The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

Office of the President
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July 31, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: HHS-OS-2018-0008; Compliance with Statutory Program Integrity Requirements

Dear Secretary Azar:

The American College of Obstetricians and Gynecologists (ACOG) appreciates the opportunity to submit comments in response to the proposed rule, "Compliance with Statutory Program Integrity Requirements" (Proposed Rule), published in the Federal Register on June 1, 2018 by the Department of Health and Human Services (HHS). The Proposed Rule would fundamentally undermine Title X of the Public Health Service Act ("Title X"). It puts at risk the patient-physician relationship and the high-quality evidence-based care that millions of women, men, and adolescents receive each year. The Proposed Rule constitutes an improper restriction on the practice of medicine that, if implemented, would threaten access to reproductive health options and effective family planning methods for the patients who receive care through Title X. It would also place physicians in ethically compromised situations. It contains arbitrary standards and medically inaccurate terminology and, thus, represents a political attempt to interfere with the health care access available to low-income women, and to improperly restrict care that physicians and other medical professionals serving these populations are able to provide.

ACOG is the nation's leading organization of physicians who provide health services unique to women. As the only national medical specialty society of women's health physicians, ACOG has more than 58,000 members representing more than 90 percent of all board-certified obstetrician-gynecologists (ob-gyns) in the United States. ACOG advocates for policies that ensure access to health care for women throughout their lives and believes that a full array of clinical services should be available to women without costly delays or the imposition of cultural, geographic, financial, or legal barriers. Few federal programs are as important to women's health care access as the Title X program. The services presently available through Title X health care providers include Food and Drug Administration (FDA)-approved contraceptive methods and counseling services, well-woman exams, breast and cervical cancer screenings, screening and treatment for sexually transmitted infections (STIs), testing for HIV, pregnancy testing and counseling, and other patient education and/or health referrals. Title X funds are not used for abortions. ACOG affirms the efforts of its members and other medical providers who practice at Title X-funded facilities to provide access to high-quality reproductive health care to all people regardless of their financial circumstances.

Contrary to the preamble of the Proposed Rule, which states that "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,"[i] the proposed changes to the Title X program would jeopardize access to family planning and preventive health care for more than four million low-income women, men, and adolescents, and is antithetical to physicians' codes of ethics and commitment to high-quality patient care. The Proposed Rule is laden with medically inaccurate terminology, prioritizing ideology over scientific evidence, exposing the arbitrary nature of the proposed regulation. For these reasons and those explained in full below, we call for the Proposed Rule's immediate and complete withdrawal.

I. The Title X program plays a critical role in our nation's public health safety net.

As the only federal grant program dedicated exclusively to providing low-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 every woman regardless of her financial circumstances. Rates of adverse reproductive health outcomes are higher among low-income and minority women, and unintended pregnancy rates are highest among those least able to afford contraception.[ii] 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."[iii]

The care made available to women through the Title X program has contributed to the dramatic decline in the unintended pregnancy rate in the United States, now at a 30-year low.[iv] Improved access to contraception and information for adolescents, including those provided by Title X projects, has contributed to a record low teen pregnancy rate.[v] The services provided by Title X projects help prevent nearly one million unintended pregnancies each year.[vi]

In addition to pregnancy prevention, Title X projects meet other reproductive health needs for women, men, and adolescents. In 2016, Title X projects provided nearly five million STI tests, and provided more than 700,000 Pap tests and 900,000 clinical breast exams.[vii] Further, it is estimated that in 2010 alone, services provided by Title X projects helped avert 53,450 chlamydia infections, 8,810 gonorrhea infections, 250 HIV infections, and 6,920 cases of pelvic inflammatory disease.[viii]

The Title X program has improved the lives of women and their families, enabling many women to achieve greater educational, financial, and employment success and stability. These public health strides help American society in many ways, including by saving taxpayer dollars. Because of the high-quality health care that individuals have received through the Title X program, there is an estimated taxpayer savings of $7.09 for every dollar invested in the Title X program.[ix]

The Proposed Rule would undermine the Title X program and detrimentally restrict the ability of patients to access care. If implemented, the Proposed Rule would limit access to vital preventive and often life-saving services for the more than four million patients seeking care annually at Title X-funded facilities. In addition, it would reverse our nation's historic achievements in reducing unplanned and teen pregnancy rates, and make evidence-based contraception methods

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inaccessible to women who otherwise cannot afford them, turning back the clock on women's health.

II. The Proposed Rule would interfere with the patient-physician relationship, restrict the information available to patients, and hinder the ability of physicians to practice medicine in accordance with their ethical obligations.

