AMA
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The Honorable Alex M. Azar, II
Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Compliance with Statutory Program Integrity Requirements (RIN 0937-ZA00), 83 Fed. Reg. 25502 (June 1, 2018)

Dear Secretary Azar:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments to the Department of Health & Human Services (HHS) in response to the Notice of Proposed Rulemaking (Proposed Rule or NPRM) on "Compliance with Statutory Program Integrity Requirements" issued by the Office of Population Affairs (OPA). In its NPRM, HHS proposes to significantly revise the regulations governing the federal Title X family planning program (Title X). The Proposed Rule would withhold federal funds to qualified family planning providers such as Planned Parenthood 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.

For the reasons discussed in more detail below, the AMA strongly opposes this Proposed Rule. We are very concerned that the proposed changes, if implemented, would undermine patients' access to high-quality medical care and information, dangerously interfere with the patient-physician relationship and conflict with physicians' ethical obligations, exclude qualified providers, and jeopardize public health. Given our concerns, we urge HHS to withdraw this NPRM.

<u>The Proposed Rule Would Interfere With the Patient-Physician/Provider Relationship</u>

The AMA 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 the AMA. 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.

From ancient times, physicians have recognized that the health and well-being of patients depends upon a collaborative effort between physician and patient. Patients share with physicians the responsibility for their own health care. The patient-physician relationship is of greatest benefit to patients when they bring medical problems to the attention of their physicians in a timely fashion, provide information about their medical condition to the best of their ability, and work with their physicians in a mutually respectful alliance. This relationship is built upon trust. A physician must always have the ability to freely communicate with his or her patient, providing information to patients about their health and safety, without fear of intrusion by government and/or other third parties. Regulations that restrict the ability of physicians to explain all options to their patients and refer them, whatever their health care needs, compromise this relationship and force physicians and other health care providers to withhold information that their patients need to make decisions about their care.

The Proposed Rule would violate these core principles by restricting the counseling and referrals that can be provided to patients and by directing clinicians to withhold information critical to patient decision-making. Under section 59.5(a)(5) of the current regulations, Title X projects are required to provide pregnant patients information and counseling regarding the full range of reproductive health options: prenatal care and delivery; infant care, foster care or adoption; and pregnancy termination. 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 referral upon request, except with respect to any option(s) about which the patient indicates she does not want information and counseling.

Specifically, the NPRM eliminates the current requirement that Title X projects provide neutral, factual, nondirective options counseling regarding <u>all</u> of a pregnant patient's options—including abortion—upon request. It appears to be up to each site and organization that participates to decide whether to mention abortion as an option, and it is not exactly clear the extent to which counseling for abortion would be allowed. Although HHS states in the Preamble to the Proposed Rule that a physician—and only a physician—could continue to offer nondirective counseling on abortion as an option, the actual text of the NPRM is silent on this issue.

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. However, the NPRM adds vague and confusing language that Title X projects shall not promote, encourage, support, or present abortion as a method of family planning. These terms are not defined in the regulatory text. At the very least, this language could have a chilling effect on physicians and other providers when counseling patients on their options. Moreover, the Proposed Rule requires that Title X projects must refer pregnant patients "for appropriate prenatal and/or social services (such as prenatal care and delivery, infant care, foster care, or adoption)" regardless of a patient's wishes, interest in such a referral, or health status (Section 59.14, NPRM). Title X projects would also be required to assist patients with setting up a referral appointment "to optimize the health of the mother and unborn child." Furthermore, the NPRM would prohibit a Title X project from using prenatal, social service, emergency medical or other referrals as an indirect means of encouraging or promoting abortion as a method of family planning.

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. 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.

The proposed changes on counseling and referral described above would not only undermine the patient-physician relationship, but also could force physicians to violate their ethical obligations. The inability to counsel patients about all of their options in the event of a pregnancy and to provide any and all appropriate referrals, including for abortion services, are contrary to the AMA's *Code of Medical Ethics*, which provides that patients have the right

> "to receive information from their physicians and to have the opportunity to discuss the benefits, risks, and costs of appropriate treatment alternatives…patients should be able to expect that their physicians will provide guidance about what they consider the optimal course of action for the patient based on the physician's objective professional judgment." (Opinion E-1.1.3)

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 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, the AMA believes there is no such compelling interest.

The Proposed Rule Would Undermine Access to Evidence-Based Family Planning Methods

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 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.

