ENDOCRINE SOCIETY
Hormone Science to Health

July 31, 2018

Alex Azar
Secretary
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Re: Compliance with Statutory Program Integrity Requirements [Docket No.: HHS-OS-2018-0008]

Dear Secretary Azar:

On behalf of the Endocrine Society, I offer the following comments on the Notice of Proposed Rulemaking (NPRM) related to statutory requirements for Title X grant recipients. The Endocrine Society is the world's largest professional organization of endocrinologists, representing the interests of over 18,000 clinicians and scientists engaged in the treatment and research of endocrine disorders, including diseases such as diabetes, thyroid disease, infertility, and obesity. Many of our members treat adolescents and women with reproductive health issues; we believe strongly that everyone should have easily accessible, affordable health care from the provider of their choice. As highlighted in the NPRM, "as the number of Americans at or below the poverty level has increased, the need to prioritize the use of Title X funds for the provision of family planning services has as well." We are concerned that the proposed changes to the Title X funding program will eliminate this right for many people who depend on Title X-funded facilities for their healthcare.

Title X is an important source of funding for both contraceptive and preventive services to women. The Centers for Disease Control and Prevention (CDC) estimates that unintended pregnancies cost American taxpayers at least $21 billion each year.[1] Nationally, 68 percent of these unintended pregnancies were paid for by public insurance programs including Medicaid, Children's Health Insurance Program, and the Indian Health Service.[2] Offering affordable access to contraception can have a measurable impact on these costs. For every public dollar invested in contraception, short-term Medicaid expenditures are reduced by $7.09 for the pregnancy, delivery, and early childhood care related to births from unintended pregnancies.[3]

[1] Centers for Disease Control and Prevention. *Women's Reproductive Health*; 2016. https://www.cdc.gov/chronicdisease/resources/publications/aag/pdf/2016/aag-reproductive-health.pdf. Accessed April 28, 2017.
[2] Guttmacher Institute. Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care. February 2015. https://www.guttmacher.org/sites/default/files/report_pdf/public-costs-of-up-2010.pdf.
[3] Guttmacher Institute. Contraceptive Use in the United States. https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states. September 2016. Accessed April 28, 2017.

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Surveys conducted prior to the implementation of the Affordable Care Act found that 34 percent of women voters reported having struggled with the cost of prescription birth control.[4] Among young adult women who are at most risk for having unintended pregnancies, 55 percent struggled with the cost of prescription birth control and reported times when they were unable to afford it.[5]

In 2015, a study found that Title X-funded health centers prevented 822,000 unintended pregnancies, resulting in savings of $7 billion to federal and state governments.[6] A recent analysis by Guttmacher Institute found that federally qualified health center (FQHC) sites in 27 states would need to at least double their contraceptive client caseloads if Title X funding is withheld from non-FQHCs. Nine of these states would need to at least triple their case load.[7] This would create an insurmountable access problem for women in need of contraceptive services.

Endocrinologists frequently prescribe hormonal contraception to treat a variety of medical conditions. Although the majority of women use contraception to prevent pregnancy, 58 percent of pill users also cite non-contraceptive health benefits such as treatment for excessive menstrual bleeding, menstrual pain, and acne as reasons for using the method.[8] Hormonal contraception can also reduce a woman's risk of developing ovarian and endometrial cancer.[9] In fact, fourteen percent of oral contraceptive users—1.5 million women—rely on this method exclusively for non-contraceptive purposes.[10]

We believe that many provisions within the NPRM threaten access to medically-necessary preventive and reproductive healthcare for women and adolescents. Our comments focus on the following provisions:

- Review criteria for grantee selection
- Requirements that must be met by Title X grantees

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[4] Planned Parenthood. Survey: Nearly Three in Four Voters in America Support Fully Covering Prescription Birth Control. http://www.plannedparenthood.org/about-us/newsroom/press-releases/survey-nearly-three-four-voters-america-support-fully-covering-prescription-birth-control-33863.htm. May 14, 2014.

[5] *Ibid*.

[6] Guttmacher Institute. Federally Qualified Health Centers: Vital Sources of Care, No Substitute for the Family Planning Safety Net. Guttmacher Policy Review. Volume 20: 2017. https://www.guttmacher.org/gpr/2017/05/federally-qualified-health-centers-vital-sources-care-no-substitute-family-planning.

[7] *Ibid.*

[8] Guttmacher Institute. Contraceptive Use in the United States. https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states. September 2016. Accessed April 28, 2017.

[9] National Institutes of Health/National Cancer Institute. Oral Contraceptives and Cancer Risk. https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/oral-contraceptives-fact-sheet. Reviewed March 2012. Accessed April 28, 2017.

[10] Jones RK, *Beyond Birth Control: The Overlooked Benefits of Oral Contraceptive Pills*, New York: Guttmacher Institute, 2011.