ACOG's Code of Professional Ethics for ob-gyns unequivocally states that "the patient-physician relationship is the central focus of all ethical concerns, and the welfare of the patient must form the basis of all medical judgments."[x] The patient-physician relationship is essential to the provision of safe and quality medical care, and political efforts to regulate elements of patient care and counseling can drive a wedge between a patient and her medical provider.[xi] HHS acknowledges in the preamble of the Proposed Rule that:

> "…[O]pen communication in the doctor-patient relationship would foster better over-all care for patients. While the benefit of open and honest communication between a patient and her doctor is difficult to quantify, one study showed that even "the quality of communication [between the physician and patient] affects outcomes . . . [and] influences how often, and if at all, a patient would return to that same physician." Facilitating open communication between providers and their patients helps to eliminate barriers to care, particularly for minorities."[xii]

However, if implemented, the Proposed Rule would put the patient-physician relationship in jeopardy by placing restrictions on the ability of physicians to make available important medical information, permitting physicians to withhold information from pregnant women about the full range of their options, and erecting greater barriers to care, especially for minority populations.

1. *The Proposed Rule includes vague restrictions on counseling and removes the requirement that providers offer nondirective pregnancy options counseling, limiting information available to women.*

ACOG supports a woman's right to decide whether to have children, to determine the number and spacing of her children, and to have the information, education, and access to health services to make those decisions.[xiii] ACOG's Code of Professional Ethics states that physician respect for the right of patients to make their own choices about their health care is fundamental.[xiv] Physicians have an "ethical obligation to provide accurate information that is required for the patient to make a fully informed decision."[xv] Yet, the Proposed Rule removes the requirement that providers receiving Title X funds offer the opportunity for pregnant women to receive nondirective counseling and information about their full range of pregnancy options, including prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination. This concerning deletion also removes the exception that counseling of pregnant women exclude those "option(s) about which the pregnant woman indicates she does not wish to receive."[xvi] If implemented, the Proposed Rule would permit providers to withhold information from patients, and would permit, and in some cases require, the provision of counseling, information, and referral for services that the patient has clearly stated she does not wish to receive. In the case where a patient seeks counseling once pregnant, under the Proposed Rule a provider would not be permitted to offer such counseling, and instead would be required to provide the patient with a list of prenatal and/or social services, and would require that the patient "be provided with

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information necessary to protect her health and the health of her unborn child."[xvii] ACOG opposes efforts to restrict the medical information that Title X providers can make available to their patients, especially where, as here, the restriction would prevent Title X providers from sharing complete and accurate medical information necessary to ensure that their patients are able to make fully informed medical decisions and obtain timely care.[xviii] Moreover, it is imperative that HHS, the nation's foremost health policy agency, understand and orient all of its activities on a foundation firmly based on scientifically valid and appropriate terms and evidence. The term "unborn child" used in §59.14(b) of the Proposed Rule is not a medical term and should not be used in regulations governing a federal public health program. The agency's use of terms such as this only further emphasizes the fact that the Proposed Rule is ideologically driven and does not align with evidence-based medicine.

In addition to improperly restricting a physician's ability to provide complete and accurate information to his or her patients, the requirements in the Proposed Rule surrounding what information a physician is permitted to share during nondirective counseling are vague and confusing. Specifically, the Proposed Rule contains a new requirement that grantees are not permitted to "promote, refer for, support, or present" abortion as a method of family planning.[xix] It is unclear to what extent counseling that references abortion would be permissible. For instance, would sharing ACOG's patient education document, Frequently Asked Questions #168 "Pregnancy Choices: Raising the Baby, Adoption, and Abortion" be considered a violation?[xx] Without additional guidance, grantees may interpret this language as a complete prohibition on any conversation with their patients that references abortion. At a minimum, these changes would have a chilling effect on providers, who could fear even mentioning the word abortion while counseling a patient on their options would violate the Title X regulations. Merely stating in the preamble of the Proposed Rule that "a doctor would be permitted to provide nondirective counseling on abortion," while subjecting that counseling to vague and confusing restrictions, is not sufficient to describe the requirements the Proposed Rule is seeking to impose.

2. *The Proposed Rule dictates how physicians treat their patients, denies the ability of physicians to refer for abortion care, and discriminates among providers.*

Safe, legal abortion is a necessary component of women's health care. In the United States, where nearly half of all pregnancies are unintended, almost one third of women will seek an abortion by age 45.[xxi] Despite reductions in the unintended pregnancy and abortion rates in recent years, rates remain higher among low-income and minority populations.[xxii] Many factors influence or necessitate a woman's decision to seek abortion care. They include, but are not limited to, contraceptive failure, barriers to contraceptive use and access, rape, incest, intimate partner violence, fetal anomalies, and exposure to teratogenic medications. Additionally, pregnancy complications may be so severe that an abortion is the only measure to preserve a woman's health or save her life.[xxiii] As is acknowledged in the preamble of the Proposed Rule, Title X funds have never been used for abortion. However, the Proposed Rule goes beyond the statute in an effort to further restrict access to abortion care outside of the Title X program.

