Thus, implementing the rule would not achieve HHS' stated goals.

Yet HHS does not provide any evidence-based, quantifiable benefits of the rule. HHS also fails to provide proven estimates of compliance costs—for example, providers' costs to build new physical facilities and financial infrastructure, to alter electronic health record systems, and/or to hire additional staff personnel, all of which would differ in quantity and cost based on clinic location and client demand. HHS' present assessment is not grounded in reasoned analyses. An accurate assessment of the economic impacts of this rule would certainly exceed the $100 million threshold.

If implemented in its present form, this rule would primarily serve to exclude Planned Parenthood clinics from the Title X network; however, HHS ignores the devastating monetary costs and negative health outcomes resulting from doing so. Presently, the Title X program

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[71] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25521.
[72] Kinsey Hasstedt, *A Domestic Gag rule and More: The Administration's Proposed Changes to Title X,* GUTTMACHER INST., https://www.guttmacher.org/article/2018/06/domestic-gag-rule-and-more-administrations-proposed-changes-title-x.
[73] Letter to HHS from United States Senators and Congress people, https://www.warren.senate.gov/imo/media/doc/2018.05.14%20Letter%20to%20HHS%20Opposing%20Domestic%20Gag%20on%20Title%20X.pdf.

provides $286 million in grants to 4,000 diverse providers nationwide.[74] Planned Parenthood is one such provider with 500 clinics nationwide, serving more than 40% of Title X clients and 1.6 million women each year for their contraceptive needs.[75] Research has shown that Planned Parenthood sites are better able to deliver high-quality contraceptive care to greater numbers of clients than other types of safety-net providers.[76] Removing Planned Parenthood sites from the Title X network due to noncompliance with this rule, however, would require all other Title X sites to increase their client caseloads by 70% to maintain the program's current reach.[77] Thirteen states would have to double their contraceptive client caseloads at the very least.[78]

Lastly, the rule does not clearly define whether providers would bear the financial burden of compliance out of their current Title X funds and limited revenues, or whether HHS and OPA will increase grant awards. If HHS continues to provide an estimated $280 million in funding to Title X providers, almost $50 million, according to HHS' calculations—a severe underestimate—would be spent on compliance with the rule. This would inevitably decrease clients' access to quality services and/or force clinic closures, as occurred upon implementation of Protecting Life in Global Health Assistance rule.[79]

Whether taxpayer contributions must cover increased health system costs or go towards increasing the annual Title X grant budget, whether HHS must limit grant amounts to grantees out of its present budget to cover the costs for compliance, or whether grantees must consume compliance costs on their own, HHS will not achieve the rule's stated goals and patients would be cut off from essential preventive, contraceptive, and counseling services.

Recommendations

We urge HHS to collaborate with medical practitioners, Title X providers, and health economists to calculate the inclusive costs on providers, patients, the health system, taxpayers, and HHS and OPA themselves, as required for compliance with the proposed rule. Without an evidence base and providing quantifiable benefits of this rule, HHS' justifications fall short of coherence. Using HHS' own stated definition for what is considered "economically significant," the health and economic effects of the rule would negatively affect economic productivity, public health, safety, and a host of vulnerable communities and their local governments. Already low-income patients

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[74] Kinsey Hasstedt, *Trump Administration Looks to Impose "Domestic Gag Rule," Continuing its Assault on Reproductive Health and Rights,* GUTTMACHER INST., https://www.guttmacher.org/article/2018/06/trump-administration-looks-impose-domestic-gag-rule-continuing-its-assault.

[75] Kinsey Hasstedt, *Beyond the Rhetoric: The Real-World Impact of Attacks on Planned Parenthood and Title X,* GUTTMACHER INST., https://www.guttmacher.org/gpr/2017/08/beyond-rhetoric-real-world-impact-attacks-planned-parenthood-and-title-x.

[76] Kinsey Hasstedt*, Understanding Planned Parenthood's Critical Role in the Nation's Family Planning Safety Net,* GUTTMACHER INST., https://www.guttmacher.org/gpr/2017/01/understanding-planned-parenthoods-critical-role-nations-family-planning-safety-net.

[77] Kinsey Hasstedt, *A Domestic Gag rule and More: The Administration's Proposed Changes to Title X,* GUTTMACHER INST., https://www.guttmacher.org/article/2018/06/domestic-gag-rule-and-more-administrations-proposed-changes-title-x.

[78] Kinsey Hasstedt, *A Domestic Gag rule and More: The Administration's Proposed Changes to Title X,* GUTTMACHER INST., https://www.guttmacher.org/article/2018/06/domestic-gag-rule-and-more-administrations-proposed-changes-title-x.

[79] Ann Starrs, *The Trump Global Gag Rule: An Attack on US Family Planning and Global Health Aid,* THE LANCET (Feb. 4, 2017), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)30270-2/fulltext.

exiting the workforce as a result of unseen to and exacerbated health conditions would not only affect the scope of public health and thwart health care progress, but would also affect the consumption of emergency care services upon patients delaying or forgoing care—increasing the burdens on local and national health care systems and requiring greater taxpayer contributions. In addition to recalculating the expansive costs of compliance, we also urge HHS to clearly define whether HHS and OPA will increase the annual Title X grant budget to consume providers' costs for compliance or whether providers would have to consume these severely high costs on their own from limited grant monies and revenues. In either case, HHS must recognize that its stated goals will not be achieved.

Thank you, again, for the opportunity to comment. We call on HHS to continue its commitment to public health, by way of supporting the Title X program's vital role in national family planning, in ways that ensure individuals in need have access to quality, comprehensive, and affordable services. FAPP looks forward to HHS' response to our comments and recommendations, as well as to HHS' response to the 100+ professional organizations[80] and Congress people,[81] who have expressed their opposition to this rule.

Please contact Kathie Hiers with AIDS Alabama (kathie@aidsalabama.org), Ann Lefert with the National Association of State & Territorial AIDS Directors (alefert@NASTAD.org), Mike Weir with the National Association of State & Territorial AIDS Directors (mweir@NASTAD.org), or Robert Greenwald with the Treatment Access Expansion Project (rgreenwa@law.harvard.edu) if we can be of assistance.

Respectfully submitted by the undersigned organizations:

AIDS Action Baltimore
AIDS Alliance for Women, Infants, Children, Youth & Families
AIDS Foundation of Chicago
AIDS United
American Academy of HIV Medicine
APLA Health
Association of Nurses in AIDS Care
AVAC
Bailey House, Inc.
Center for Health Law and Policy Innovation
ETR
HealthHIV
HIV Medicine Association
Howard Brown Health

[80] *AHA Joins Over 110 Orgs Urging HHS Not to Reinstate "Domestic Gag Rule,"* AMERICAN HUMANIST ASSOC. *(May 21, 2018),* https://americanhumanist.org/featured/aha-joins-110-orgs-urging-hhs-not-reinstate-domestic-gag-rule/.

[81] Letter to HHS from United States Senators and Congress people, https://www.warren.senate.gov/imo/media/doc/2018.05.14%20Letter%20to%20HHS%20Opposing%20Domestic%20Gag%20on%20Title%20X.pdf.

Latino Commission on AIDS
LLHC
Nashville CARES
NASTAD
National Black Justice Coalition
National Black Women's HIV/AIDS Network
National Coalition for LGBT Health
National Coalition of STD Directors
National Working Positive Coalition
NMAC
Open Door Clinic of Greater Elgin
Southern AIDS Coalition
Treatment Access Expansion Project
Treatment Action Group