- Family involvement in family planning decisions
- Requirements related to abortion
- Expanded definition of "low-income"
- Eliminating the nondirective counseling option

59.7(b) Review criteria for grantee selection

The current Title X statue specifies seven criteria for selecting grantees, including number of low-income women served, need for family planning services locally, and availability of non-federal resources within the community. An objective merit review panel of experts scores each project based on the seven criteria to determine the best applications. The NPRM alters the review criteria and gives the HHS the ability to eliminate any application that is deemed to not clearly address how the proposal will satisfy the requirements, even before it reaches the merit review panel. The NPRM provides no details for how HHS will determine whether an application clearly addresses the requirements to the Department's satisfaction nor any mechanism for oversight of this initial compliance review. We are concerned that the vagueness of the requirements will preemptively eliminate qualified proposals or discourage organizations from submitting applications because they do not understand what is required to pass this initial review. **We urge HHS to eliminate the proposed initial review and allow all grant applications to be reviewed on merit by an objective panel of experts.** It is important that all potential grantees have an equal opportunity to be awarded a grant to ensure that there is geographic diversity in Title X clinics and full access to all medically-approved methods of family planning.

Section 59.5(a) Requirements that must be met by a family planning project

We are concerned that Title X grant recipients will not be required to provide the full spectrum of family planning methods. As outlined in the NPRM, grant recipients may provide as few as one family planning service "as long as the overall project provides a broad range of acceptable and effective family planning methods and services." Although the NPRM aims to ensure access to a broad range of services through each Title X project, there are no requirements for ensuring that these services are equally accessible to all. For instance, it will be acceptable for an organization to provide only "natural family planning" services if another organization provides other family planning services; these facilities could be inaccessible to some patients in a community if they are in geographically distant locations, thereby effectively forcing the patient to choose a family planning method based on their location. **If the Final Rule allows an organization to provide only a subset of family planning services, there must be the requirement that another organization provides the other services within a five-mile radius and be accessible by public transportation.**

59.5(14) Family involvement in family planning decisions

The NPRM includes provisions that require grantees to encourage and document attempts to include parents or guardians in family planning decisions when an adolescent visits the clinic as a condition of allowing unemancipated minors to receive confidential services based on their own

resources (as opposed to the family's income). If the grantee fails to do either of these things, the NPRM indicates that the government would seek to prevent the unemancipated minor from receiving confidential services for free. We are concerned that the proposed requirements will be a barrier to an individual receiving confidential services. These providers are often the only resource that adolescents have for accessing contraception, preventing 440,000 teen pregnancies every year.[11] **HHS must eliminate this requirement to preserve the patient/provider relationship and protect the confidentiality that patients have come to expect in the health care system, regardless of their age.**

59.15 Maintenance of physical and financial separation and 59.16 Prohibition on activities that encourage, promote, or advocate for abortion

The NPRM seeks to strengthen the program integrity requirements to ensure that no Title X funding is used for services that indirectly or directly support the provision of abortion as a family-planning method as the Department of Health and Human Services (HHS) does not view abortion as a method of family planning that allows an "individual to determine freely the number and spacing of their children." While the Endocrine Society does not advocate for or against abortion services, the restrictions placed on Title X grant recipients related to abortion services are overly restrictive and will eliminate many current grant recipients from consideration in future years, leaving many low-income women and teens without access to care. As outlined in the NPRM, any services related to abortion must be separate from Title X services, including separate financial accounting systems and separate facilities. This level of separation is unnecessary to ensure compliance with the existing statutes related to the prohibition of the use of federal funds for any service related to abortion. **We urge HHS to continue to allow Title X grant recipients to provide abortion related counseling or services in the same facility as Title X services to ensure that every health care program geared toward low-income women continues to be eligible for grant funding.**

59.2(b) Expanded definition of "low income"

HHS recognizes in the NPRM that some women are unable to obtain certain family planning services under their employer-sponsored health plan due to their employer's religious or moral beliefs. While the Society believes that all women should have access to contraception at no cost through their employer-sponsored plan regardless of the employer's religious or moral beliefs, we support efforts to ensure that those who do not have access through their employer's plan do not face additional challenges in obtaining contraception. However, we are concerned that increasing the population that is eligible to receive services through Title X will divert financial resources from providing care to women who are truly low-income and who have few alternatives. **HHS must acknowledge this with increased funding for the Title X program.**

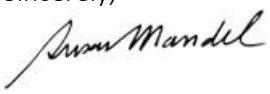
[11] Healthy People 2020. Progress Review Webinar: Family Planning and Maternal, Infant, and Child Health. October 25, 2017.

Eliminating the non-directive counseling option

Current regulations require Title X programs to offer pregnant women information and counseling on prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination; that is neutral, factual and nondirective. The NPRM eliminates this requirement and expands the prohibition on providing abortion as a method of family planning and adds that Title X projects shall not "promote, refer for, support, or present" abortion as a family planning method. We strongly oppose the elimination of the nondirective counseling option. The patient-provider relationship is based on open communication that allows for the discussion of all medical options available to the patient. Prohibiting providers from even mentioning the full spectrum of options interferes with the patient's ability to make a fully-informed decision on their own healthcare. **We urge HHS to eliminate this provision and continue to allow nondirective counseling on all medical options available to the patient.**

Thank you for considering our comments. We urge you to reconsider this NPRM to ensure that all low-income women and adolescents have access to preventive and reproductive healthcare. If we can provide any additional information, please contact Stephanie Kutler, Director, Advocacy & Policy at skutler@endocrine.org.

Sincerely,



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