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Via Electronic Submission *(**www.regulations.gov**)*

July 31, 2018

Diane Foley, M.D., FAAP
Deputy Assistant Secretary
Office of Population Affairs
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20001

Re: Compliance With Statutory Program Integrity Requirements (HHS-OS-2018-0008)

Dear Dr. Foley:

The Association of American Medical Colleges (AAMC or Association) welcomes the opportunity to comment on the Department of Health and Human Services (HHS' or the Agency's) proposed rule entitled *Compliance With Statutory Program Integrity Requirements*, 83 *Fed. Reg.* 25502 (June 1, 2018).

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Our members are all 151 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, we serve the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Together, these institutions and individuals are the American academic medicine community.

Since the 1970s the Title X program has provided grants for voluntary family planning services and remains the only federal program devoted to family planning and related preventive health services.[1] As will be described in detail below, should the rule be finalized as proposed, it will undermine standards of medical professionalism and result in harm to patients. Having family planning services available is widely recognized as essential to women's health as well as their economic well-being.[2] The rule also adds onerous reporting requirements based on the mere possibility of the funds being used for prohibited activity and extends grantee liability well-beyond what is reasonable. Should the rule be finalized as proposed it will be detrimental to the women and men who rely on Title X providers as an essential source of their health care.

[1] Congressional Research Service Report, September 3, 2014
[2] Sonfield A, *What Women Already Know: Documenting the Social and Economic Benefits of Family Planning*, Guttmacher Policy Review, Winter 2013, Vol. 16, Number 1

The benefits of the program as currently structured are clear. Among the findings of the 2016 Title X Annual Report, the most recent available on the website of the Health Resources and Services Administration, are the following[3]:

- Title X providers serve a vulnerable population, most of whom are female, low income, and young. In 2016 Title X-funded providers served more than 4 million family planning users (i.e., clients) through almost 6.7 million family planning encounters.
- Title X providers are a critical source of high-quality and affordable reproductive health care for individuals with and without health insurance. 43% of Title X users are uninsured, more than triple the national rate.
- Title X providers serve a racially and ethnically diverse population.
- Title X providers offer clients a broad range of effective, medically safe contraceptive methods approved by the U.S. Food and Drug Administration

In other words, as it currently operates, Title X is an essential source of health care. No compelling evidence has been presented to support the proposed changes. **Therefore, the AAMC urges the Department to withdraw the proposed regulation.**

The Proposed Rule is Incongruous with Medical Professionalism

The proposed rule would ban Title X-supported providers from giving patients full information about all their health care options and direct providers to include referrals to providers that do not offer the service requested by the patient. This proposal is in direct contradiction to medical ethics that guide providers to put the needs of patients first by providing them with the complete and unbiased information that is needed for the patient to give **informed consent**.[4] The provision of safe and quality medical care relies on a strong patient-provider relationship, where patients expect medically accurate, comprehensive information and an open dialogue about options. If implemented, the proposed rule would drive a wedge between patients and their providers by placing restrictions on the information and referrals that can be provided to patients, in some instances directing providers to withhold information critical to patient decision-making. Not only is this stance at odds with the expectation that physicians share their expertise with their patients, the proposal also is incongruous with the standards of medical professionalism that are the core of a physician's education and long-held standards of an ethical practice of medicine.

The proposed regulatory language recognizes the duty of a physician to promote patient safety by acknowledging that if asked, a doctor may provide a list of licensed, qualified, comprehensive health service providers but restricts this information in several ways. First, it can be provided only if a woman who is currently pregnant clearly states that she has already decided to have an abortion.[5] And second, the list of providers cannot identify the providers who perform abortions.[6] These requirements go far beyond what is called for under Title X, which is simply that no federal funds appropriated under the program

[3] Title X Family Planning Annual Report, 2016 National Summary, August 2017, accessed at https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf
[4] Hasstedt K. (2018) *Unbiased Information on and Referral for All Pregnancy Options Are Essential to Informed Consent in Reproductive Health Care*. Guttmacher Policy Review. Available at https://www.guttmacher.org/gpr/2018/01/unbiased-information-and-referral-all-pregnancy-options-are-essential-informed-consent
[5] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. at 25531
[6] *Id.*

"shall be used in programs where abortion is a method of family planning."[7] They contravene the very tenets of medical professionalism, may endanger the health of a patient, and should not be finalized.