Like all medical matters, decisions regarding abortion should be made by patients in consultation with their health care providers and without undue interference by outside parties. Like all patients, women obtaining abortion are entitled to privacy, dignity, respect, and support.[xxiv] The Proposed Rule inappropriately regulates provider interactions with patients, going so far as to

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detail restrictions governing when a provider may offer certain referral information, and dictate how that information may be shared.

ACOG's Code of Professional Ethics states that ob-gyns should "serve as the patient's advocate and exercise all reasonable means to ensure that appropriate care is provided to the patient."[xxv] Yet, under the Proposed Rule, only when a patient who is currently pregnant "clearly states that she has already decided to have an abortion," is a physician permitted to share a list of "licensed, qualified, comprehensive health service providers (some, but not all, of which also provide abortion, in addition to comprehensive prenatal care)."[xxvi] This provision could be read to arbitrarily deny the ability of a physician to provide a referral to a woman who decides after presenting to a Title X facility for care to have an abortion. In addition, the Proposed Rule states that "The list shall not identify the providers who perform abortion as such."[xxvii] This proposed regulation restricts the ability of physicians to provide clear, direct information to patients, and it even goes so far as to actively require physicians to withhold full and accurate information and provide referrals to providers that do not offer the service requested by the patient.

The Proposed Rule further clarifies in the examples provided in proposed §59.14(e) that projects do not have to provide any referrals to abortion providers, even if directly requested by the patient, meaning that these changes would also lead to inconsistency in the information offered to patients at different Title X facilities. These provisions represent an improper intrusion into the patient-physician relationship, the importance of which is underscored in the preamble of the Proposed Rule. HHS has provided no justification for this complex and incredibly prescriptive requirement, nor is it supported by the statute. The result of such a regulation would be to mislead patients and delay their access to abortion care, placing providers in ethically compromised positions.

As written, the Proposed Rule requires that a list of referrals for abortion defined by proposed §59.14(a) be provided by a medical doctor, and the preamble of the Proposed Rule suggests that counseling is also confined to a physician. This restriction will unnecessarily further limit access to information that can be – and often is today – provided by a qualified non-physician provider, and delay care for patients. ACOG recognizes that advanced practice clinicians, such as nurse-midwives, physician assistants, and nurse practitioners, possess the clinical skills necessary to provide first-trimester medical abortion.[xxviii] There is no question that these non-physician providers are qualified to provide counseling and referrals to patients. In addition, roughly half of counties in the United States lack an ob-gyn, and those shortages are exacerbated in rural and underserved communities.[xxix] Ob-gyn workforce shortages are expected to increase – not decrease – in the coming years, with a projected shortage of 18 percent by 2030.[xxx] Through arbitrarily limiting the providers who can provide referrals to physicians, the Proposed Rule erects an unnecessary and unsupported barrier to care.

The requirement that the list of referral providers be restricted only to those physicians who provide comprehensive prenatal care (as opposed to providers who only offer gynecological services) would further limit the care options offered to patients, and is not consistent with evidence-based medicine. The Proposed Rule would exclude physicians and medical providers who specialize in the provision of abortion and contraception. In addition, the Proposed Rule's restrictions on referred providers would exclude older ob-gyns who have retired their obstetric practice but continue to provide gynecologic care, including abortion. According to ACOG's 2015 Survey on Professional Liability, the average age at which surveyed physicians stopped

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practicing obstetrics was 48 years, which is considered the near-midpoint of a physician's career.[xxxi]

In cases where a patient is pregnant and does not "clearly state" her decision to have an abortion, the Proposed Rule requires that the patient be "referred for appropriate prenatal and/or social services (such as prenatal care and delivery, infant care, foster care, or adoption), and shall be given assistance with setting up a referral appointment to optimize the health of the mother and unborn child."[xxxii] In addition to the inappropriate use of nonmedical language, as already addressed, proposed §59.14(b) undermines the patient-physician relationship, and is not reflective of the realities of that relationship, where a patient regularly seeks the counsel of their provider. It is also counter to the ethical obligations that physicians have to provide a pregnant woman who may be ambivalent about her pregnancy full information about all options in a balanced manner, including raising the child herself, placing the child for adoption, and abortion. ACOG has long recognized the physician's "ethical obligation to provide accurate information that is required for the patient to make a fully informed decision."[xxxiii]

The restrictions on counseling and referral information that can be shared by Title X providers may put them at increased risk of medical liability. As one example, the decision in *Wickline v. State of California* found that "it is no defense in a medical liability case to argue that physicians simply have followed a payer's instructions."[xxxiv] Ob-gyns already face greater liability risks than many of their physician colleagues, and many ob-gyns report changing their practice due to liability risks. Of those ob-gyns surveyed by ACOG in 2015, "delay in or failure to diagnose" was cited as one of the top three gynecologic liability allegations.[xxxv] By restricting the provision of clear, direct referrals to patients, based on the politically motivated requirements in proposed §59.14(a), the patient is faced with unnecessary barriers and delayed access to care, placing Title X providers at elevated risk of liability.

