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, Docket ID No. HHS-OS-2018-0008 (RIN: 0937-ZA00)

Dear Secretary Azar:

On behalf of more than 43,000 physician members and medical students of the California Medical Association (CMA), we appreciate the opportunity to provide comments on the Department of Health and Human Services’ (the “Department”) proposed changes (“Proposed Rule”) to the regulations governing the Title X program, published in the Federal Register on June 1, 2018.¹ Through a comprehensive program of legislative, legal, regulatory, economic and social advocacy, CMA promotes the science and art of medicine, the care and well-being of patients, the protection of the public health, and the betterment of the medical profession.

The Proposed Rule would withhold federal funds to qualified family planning providers that also offer abortion services; prohibit in most cases referrals for abortion and restrict counseling about abortion services; eliminate current requirements that Title X sites offer a broad range of medically approved family planning methods and nondirective pregnancy options counseling; and direct new funds to faith-based and other organizations that promote fertility awareness and abstinence as methods of family planning rather than the full range of evidence-based family planning methods.

Established in 1970, Title X is the sole federal program dedicated to funding family planning services for low-income individuals. Title X supports the delivery of family planning and related services including contraception, STD prevention and treatment, pregnancy tests, and life-saving cancer screenings. According to the Guttmacher Institute, more than $7 billion in taxpayer dollars are saved every year by preventing unintended pregnancies and by early treatment of breast and cervical cancer through Title X health centers nationwide. California’s Title X provider network is the largest in the nation and serves over 1,000,000 low-income individuals

¹ Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. 25502 (June 1, 2018) (to be codified at 42 CFR Part 59).
throughout the state – over 25% of Title X patients nationwide. In California, $1.3 billion is saved annually thanks to public investment in family planning and related services provided at Title X-funded health centers.

The proposed changes would severely undermine the effectiveness of the Title X program.\textsuperscript{2} 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. The rule would interfere with the physician-patient relationship, undermine established medical access, and prevent low-income people from accessing the full range of reproductive health care. For these reasons, and those outlined below, CMA strongly opposes the Proposed Rule changes and requests that HHS maintain Title X program regulations in their current form.

I. The Notice of Proposed Rulemaking (“NPRM”) would interfere with the physician-patient relationship and prevent physicians from providing medically-accurate information

The NPRM 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.\textsuperscript{3} That requirement would be replaced with a complete ban on health care providers giving abortion referrals.\textsuperscript{4} This provision would restrict providers from speaking freely with their patients, violates core ethical standards, and undermines the physician-patient relationship.

**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.\textsuperscript{5}

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.\textsuperscript{6} Title X regulations currently direct Title X projects to


\textsuperscript{3} 42 C.F.R. § 59.5(a)(5).

\textsuperscript{4} Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25,531.

\textsuperscript{5} 42 C.F.R. § 59.5(a)(5).

\textsuperscript{6} 83 Fed. Reg. at 25530 (§ 59.5(a)).
“[o]ffer pregnant women the opportunity to be provided information and counseling” on all pregnancy options. The Title X statute states that no federal funds appropriated under the program shall be used in programs where abortion is a method of family planning. This provision has generally been interpreted throughout the program’s history as meaning that Title X funds cannot be used to pay for or support abortion, which is reflected in the current regulations. 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. At a minimum, these changes would have a chilling effect on physicians, who could fear even mentioning the word abortion while counseling a pregnant patient on their options would violate the Title X regulations.

Second, HHS seeks to prohibit Title X projects from providing abortion referrals. The proposed rule would eliminate the options counseling requirement in its entirety. In addition to eliminating the requirement for nondirective pregnancy options counseling, the NPRM seeks to ban Title X projects from providing abortion referrals. The Proposed Rule would allow a limited exception if a pregnant patient has already decided to have an abortion and explicitly requests a referral. In this situation, a physician—and no other clinical staff—would be permitted, but not required, to provide the patient with a list of licensed, qualified, and comprehensive health care providers, some of which may or may not provide abortion services, in addition to prenatal care. However, the list cannot identify the providers that perform abortions and the physician may not indicate which providers on the list offer abortion services, thus requiring the patient to vet the listed providers themselves to receive the care they seek. If a pregnant patient does not explicitly state that she has decided to have an abortion, but requests a referral for one, the patient can only be given list of providers which do not provide abortion but do provide prenatal care.

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).” However, neither the physician nor the list may indicate which providers on this list offer abortion services. 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

7 42 C.F.R. § 59.5(a)(5).
8 Id.
11 Id.
12 Id.
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.”

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. This proposal directly conflicts with the requirements of medical professional associations, including the American College of Obstetricians and Gynecologists and the American College of Physicians, which assert that patients should receive complete and accurate information to inform their health care decisions. 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.” Similarly, the American Medical Association states in its Code of Medical Ethics that providers “present relevant information accurately and sensitively, in keeping with the patient’s preferences” and that “withholding information without the patient’s knowledge or consent is ethically unacceptable.” That is why both the American Medical Association and the American Nurses Association, among others, have publicly announced their strong objection to the NPRM.

