



AMERICAN PUBLIC HEALTH ASSOCIATION
For science. For action. For health.

July 30, 2018

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: HHS–OS–2018–0008, Proposed Rule for Compliance With Statutory Program Integrity Requirements

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

On behalf of the American Public Health Association, a diverse community of public health professionals that champions the health of all people and communities, I appreciate the opportunity to comment on the Department of Health and Human Services' proposed rule entitled Compliance with Statutory Program Integrity Requirements.¹ The proposed rule would significantly and detrimentally alter the Title X Family Planning Program, which has provided vital sexual and reproductive health services to people across the country for more than 40 years, and today provides services to 4 million people in the United States.

As an organization committed to improving the health of the nation, we write to express our strong opposition to this proposed rule. Specifically, the proposed rule would interfere with the doctor-patient relationship and deny Title X patients critical information about their health and

¹ Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. 25,502 (proposed Jun. 1, 2018) (to be codified at 42 C.F.R. pt. 59).

health care options. Secondly, it is clearly designed to make it impossible for reproductive health-focused providers, like Planned Parenthood health centers, to continue to serve people through the program. Third, it would undermine Title X's goals of providing comprehensive reproductive health services to people with low incomes. Additionally, the proposed rule radically underestimates the likely costs it will impose on patients, providers and on society. Finally, the rule would exacerbate existing health disparities. The combined result of these changes would be disastrous for public health in the United States.

I. The Proposed Rule would interfere with the doctor-patient relationship and deny patients information that they need to make the best decisions for themselves and their families.

The proposed rule would ban Title X providers from giving women full information about their health care options. Specifically, the proposed rule would eliminate the existing requirement that patients be provided with referrals upon request for the full range of pregnancy options, including prenatal care and delivery; infant care, foster care, or adoption; and abortion.² That requirement would be replaced with a complete ban on health care providers giving abortion referrals.³ Many experts call this provision a “gag rule,” since it would restrict providers from speaking freely with their patients. The gag rule violates core ethical standards and undermines the patient-provider relationship.

This rule conflicts with a fundamental principle that guides health care providers every day: patients' needs are paramount and providers have an ethical obligation to put the needs of patients first. The prohibition on abortion referrals contravenes medical ethics and leaves providers in the position of not providing the best level of medical care or no longer participating in the Title X program, thereby potentially leaving their patients without access to care at all.

In addition to the prohibition on abortion referral, the proposed rule also eliminates longstanding requirements guaranteeing patients in Title X information about all of their health care options. Title X regulations currently direct Title X projects to “[o]ffer pregnant women the opportunity to be provided information and counseling” on all pregnancy options.⁴ All such counseling must be neutral, factual, and nondirective.⁵ The proposed rule would eliminate the options counseling requirement in its entirety.

This is problematic for at least two reasons. First, the proposed rule contemplates that some providers would not provide this counseling for asserted religious or moral reasons, but it does not contain any requirement that those providers advise patients of their refusal. Therefore, patients will not even know if they are getting complete information. Second, even for providers who want to offer their patients information about all of their health care options, the proposed rule creates confusion. On the one hand, the preamble includes language stating that doctors (and only doctors) could continue to offer nondirective counseling on abortion as a health care option, the operative language of the rule is completely silent on the subject. Particularly, combined with the prohibition on referrals, providers may not understand whether, or who, can provide abortion counseling to patients that request it.

² 42 C.F.R. § 59.5(a)(5).

³ Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25,531.

⁹ 42 C.F.R. § 59.5(a)(5).

¹⁰ *Id.*

Limiting support for comprehensive reproductive health services takes us back to failed policies that harm women's health. The gag rule has been associated with an increase in abortions, an increase in maternal deaths and encouraging unsafe abortions. APHA has long recognized access to the full range of reproductive and sexual health care services, including abortion, as a fundamental right⁶. Without access to these services, the health of women and girls is at risk. These services are essential for women's lives, for population health and for advancing income equality, women's rights and women's individual freedom.

II. The Proposed Rule is clearly designed to make it impossible for specialized reproductive health providers to continue to participate in the Title X program, threatening access to critical care services for thousands of people across the United States.

The proposed rule is clearly designed to make it impossible for reproductive health-focused providers, like Planned Parenthood health centers, to continue to serve patients in Title X. First, the proposed rule would require Title X recipients to physically and financially separate Title X project activities from any of their abortion-related activities, including abortion referrals.⁷ These provisions completely ignore that specialized providers have for decades played an important -- and irreplaceable role -- in the Title X program.

The rule would grant broad discretion to HHS to evaluate an individual Title X recipient's compliance with the new physical and financial separation standard by instructing HHS to employ a "facts and circumstances" test in order to determine whether a Title X project has achieved "objective integrity and independence" from abortion-related activities.⁸ In its analysis, the agency would be required to consider at least four factors:

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.⁹

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

⁶ American Public Health Association, *Restricted Access to Abortion Violates Human Rights, Precludes Reproductive Justice, and Demands Public Health Intervention* (Nov 3, 2015) available at <https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2016/01/04/11/24/restricted-access-to-abortion-violates-human-rights>

¹¹ *Compliance With Statutory Program Integrity Requirements*, 83 Fed. Reg. at 25,532.