Restrictions on counseling and referrals undercut a woman's access to safe, legal abortion and jeopardize quality of care. The Institute of Medicine (now National Academy of Medicine) study titled "Crossing the Quality Chasm: A New Health System for the 21st Century" defines high quality care as health care that is safe, effective, patient-centered, timely, efficient, and equitable.[xxxvi] Any changes to the regulations governing the Title X program should aim to advance the quality of care received, in order to best meet patient needs and improve the safety, reliability, responsiveness, integration and availability of care. ACOG has long recognized that "[l]aws [or regulations] should not interfere with the ability of physicians to determine appropriate treatment options and have open, honest, and confidential communications with their patients. Nor should laws [or regulations] interfere with the patient's right to be counseled by a physician according to the best currently available medical evidence and the physician's professional medical judgment."[xxxvii] The Proposed Rule's restrictions on counseling and referral for abortion are a violation of the patient-physician relationship, undermine the quality of care provided to patients, place physicians in ethically compromising situations, and, accordingly, should not be implemented.

III. The Proposed Rule's onerous new reporting requirements for grantees raise safety concerns and are not required to ensure statutory compliance.

The Title X program, as currently regulated, has considerable oversight and reporting requirements. Yet, the Proposed Rule seeks unprecedented additional oversight of Title X

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grantees' subrecipients, referral agencies and individuals, and other partners. The stated purpose of the newly proposed §59.5(a)(13) is to "ensure transparency in the delivery of services" by requiring that all grant applications and required reports include (1) name, location, expertise, and services provided or to be provided by subrecipients, referral individuals and agencies; (2) detailed description of collaboration with those entities, as well as less formal community partners; and (3) a clear explanation of how a grantee will "ensure adequate oversight and accountability for the quality and effectiveness of outcomes" for patients seen by subrecipients or referrals.[xxxviii] The preamble appears to call into question the "governmental accountability for [Title X] funds" if HHS does not have this information, but does not offer any evidence to support this claim and fails to adequately justify these new requirements, nor account for the added costs to grantees.[xxxix] These requirements are burdensome at best and dangerous at worst; they do not improve patient care and are contradictory to other initiatives currently being undertaken at HHS.

1. *The Proposed Rule is inconsistent with other administrative efforts to reduce regulatory burden.*

President Donald Trump's Executive Order to "lower regulatory burdens on the American people," and the Centers for Medicare and Medicaid Services' (CMS) initiative titled "Patients Over Paperwork" are representative of an Administration-wide effort to reduce unnecessary regulatory burdens in federal programs, in particular those that impact health care providers.[xl] The stated goals of the Patients Over Paperwork initiative are to streamline regulations in order to "reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience."[xli] Despite this trend elsewhere within the Administration and HHS, the Proposed Rule seeks to add to the regulatory burden of the Title X program, by implementing new costly and time-consuming reporting requirements.

2. *The Proposed Rule's requirement that grantees report on all referral agencies and individuals, including services provided, is burdensome and raises safety concerns.*

It is not standard practice for providers to keep a dedicated and exhaustive list of all of the providers they interact with, whether through referral or consultation, nor to keep a comprehensive list of the services provided by those colleagues. The Proposed Rule would require Title X-funded entities to track services among referral networks that they are not funded to provide, and appears to suggest that Title X-funded entities would be held accountable for outcomes of patients who receive services at other facilities. This is outside the scope and purpose of the Title X program, and holds Title X providers to an unreasonable standard that is inconsistent with other federally-funded programs.

The collection and reporting to HHS of the names, locations, expertise, and services provided by referral agencies and individuals, as required by proposed §59.5(a)(13)(i), raises several serious questions and concerns. For instance, what happens if a referral agency or individual is inadvertently left off of an application or report to HHS? Is a patient then unable to be referred to or receive care from that agency or individual? Alternatively, how would HHS manage a request by an agency or individual that wishes to be removed from a reported list? In addition, because the Proposed Rule only permits referral for abortion to providers who also offer comprehensive prenatal care, proposed §59.5(a)(13)(i) would require grantees to provide the names and locations of those providers who may not otherwise advertise their abortion services to the

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public. It is unclear what purpose collecting this information would serve aside from establishing an inventory or registry at HHS of the names and locations of abortion providers. Abortion providers face violence and threats to themselves, their staff, and their families.[xlii] The Proposed Rule provides no assurance of confidentiality for those referral providers listed, nor does it provide a guarantee that the information would not be used for other purposes.