Physicians’ inability to comply with their ethical obligations could not only harm the patient-physician relationship, but also could result in harm to their pregnant patients at Title X projects, especially if such patients are delayed in finding abortion providers. Moreover, any restriction on the right of patients and physicians to communicate freely would require assertion of a

13 Id.
compelling government interest. While HHS has suggested some general rationales for its proposed amendments, it has not indicated such a compelling interest for the proposed restrictions. In fact, CMA believes there is no such compelling interest.

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.\(^2\)

**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.\(^2\)

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.

CMA strongly opposes any government interference in the exam room, especially legislation or regulations that attempt to dictate the content of physicians’ conversations with their patients. Protecting the sanctity of the patient-physician relationship, including defending the freedom of communication between patients and their physicians, is a core priority for CMA. The ability of physicians to have open, frank, and confidential communications with their patients has always been a fundamental tenet of high quality medical care.

**II. 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


\(^{22}\) 83 Fed. Reg. 25531.
contraceptive methods leads to better health outcomes. Women who are able to use the method of their choice are more likely to use contraception consistently and effectively. When women use contraception consistently and correctly, their risk of unintended pregnancy drops significantly.

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 Health Resources & Services Administration (HRSA) to define those services. 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. 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. 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. The evidence-based recommendations support offering a full range of FDA-approved contraceptive methods. California law requires health plans to cover as well as all FDA-approved methods of contraception without cost-sharing.

The current Title X regulations require funded projects to provide medical services related to family planning and to offer a broad range of acceptable and effective medically approved family planning services. For example, the Affordable Care Act requires most private plans to cover women’s preventive health services with no cost sharing and directs the Health Resources & Services Administration (HRSA) to define those services. 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. 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. 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. The evidence-based recommendations support offering a full range of FDA-approved contraceptive methods. California law requires health plans to cover as well as all FDA-approved methods of contraception without cost-sharing.

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planning methods. The NPRM eliminates the requirement that projects offer the full range of family planning methods, and further eliminates “medically approved” from the current regulatory requirement. The Proposed Rule would no longer require that sites follow the Quality Family Planning guidelines of the Centers for Disease Control and Prevention and the OPA. Instead, HHS emphasizes non-medical services, such as abstinence, natural family planning, and adoption as a way to manage infertility. HHS’ emphasis on non-medical services is contradicted by data showing that fertility awareness methods are among the least effective methods of family planning, and the Food and Drug Administration has warned that these are not reliable forms of contraception.

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. 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. Significantly, data shows that fertility awareness methods are among the least effective family planning methods. In fact, the FDA has warned that these methods are not reliable forms of contraception. This is likely one of the reasons why very few women choose to use natural family planning to prevent pregnancy.

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).” 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

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32 83 Fed Reg. at 25529 (§ 59.2).
34 QFP, supra note 24, at 47.
37 42 C.F.R. § 59.5(a)(1).
guidelines in 2016. 38 Notably, HHS refrains from directly quoting the guidelines, which indicate that fertility awareness methods are “less effective,” but “should be provided for women desiring an alternative method.”39

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.40 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.41 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.42 It is clear that HHS designed the proposed rules to cater to providers who refuse to provide the full range of 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. If finalized, the proposed rule would likely reverse the progress Title X providers have made in offering comprehensive 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.

Contrary to HHS’ assertion that its proposed changes will improve access to and the quality of care at Title X projects, CMA believes that the proposed revisions discussed above will undermine the quality and standard of care upon which millions of women depend for their reproductive health care. Moreover, the Proposed Rule threatens to reverse decades of progress in reducing unintended and teen pregnancy: the United States currently has a 30-year low in unplanned pregnancy and an all-time low in teen pregnancy. Access to affordable contraception, including through programs funded by Title X, has helped make these results possible.

38 83 Fed Reg. at 25515.
39 Women’s Preventive Services Guidelines, supra note 27.
40 83 Fed. Reg. at 25516.
42 83 Fed. Reg. at 25516.
Conclusion

In conclusion, Title X is the only federal program dedicated specifically to providing low-income patients with essential family planning and preventive health services and information. As such, it plays a vital role in the nation’s public health safety net by ensuring that timely, safe, and evidence-based care is available to women, men, and adolescents, regardless of their financial circumstances. In addition to pregnancy prevention, Title X projects provide other important health services, including sexually transmitted infection testing and treatment, Pap tests, and clinical breast exams. CMA believes that this Proposed Rule, if finalized, would limit access to critically needed care and services for millions of individuals who depend upon the Title X program for their care and would result in harm to patients and the public’s health. We urge HHS to withdraw this proposal.

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 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 Procedures Act. If you have questions about these comments, please contact me at jrubenstein@cmadocs.org or (916) 551-2554.

Sincerely,

Jessica Rubenstein
Associate Director
Center for Health Policy
California Medical Association