¹² *Compliance With Statutory Program Integrity Requirements*, 83 Fed. Reg. at 25,532.

¹³ *Id.*

protection is afforded by the imposition of a requirement for ‘physical’ separation.”¹⁰ A notice issued by HHS further made clear that Title X service sites could use common waiting rooms, staff, and filing systems for abortion-related activities and Title X project activities.¹¹ HHS fails to justify why this reversal is warranted. Moreover, these factors go even further than a 1988 domestic gag rule issued by the Reagan administration. Even so, HHS states that the standard still may not go far enough in separating Title X services from abortion.

These provisions are clearly designed to destabilize the Title X network by pushing out reproductive health-focused providers and bringing in providers that do not focus on reproductive health care. This would undermine the mission of Title X to increase access to family planning and sexual health care services, including the contraceptive methods of a patient’s choice, for low-income, uninsured, underinsured and underserved individuals. Moreover, evidence shows that Title X patients may prefer to see a provider that specializes in reproductive health. Specialized clinics can offer better or faster services such as having oral contraceptives available on site or same day IUD insertion.¹² Also, women trust OB/GYN specialists and are generally more likely to talk with them about health concerns both within and outside the scope of sexual and reproductive health care.¹³ Thirty-five percent of women report their OB/GYN being their primary health care provider.¹⁴

Planned Parenthood plays a critical and outsized role in the Title X program. Nationwide, Planned Parenthood health centers serve more than 40 percent of Title X patients. Eliminating Planned Parenthood from the Title X program would leave many people without access to care. In states that have eliminated Planned Parenthood from their family planning programs, the public health results have been disastrous. For instance, a recent study in the *New England Journal of Medicine* showed that blocking patients from going to Planned Parenthood in Texas had serious public health consequences.¹⁵ The study found a 35 percent decline in women in publicly funded programs using the most effective methods of birth control. Further, denying women access to the contraceptive care that they needed led to a dramatic 27 percent increase in births among women who had previously accessed injectable contraception through those programs. Moreover, public health officials fear a domestic gag rule, “could cripple federal efforts to stop a dramatic increase in sexually transmitted diseases in the U.S.”¹⁶

III. The Proposed Rule would radically change the Title X program, adversely impacting the health of people across the nation.

The proposed rule would threaten Title X program protections that are designed to ensure access to the full range of contraceptive methods. Currently, Title X projects must, by statute and

¹⁴ Standards of Compliance for Abortion Related Services in Family Planning Services Projects, 65 Fed. Reg. 41,270, 41,276 (Jul. 3, 2000).

¹⁵ Provision of Abortion-Related Services in Family Planning Projects, 65 Fed. Reg. 41,281, 41,282 (Jul. 3, 2000).

¹² Frost, J.J., Gold, R.B., Bucek A., *Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in Meeting Women’s Health Care Needs*, *Women’s Health Issues*, 22(6) (2012), e519-e525.

¹³ PerryUndem, “Research Findings: Women + OB/GYN Providers,” (Nov. 2013), available at https://www.plannedparenthood.org/files/4914/0656/5723/PPFA_OBGYN_Report.FINAL.pdf.

¹⁴ *Id.*

¹⁶ Amanda J. Stevenson et al. “Effect of Removal of Planned Parenthood from the Texas Women’s Health Program,” *New England Journal of Medicine*, Vol. 374, available at <http://www.nejm.org/doi/full/10.1056/NEJMs1511902#t=article>.

¹⁷ Michelle Andrews, *Trump’s Redirection Of Family Planning Funds Could Undercut STD Fight*, NPR (June 12, 2018), available at <https://www.npr.org/sections/health-shots/2018/06/12/618902785/trumps-redirection-of-family-planning-funds-could-undercut-std-fight>

regulation, offer a broad range of acceptable and effective family planning methods and services.¹⁷ Access to “the full range of FDA-approved contraceptive methods” has also been deemed an essential feature of quality family planning by 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.¹⁸ While HHS cannot alter the statutory requirement that Title X projects offer “a broad range of acceptable and effective family planning methods and services,¹⁹ the proposed rule goes out of its way to emphasize that “projects are not required to provide every acceptable and effective family planning method or service,” giving Title X projects authority to exclude methods or services of their choosing.²⁰ Moreover, the proposed rule would remove the requirement that family planning methods available from Title X projects must be “medically approved.”²¹

Collectively, these changes appear intended to allow Title X projects to deny patients access to the full complement of effective contraceptive methods. We are very concerned that this lowering of the threshold for participation in Title X will result in organizations with little or no experience providing sexual and reproductive health care participating in the program, which in turn would inevitably lead to reduced access to a broad range of methods for patients. All people seeking care in Title X programs are entitled to access the contraceptive method that works best for their individual circumstances, and that requires access to all methods of contraception. Indeed, this was the very purpose of the Title X program in the first place. At the time, Congress stated that Title X’s purpose was “making *comprehensive* voluntary family planning services readily available to all persons desiring such services.”²²

Moreover, in the proposed rule HHS makes a number of unsupported contentions about the benefits of the rule, including that it would improve access to and the quality of care provided at Title X sites.²³ In fact, the United States is currently experiencing a 30-year low in unintended pregnancy and an all-time low in teen pregnancy. These results have been achieved in large part due to access to affordable contraception - in particular the most effective methods of contraception - including through programs like Title X. This rule threatens to turn back the progress that has been made.