HHS seeks comment on whether HHS should impose additional policies or requirements on referral agencies, specifically "expanding the requirement that referral agencies that do not receive Title X funds but nevertheless provide information, counseling, or services to Title X clients be subject to the same reporting and compliance requirements as do grantees and subrecipients."[xliii] Such an expansion of reporting requirements is well beyond the scope of the Title X program and should not be pursued. Requiring providers that do not receive federal Title X funding to comply with onerous reporting requirements is inappropriate and would serve as a disincentive for those providers to serve as referrals for Title X patients. This would exacerbate barriers to specialty care already faced by low-income patients, particularly those living in rural or other underserved communities.[xliv]

IV. The Proposed Rule undermines access to evidence-based family planning methods.

All people seeking care in Title X programs should have access to the contraceptive method that works best for their individual circumstances. We are concerned that the Proposed Rule lowers the threshold on the contraceptive services available at Title X-funded organizations, limiting access to a woman's contraceptive method of choice, and negatively impacting the quality of care provided to patients. The Proposed Rule also appears to prioritize new Title X projects that do not offer a broad range of the most effective contraceptive methods. Collectively, if implemented, these changes will result in reduced access to the most effective contraception methods, threatening to reverse decades of progress, including our nation's historic achievements in reducing unplanned and teen pregnancy rates.

1. The Proposed Rule lowers the standards for what family planning services must be offered.

As stated above, ACOG supports a woman's right to decide whether to have children, and to determine the number and spacing of her children. ACOG believes a woman must have unhindered access to information, education, and health services, including the full range of contraceptive methods, in order to make the best decision for herself and her family.[xlv] Currently, Title X projects must provide a "broad range of acceptable and effective medically approved family planning methods (including natural family planning) and services."[xlvi] Access to "the full range of FDA-approved contraceptive methods" has likewise 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, the Quality Family Planning (QFP) recommendations.[xlvii] Despite this body of evidence, the Proposed Rule removes the requirement that methods of family planning be "medically approved," instead placing increased emphasis on the provision of natural family planning (NFP) and "other fertility-awareness based methods."[xlviii] In contrast, the QFP recommendations emphasize that family planning care should be "medically accurate, balanced, and provided in a nonjudgmental manner."[xlix] This modification to the requirements that must be met by family planning projects, together with the newly proposed definition of "family

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planning" appears to be diluting long-standing Title X program requirements, lowering the standards governing the services that must be offered. These changes threaten the quality of family planning available to Title X patients. In addition, the Proposed Rule inserts "adoption" as a service to be offered by a family planning project.[l] Such an expansion of services is puzzling and appears outside the intended scope of the Title X program.

2. *The Proposed Rule's permissive language may result in fewer Title X-funded sites providing the broad range of contraceptive methods that have been a core part of the program since its inception.*

The current regulations allow, though do not encourage, organizations receiving Title X funds to offer only a single method of family planning "as long as the entire project offers a broad range of family planning services."[li] The Proposed Rule is much more permissive, appearing to encourage the inclusion of more providers within a Title X project that only offer a single contraceptive method or very limited methods, putting at risk access to the most effective – and often most desired and expensive – forms of contraception, such as long-acting reversible contraception (LARC).[lii]

The Proposed Rule appears to justify this new emphasis by stating in the preamble that "it has become increasingly difficult and expensive for a Title X project to offer all acceptable and effective forms of family planning."[liii] However, the Proposed Rule does not provide evidence to support this statement. In fact, a recent study by the Kaiser Family Foundation and George Washington University found that Title X-funded health centers are far more likely than non-Title X-funded health centers to provide a larger range of effective family planning methods onsite and to offer services associated with high quality care.[liv] This study found that health centers that receive Title X funds were nearly twice as likely to offer onsite dispensing of oral contraceptives (78 percent versus 41 percent) and more than 1.5 times more likely to offer LARCs, including the contraceptive implant and intrauterine devices (IUDs).[lv] In fact, the availability of onsite oral contraceptive pills has significantly decreased among clinics that do not receive Title X funding, from 53 percent in 2011 to 41 percent in 2017.[lvi] While the Proposed Rule suggests the proposed changes would improve access to and quality of care provided at Title X-funded sites, evidence indicates that Title X-funded sites are more likely than non-Title X-funded sites to follow recommendations of the U.S. Preventive Services Task Force and QFP recommendations, such as screening sexually active women age 25 or younger for chlamydia that can result in infertility if untreated. [lvii,lviii]

Additionally, while Title X does not currently require each service site to offer the full range of contraceptive methods, Title X service sites are required to consult with existing local and regional projects that serve the same population. The Proposed Rule removes the requirement that new Title X applicants communicate with existing health resources serving the same area. By removing this requirement for open communication and coordination between service sites for a shared population, there is no assurance that the population in a particular area has sufficient access to a broad range of the most effective methods of contraception. The Proposed Rule erroneously argues that "loosening the status quo" will allow sites a broader reach, but there is no evidence to support this assumption.[lix]