The Proposed Changes to the Title X Program Jeopardize Public Health

The proposed rule would change the Title X program in significant ways by undermining access to evidence-based medicine, and threatening confidentiality protections. Title X has contributed to the dramatic decline in the unintended pregnancy rate in the United States, [8] now at a 30-year low. Improved access to contraception and information for adolescents, including those provided by Title X projects, has contributed to a record low teen pregnancy rate.[9] The services provided by Title X projects help prevent nearly one million unintended pregnancies each year.[10] The proposed rule threatens to reverse this historic progress.

The proposed rule would remove the requirement that methods of family planning be "medically approved," and instead places increased emphasis on the provision of natural family planning and "other fertility-awareness based methods."[11] While the current regulations allow, though do not encourage, organizations receiving Title X funds to offer only a single method of family planning, the proposed rule is much more directive. It encourages the inclusion of more providers within a Title X project that only offer a single method or very limited methods, putting at risk access to the most effective – and often most desired– forms of contraception, such as long-acting reversible contraception (LARC).[12] Everyone seeking care from Title X-supported providers should have access to the evidence-based contraceptive method that works best for their individual circumstances.

The proposed rule would require Title X-supported providers to put reporting and notification laws ahead of patient needs, including documentation of "specific actions taken by the provider to encourage an unemancipated minor to involve her/his family in her/his decision to seek family planning services."[13] These requirements undermine the program's historically strong confidentiality protections, without which minors may be more likely to delay or forego needed care. The American Academy of Pediatrics' Committee on Adolescence finds that "…policies supporting adolescent consent and protecting adolescent confidentiality are in the best interests of adolescents. Accordingly, best practice guidelines recommend confidentiality around sexuality and sexually transmitted infections (STIs) and minor consent for contraception."[14] The Title X Program should continue to ensure that adolescents are able to find confidential care consistent with the standard of care for all adolescents in 2018, while maintaining compliance with all state and federal laws.

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[7] 42 U.S.C. 300, § 1008
[8] Finer LB and Zolna MR, *Declines in unintended pregnancy in the United States*, 2008–2011. N Engl J Med 2016; 374:843–852.
[9] Martin JA, Hamilton BE, Osterman MJ, Driscoll AK, Drake P. (2018).*Births: Final data for 2016*. Hyattsville, MD: National Center for Health Statistics. *Available at* https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_01.pdf - PDF.
[10] Guttmacher Institute. *Fact Sheet: Publicly Funded Family Planning Services in the United States*. September 2016. *Available at* https://www.guttmacher.org/sites/default/files/factsheet/fb_contraceptive_serv_0.pdf
[11] 83 Fed. Reg. at 25530.
[12] Secura G et al., *The Contraceptive CHOICE Project: Reducing Barriers to Long-Acting Reversible Contraception*. Am J Obstet Gynecol. 2010 Aug; 203(2): 115.e1–115.e7. http://doi.org/10.1016/j.ajog.2010.04.017
[13] 83 Fed. Reg. at 25530
[14] Contraception for Adolescents. COMMITTEE ON ADOLESCENCE. Pediatrics. Sep 2014, peds.2014-2299; DOI: 10.1542/peds.2014-2299.

Providers are obligated to prioritize the needs of patients in their daily decision making, and we are concerned that these significant changes proposed to the Title X Program, if implemented, threaten to reverse decades of public health progress, including our nation's historic achievements in reducing unplanned and teen pregnancy rates.

The Proposed Rule Will Harm Lower Income Americans and Patients in Rural Areas

The proposed rule would require Title X-supported health centers to offer comprehensive primary care services or be near a primary care provider – requirements not all health centers would be able to fulfill, and which could result in their closure. It would also encourage a Title X-supported center that meets these requirements to only offer a single method or a limited number of methods of family planning. If finalized, these changes in policy will create or exacerbate inequities in health care access for Americans whose access may already be limited due to their geographic residence or financial means. For rural- and frontier-dwelling Americans who reside in a health professional shortage area, access to certain services might functionally cease to exist because of the proposed rule as seeking care in distant locales might be too burdensome or expensive. This holds, too, for lower income Americans who lack the financial means to seek out care or counseling when their primary physicians decline to provide comprehensive family planning services.