Moreover, although the current regulations allow Title X-funded organizations to offer only a single method of family planning, the NPRM is more permissive and seems to encourage more single-method or limited number of methods within a project. These changes could result, for example, in a Title X project that provides only natural family planning and other fertility awareness-based methods, along with abstinence only education for adolescents. These revised provisions change the historic emphasis under both the Title X statute and current regulations that projects must provide a broad range of acceptable and effective medically approved family planning methods.

All individuals seeking care in Title X programs should have access to the contraceptive method that works best for their circumstances. Evidence shows that women who have access to and are able to use the contraceptive method of their choice are more likely to use contraception consistently and effectively, thereby reducing their risk of unintended pregnancy. Contrary to HHS' assertion that its proposed changes will improve access to and the quality of care at Title X projects, the AMA 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.

The Proposed Rule Would Inappropriately Exclude Qualified Providers

The Proposed Rule would essentially disqualify any provider that offers abortion services or is affiliated with an abortion provider from receiving Title X funds. It appears designed to make it extremely difficult, if not impossible, for specialized reproductive health providers, such as Planned Parenthood, to continue to participate in Title X. The statute governing Title X requires that program funds can only go to entities where abortion is not a method of family planning. Under current regulations, Title X projects are banned from using Title X funds to pay for abortions and must keep any abortion-related financially separate from their Title X activities. The Proposed Rule, however, would require that Title X activities have full physical and financial separation from abortion-related activities. In addition to separate accounting and electronic and paper health records, providers would need to have separate treatment, consultation, examination and waiting rooms, office entrances and exits, workstations, signs, phone numbers, email addresses, educational services, websites, and staff. HHS fails to justify why physical separation is needed.

Another proposed change would require Title X projects to offer comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity. This is inappropriate since providing comprehensive primary care services is not a permissible use of Title X funds and the best referrals for Title X funds are not necessarily defined solely by physical proximity. Moreover, some stand-alone family planning clinics, especially in rural areas, may not be near primary health providers, and may not qualify for funding under this requirement.

These provisions, taken as a whole, would make it impossible for clinics like Planned Parenthood and any other provider that also offers abortion services to comply with the new requirements of the program. Furthermore, restrictions on infrastructure support and affiliations would make it impossible for them to continue to participate in Title X. It is unlikely that other providers in many areas of the country, especially in rural and medically underserved communities, would be able to adequately fill the gap left by qualified providers being forced to close.

The implications of these proposed changes are significant, putting at risk access to quality family planning and preventive care services for more than 40 percent, or nearly two million, Title X patients. In states that have excluded certain providers from their family planning programs, research shows serious public health consequences. For example, a study published in the *New England Journal of Medicine* found that blocking patients from going to Planned Parenthood in Texas resulted in a 35 percent decline in women in publicly-funded programs using the most effective forms of birth control and that denying women access to the contraceptive care they needed led to a 27 percent increase in births (among women who had previously used injectable contraception through these program).

Additional Provisions Would Negatively Impact Access to Care

Another proposed change in the NPRM would redefine "low-income family" to include women whose employer-based health insurance coverage does not cover contraception due to the employer's religious or moral objections. This expanded definition would potentially require Title X providers to provide free contraceptive services to women of all incomes. The Title X program is already underfunded and overburdened and the Proposed Rule could result in even fewer resources to serve low-income patients.

The NPRM also threatens patient confidentiality protections, particularly for adolescents. Title X has long required that both adults and adolescents receive confidential family planning services. The current regulations require sites to consider if minors qualify for free family planning services based on their income alone. While the Title X statute encourages family involvement in minors' family planning decisions, the Proposed Rule tries to make such involvement mandatory by changing the definition of "low-income family" to require that Title X providers document in the medical records of unemancipated minors the specific actions taken by the provider to encourage the minor to involve his or her family. This requirement would be a condition of allowing such minors to receive confidential services based on their own resources. This requirement could undermine the provider's expertise and judgment about whether encouraging family participation is feasible or desirable based on the minor's circumstances. In addition, new proposed documentation and reporting requirements, such as the age of each minor patient, the age of each minor's sexual partner(s), if required by law, and special screening of any patient under the age of consent who has a sexually transmitted disease or is pregnant, could undermine the relationship between the minor patient and their Title X provider and prevent such minors who have confidentiality concerns from seeking needed medical services. HHS needs to ensure that Title X projects can continue to provide confidential care for adolescents while complying with all state and federal laws.

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. The AMA 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.

Sincerely,

James L. Madara, MD