3. *The Proposed Rule appears to give preference to Title X projects that provide only limited contraception options, risking access to comprehensive contraceptive care for large parts of the traditional Title X population.*

By lowering the threshold for participation in the Title X program, we are concerned that HHS will prioritize organizations with little or no experience providing sexual and reproductive health care. While NFP and fertility awareness-based methods of family planning have always been included in the full range of contraceptive options offered to women seeking family planning care, the new emphasis on NFP in the Proposed Rule is a major departure from the previous focus on counseling women on the most effective methods. When fertility awareness is used to prevent pregnancy, in the first year of typical use, as many as one in four women will have an unintended pregnancy.[lx] Underserved women, including those who are low-income, already experience the highest rates of unintended pregnancy and abortion, and the Proposed Rule could further exacerbate those disparities.[lxi]

HHS's apparent preference for organizations utilizing fertility awareness-based methods could leave large populations without access to the most effective methods of family planning. Medically underserved populations, including racial and ethnic minorities, LGBTQ individuals, and adolescents will be most harmed by this reduction in access. ACOG's recommendations for adolescent contraceptive care specifically advise that discussions about contraception begin with the most effective methods first.[lxii] Deviating from this recommendation is of significant concern as there is a knowledge gap among this population. Data on unmarried young adults aged 18-29 years in the U.S. suggests misperceptions are common regarding contraception use, and there is a gap between intent and behavior in preventing unintended pregnancy.[lxiii] Encouraging more single-method or limited method service providers within a Title X project will threaten access to comprehensive information about the full range of contraception methods, and is at odds with evidence-based recommendations.

Moreover, the suggested preference for providers offering only NFP methods over medical providers who offer a larger range of FDA-approved contraceptive methods is out of proportion with the known preferences of many Americans. The Proposed Rule contends many people would prefer "single-method NFP service sites," however, utilization of NFP methods in the U.S. is in fact low, with only approximately 2 percent of sexually active women aged 15-44 choosing NFP in 2014.[lxiv,lxv] By contrast, 67 percent of women who use contraception choose more effective methods of contraception (the pill, patch, implant, injectable, vaginal ring, and condom).[lxvi] Clinical recommendations including both the QFP recommendations and the Health Resources and Services Administration-supported Women's Preventive Services Initiative (WPSI) assert that offering the full range of FDA-approved methods is a core component of quality family planning care.[lxvii] The proposed changes would put at risk women's access to their preferred method of contraception. How does HHS plan to ensure that quality care is safeguarded for all Title X patients, including the QFP and ACOG recommendations that women have access to their preferred method of contraception?[lxviii,lxix]

Of note, the preamble of the Proposed Rule references ACOG and WPSI's inclusion of "fertility awareness-based methods" in its clinical recommendations of contraception as a women's preventive service. However, HHS selectively excludes the substance of WPSI's clinical recommendations for contraception, incorrectly suggesting that ACOG either supports fertility awareness-based methods over other methods, or views fertility awareness-based methods as

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equally effective as FDA-approved methods.[lxx] Indeed, the WPSI recommendations were clear that fertility awareness-based methods are "less effective" than FDA approved methods of contraception but should be provided for women desiring an alternative method. To ensure there is no confusion as to ACOG and WPSI recommendations, read in full, the WPSI clinical recommendation for contraception states:

> "The Women's Preventive Services Initiative recommends that adolescent and adult women have access to the full range of female-controlled contraceptives to prevent unintended pregnancy and improve birth outcomes. Contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (eg, management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method). The Women's Preventive Services Initiative recommends that the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures be available as part of contraceptive care.
>
> The full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration include: (1) sterilization surgery for women, (2) surgical sterilization via implant for women, (3) implantable rods, (4) copper intrauterine devices, (5) intrauterine devices with progestin (all durations and doses), (6) the shot or injection, (7) oral contraceptives (combined pill), 8) oral contraceptives (progestin only, and), (9) oral contraceptives (extended or continuous use), (10) the contraceptive patch, (11) vaginal contraceptive rings, (12) diaphragms, (13) contraceptive sponges, (14) cervical caps, (15) female condoms, (16) spermicides, and (17) emergency contraception (levonorgestrel), and (18) emergency contraception (ulipristal acetate), and additional methods as identified by the FDA. Additionally, instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method."[lxxi]

It is ACOG's unequivocal position that all women and adolescents should have unhindered and affordable access to comprehensive contraceptive care and contraceptive methods as an integral component of women's health care. The Proposed Rule threatens that access.

V. The Proposed Rule creates substantial burdens on qualified providers and puts at risk access to quality family planning services for low-income women and adolescents.

The Proposed Rule is designed to make it impossible for specialized reproductive health providers, like Planned Parenthood health centers, to continue to participate in the program, by requiring more than mere programmatic separation between Title X project activities and abortion-related activities, including referrals and counseling. These requirements threaten patient access to comprehensive reproductive health care, ignore the significant role specialized providers play in the Title X program, and further marginalize comprehensive reproductive health-focused providers from mainstream medical care.