¹⁸ 42 U.S.C. § 300(a); 42 C.F.R. § 59.5(a)(1). While the entire project is held to the “broad range” standard under the current rules, each participating entity is not. So “[i]f an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services.”

¹⁹ 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>.

²⁰ Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. 25,502 (proposed Jun. 1, 2018) (to be codified at 42 C.F.R. pt. 59).

²¹ Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25,530.

²² *Id.* at 25,530.

²³ Pub. L. No. 91-572, § 2(1); see S. Rep. No. 91-1004, at 2 (1970) (emphasis added).

²⁴ See, e.g., Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25,505 (“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 25,522 (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 providers and, thereby, to increase patient access to family planning services focused on optimal health outcomes for every Title X client”).

APHA supports the universal human right to voluntary, informed, affordable access to the full range of modern contraceptive methods, including emergency contraception.²⁴ Full access to contraceptive coverage is a vital component of preventive health services for women. By enabling women to choose when to have children, contraception improves women's health²⁵ and economic security.²⁶ The economic impacts of the proposed rule must be fully considered, including the effect on women's economic security and the additional health costs that result from insufficient preventive health care.

IV. The Proposed Rule fails to account for numerous costs that will be imposed on women, providers and society if it is implemented.

HHS fails to take into account most of the costs that will accrue under this rule. HHS acknowledges that the proposed rule has no quantifiable benefits. At the same time HHS significantly underestimates the projected costs by only erroneously confining its discussion of the rule's costs to include only the costs borne by entities that would have to comply with the rule, but not calculating the considerable additional costs, including for Title X patients who are no longer able to receive the health care services that they need, as well as the resultant health care costs to state and local health systems. Moreover, even HHS's calculations of the logistical and structural costs of compliance are insufficient. Remarkably, because of that failure, HHS has determined that its rulemaking is not "economically significant" because it believes the rule's economic effects would fall short of a \$100 million threshold. An accurate analysis of the costs would determine that the costs are significantly greater than \$100 million. For instance, the proposed rule's extensive new reporting requirements—from subrecipients to patient medical records—would be far more economically and administratively burdensome than HHS suggests. It would require changes in electronic health record systems and additional time in training and management that far exceed the estimated costs as outlined in the proposed rule. Furthermore, the physical separation requirements would impact all Title X providers, and seek to require wholly separate second sites to be opened in order for Title X-funded organizations to continue separate, non-Title X activities.

V. The Proposed Rule would worsen existing health disparities leaving communities that already experience worse health outcomes with less access to care

All of the harmful impacts laid out above will fall most heavily on the people who are most in need of comprehensive, affordable reproductive and sexual health care services. Because of systemic inequities, the people served by the Title X program are more likely to be people of color and to face language barriers and other barriers to care. This rule will deny people who already face health disparities access to the best possible care through experienced providers and to all methods of contraception.

²⁴ American Public Health Association. (2015) Universal Access to Contraception. Accessed October 18, 2017 from <https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2015/12/17/09/14/universal-access-to-contraception>

²⁵ Wendt A, Gibbs CM, et al. (2012) "Impact of increasing inter-pregnancy interval on maternal and infant health. *Pediatr Perinat Epidemiol*. Accessed October 18, 2017 from <https://www.ncbi.nlm.nih.gov/pubmed/22742614>

²⁶ Bailey M, Hershbein B, Miller A. 2012. The Opt-in Revolution? Contraception and the Gender Gap in Wages. National Bureau of Economic Research. Accessed October 18, 2017 from <http://www.nber.org/papers/w17922.pdf>

For nearly 50 years, the Title X family planning program has been a critical underpinning of the public health safety-net infrastructure that serves millions of low-income people each year. Title X was created to ensure that all people in the United States can access high-quality preventative sexual and reproductive health care. Title X service sites offer free and reduced-cost contraception and health services to low-income and uninsured populations. Of the 4 million patients who visit Title X providers, two-thirds live below the federal poverty level and almost half are uninsured. These health centers provide resources that are necessary for a healthy population, such as cancer screenings, STI testing and treatment, sexual education, and effective contraception, to a population that otherwise has limited access.

This federal program should be preserved and strengthened—not compromised by unnecessary over-regulation and limitations that are contrary to ethical medical practice. For all of these reasons, we strongly urge you to not finalize the proposed rule.

Sincerely,

A handwritten signature in black ink, appearing to read "Georges C. Benjamin". The signature is fluid and cursive, with a large, stylized initial "G".

Georges C. Benjamin, MD
Executive Director