As the only federal grant program dedicated exclusively to providing lower income patients with essential family planning and preventive health services and information, Title X plays a vital role in ensuring that safe, timely, and evidence-based care is available to women, men, and adolescents, regardless of their financial circumstances. Rates of adverse reproductive health outcomes are higher among lower income and minority women, and unintended pregnancy rates are highest among those least able to afford contraception. According to the HHS Office of Population Affairs website, "Access to quality family planning and reproductive health services is integral to overall good health for both men and women. Few health services are used as universally. In fact, more than 99 percent of women aged 15–44 who have ever had sexual intercourse have used at least one contraceptive method."[15]

If, as anticipated, this rule results in fewer providers receiving Title X grants, it is unclear whether community health centers can provide the care for the population that has relied on Title X clinics since the 1970's. Research[16] has found that community health centers that participate in Title X are consistently associated with more comprehensive, more accessible, and higher-quality family planning services. But these same community health centers are already operating at capacity – 4 out of 5 centers that participate in Title X do not have the capacity to accept new patients and nearly 30 percent are the only clinic in their community that provide family planning services. These researchers raise strong concerns that the proposed rule, if adopted, may result in these higher quality community health centers being "forced to be the first to head to the doors" and leave the Title X Program.[17]

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[15] Family Planning Guidelines. Office of Population Affairs. Department of Health and Human Services. https://www.hhs.gov/opa/guidelines/program-guidelines/index.html

[16] Rosenbaum S et al. *The Title X Family Planning Proposed Rule: What's At Stake For Community Health Centers?* June 25, 2018. Health Affairs Blog. *Available at* https://www.healthaffairs.org/do/10.1377/hblog20180621.675764/full/

[17] *Id.*

If implemented, the proposed rule would limit access to vital preventive services for the more than 4 million patients seeking care annually by a Title X-supported provider, increasing rates of unplanned pregnancy and other adverse reproductive health outcomes, and further exacerbating health disparities between lower and middle/upper income Americans.

The Proposed Rule Adds Burdensome Requirements

This Administration has undertaken major efforts to reduce regulatory burden, such as "Reducing Regulation and Controlling Regulatory Costs" (Executive Order 13771, issued January 30, 2017), "Enforcing the Regulatory Reform Agenda" (Executive Order 13777, issued February 24, 2017), the Centers for Medicare & Medicaid's "Patient over Paperwork" initiative (launched October 2017, in an effort to reduce unnecessary burden), and several Requests for Information regarding administrative burden. We very much appreciate this focus on unnecessary burdens. This proposed rule runs counter to this laudable goal, however, by adding administratively burdensome requirements for both Title X grantees and subrecipients.

The Department proposes additional requirements for Title X grantees beyond those of general grants management because "the Department does not believe that the general grants management requirements are sufficient to address [the issue that "grantees from a variety of federal programs commonly fail to verify personnel costs with the actual time spent on grant-supported activities compared to time spent on non-grant functions by fully documenting personnel activity reports.]". To support this proposal, several cases are cited, all of which seem to have been uncovered through existing audits. No evidence has been put forward to establish that there are widespread problems that would require expanded monitoring. For example, the proposed rule would require Title X grantees to oversee the policies and referral practices of organizations that they refer patients to for other services and clinics to track services among referral networks they are not funded to provide. Such requirements may only serve to discourage entities from seeking Title X grants, thereby hurting the patients who rely on the services provided at these entities.

Grantees would be required to generate reports with information related to subrecipients, referral agencies and individuals involved in the grantee's Title X project. The AAMC is concerned that the estimate that this would require an average of 4 hours each year greatly underestimates the actual work that will be needed. Grantees would also have to provide adequate annual training of all individuals (whether or not they are employees) serving clients. The proposed rule would apply all requirements equally to grantees and subrecipients and puts on grantees the responsibility of ensuring that that subrecipients comply with the requirement.[18] The following information would be required in Title X Program grant applications and all required reports:

- Name, location, expertise and services provided by subrecipients and referral agencies
- Detailed description of the extent of the collaboration with subrecipients, referral agencies and individuals, and with "less formal partners within the community"
- Clear explanation of how the grantee will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients and those who serve as referrals for ancillary or core services

[18] 83 Fed Reg. 25529

The Title X Program already has significant reporting requirements and oversight. If the proposed requirements are finalized they are likely to discourage entities from seeking Title X grants, thereby hurting the patients who rely on their services.

Policy decisions about public health must be firmly rooted in science, and increase access to safe, effective and timely care. The proposed rule would interfere with the patient-provider relationship, exacerbate disparities for low-income and minority women, men, and adolescents, and harm patient health. **The AAMC strongly urges the Department to withdraw the rule.**

If you would like additional information, please contact Ivy Baer, Senior Director and Regulatory Counsel, at 202-828-0499 or ibaer@aamc.org.

Sincerely,

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Chief Health Care Officer, AAMC

cc: Ivy Baer, J.D., M.P.H., AAMC
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