Requiring complete financial and physical separation is a clear effort to force out reproductive health-focused providers and prioritize providers that do not specialize in reproductive health care. Planned Parenthood plays an outsized role in the Title X program, and the loss of these

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service sites would disproportionately affect medically underserved patients including women of color, who make up more than half of all Title X patients, and women living in rural areas.[lxxii] The Proposed Rule provides HHS broad discretion to evaluate individual Title X funding recipients' compliance with the new physical and financial separation standard, considering at least four factors: (1) separate accounting records; (2) degree of separation of facilities; (3) the existence of separate personnel, electronic or paper-based health care records and work stations; and (4) the extent to which signs and other forms of identification of the Title X program are present, and signs and material referencing or promoting abortion are absent.[lxxiii] These factors reverse HHS's longstanding interpretation that if a Title X grantee can demonstrate separation of financial records, counseling and service protocols, and administrative procedures, "then it is hard to see what additional statutory protection is afforded by the imposition of a requirement for 'physical' separation."[lxxiv] HHS does not adequately justify this reversal.

The preamble of the Proposed Rule states that the "optics and practical operation of two distinct services within a single collocated space are difficult, if not impossible to overcome." However, this statement is not supported by evidence, as can be seen by the emergence of multi-specialty practices (MSPs). MSPs are defined as practices offering various types of medical specialty care within one organization. There is some evidence to suggest these practices may provide higher quality care at a lower cost, when compared to small group practices, including one analysis published in *Health Affairs* that found that patients of MSP providers received more evidence-based care than patients of non-MSP providers.[lxxv]

HHS requests comment on whether additional regulatory provisions are necessary, yet offers no justification for why even this proposed separation is warranted. The proposed reorganization of Title X provider sites will already have significant repercussions on patient access, and should be revoked. No further regulatory modifications should be pursued.

1. *Eliminating specialized reproductive health-focused providers will result in a significant gap in access that the health care system is not equipped to handle.*

Planned Parenthood sites represent only 13 percent of Title X service sites yet serve 41 percent of all Title X patients.[lxxvi] While Planned Parenthood is not explicitly named in the Proposed Rule, the dramatic changes to Title X compliance requirements would have an immense effect on Planned Parenthood service sites. Evidence demonstrates that other providers, including Federally Qualified Health Centers (FQHCs), would not have the capacity to absorb the nearly 2 million contraceptive patients who would lose access to care.[lxxvii] Not all FQHC sites offer contraceptive care services, and among those who do, the average site serves 320 contraceptive clients in a year. By contrast, the average Planned Parenthood health center serves 2,950 contraceptive clients annually.[lxxviii] Moreover, FQHC sites often score lower on critical indicators of quality contraceptive care than Planned Parenthood health centers. For example, Planned Parenthood sites are more likely to offer the full range of contraceptive methods, and specific services such as same-day insertion of LARC methods and on-site dispensing of oral contraceptives.[lxxix]

There is also strong evidence of adverse changes in contraception provision and serious public health consequences in states that have eliminated Planned Parenthood from their family planning programs. When Texas excluded Planned Parenthood from a state program serving low-income patients, the number of women using the most effective methods of birth control

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decreased by 35 percent, and the number of births covered by Medicaid increased by 27 percent.[lxxx] In addition to losing access to family planning services, communities also lose access to STI testing and treatment. When public health funding cuts in Indiana forced many clinics, including Planned Parenthood health centers, to close, rural areas of the state experienced a dramatic HIV outbreak. Access to STI testing at Planned Parenthood clinics could have minimized or even prevented the outbreak.[lxxxi] Targeting comprehensive reproductive health care providers, like Planned Parenthood, puts a larger range of health care services at risk for medically underserved communities.

We are also concerned by the requirement that grantees provide comprehensive primary care on site. Not only is that not a statutorily permissible use of Title X funds, it will further limit eligible entities, cutting otherwise qualified women's health providers from the program. The existing primary care workforce is poorly distributed, with fewer physicians, advanced practice nurses, and physician assistants located in underserved communities, particularly in rural areas. More than half of Planned Parenthood health centers are located in rural and medically underserved areas, helping to minimize the gap in both preventive and reproductive health services for populations in those communities.[lxxxii] If the Proposed Rule were implemented, the U.S. health system would not be prepared to meet this need; both ob-gyns and primary care physicians face workforce shortages. As stated above, ACOG projects an ob-gyn shortage of 18 percent by 2030, and the Association of American Medical Colleges has projected a shortfall of as many as 49,300 primary care physicians and as many as 72,700 nonprimary care physicians by 2030.[lxxxiii,lxxxiv] Limiting the eligibility of current Title X providers would exacerbate this women's health workforce shortage.

The Proposed Rule does suggest applicants can meet this requirement via a robust referral linkage with primary care providers who are "in close physical proximity," but HHS neglects to define this term.[lxxxv] For Title X clinics located in rural areas facing severe primary care provider shortages, how does HHS suggest they meet these new requirements to provide 'holistic' primary care? How will this requirement be measured in health professional shortage areas where there are few primary care providers?

If implemented, the Proposed Rule would exacerbate racial and socioeconomic disparities in access to care by leaving Title X patients, who are disproportionately black and Latinx, without alternate sources of care. Restricting access to qualified providers will increase rates of unplanned pregnancy, pregnancy complications, and undiagnosed medical conditions, leaving patients worse off than they are today.

VI. The Proposed Rule undermines critical confidentiality protections for minors, erecting additional barriers to care.

Family planning services are particularly important for adolescents. The United States has the highest adolescent pregnancy rate in the industrialized world.[lxxxvi] In addition, adolescents and young adults are more likely to acquire sexually transmitted infections than older individuals.[lxxxvii] Projects funded through Title X are expressly required by law to provide care to adolescent patients. The current Title X regulations fulfill this mandate through requiring that Title X facilities provide services to adolescents on a confidential basis. Existing law requires that Title X grantees certify that they encourage minors to include their family in their decisions to seek family planning services.

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The Proposed Rule threatens access to care for adolescents particularly through its weakening of confidentiality protections for adolescents seeking family planning care. Without these protections, adolescents, especially those without adult support systems, may be more likely to delay or not receive needed, sometimes lifesaving care.[lxxxviii] ACOG and other major medical associations support efforts to reasonably encourage adolescents to involve their parents in their decision to seek reproductive healthcare. However, when taking a health history, clinicians sometimes learn of circumstances (short of abuse) in a minor's family that make it not "practicable," or unrealistic or even harmful, to encourage the minor to involve their parents or guardians.[lxxxix] In these situations, clinicians should not be mandated to take "specific actions" to encourage the minor to do so (and then document those specific actions) as the Proposed Rule requires.[xc] ACOG and other major medical associations recommend that adolescents receive confidential, comprehensive reproductive health care without mandated parental notification or consent.[xci] According to the American Academy of Pediatrics, "…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."[xcii] Ensuring adolescent confidentiality is not only consistent with medical ethics, but also with the importance of ensuring a strong patient-physician relationship.

The Proposed Rule creates barriers to adolescents receiving confidential care. The Title X program should continue to ensure that adolescents are able to access confidential care, while maintaining compliance with all state and federal laws. Failure to do so will erect additional barriers to adolescents seeking preventive and lifesaving reproductive health care and will also undermine the patient-physician relationship.

VII. The Proposed Rule redefines "low-income family" in a way that is contrary to Title X and puts low-income patients presently relying on Title X services at risk of losing access.

The current Title X regulations require that "no charge will be made for services provided to any person from a low-income family" except to the extent that payment can be made by a third-party payer, such as commercial insurance or Medicaid.[xciii] The preamble of the Proposed Rule highlights the increased need for publicly funded family planning services, "as the number of Americans at or below the poverty level has increased," yet at the same time redefines "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.[xciv,xcv] This expanded definition would potentially require Title X providers to provide free contraceptive services to any woman whose employer objects to insurance coverage of contraception, regardless of her income. HHS has recently expanded the availability of exceptions to the contraceptive coverage requirements of the Affordable Care Act to a broad range of employers. By proposing to expand the definition of "low-income family," the Proposed Rule would greatly increase the number of women who qualify for Title X-funded services, without providing any additional funding or support to ensure the program can sustain this patient increase. The Title X program was not designed to absorb the unmet needs of all individuals above 250 percent of the federal poverty level. Additionally, Title X is designed to subsidize a program of care, not pay the full cost of any service or activity. Title X regulations encourage Title X projects to work with third-party payers to reduce the cost of the program. The Title X program is already underfunded, and

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without additional funding from Congress, the Proposed Rule would result in even fewer resources to serve low-income patients, in direct contrast to the Proposed Rule's stated intent. The Title X network does not have the capacity to serve a flurry of new middle-income patients who have insurance coverage through their employer, nor the resources to serve those patients at low- or no-cost.

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Policy decisions about public health must be firmly rooted in science, and increase access to safe, effective and timely care. Policies and regulations that improperly restrict the practice of medicine, place political preferences over medical necessities, and restrict the ability of millions of women, men, and adolescents to access high quality care should not be implemented. The Proposed Rule would interfere with the patient-physician relationship, exacerbate disparities for low-income and minority women, men, and adolescents, and harm patient health. We urge HHS to immediately withdraw the Proposed Rule. Thank you for your full consideration of our comments.

Sincerely,

Lisa M. Hollier, MD, MPH, FACOG
President

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