



July 31, 2018

The Honorable Alex Azar
Secretary of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Title X regulations (Title X of the Public Health Service Act)

Dear Secretary Azar,

The American College of Physicians (ACP) appreciates the opportunity to offer comments on the proposed rule to revise Title X regulations (Title X of the Public Health Service Act) to ensure compliance with, and enhance implementation of, the statutory requirement that none of the funds appropriated for Title X may be used in programs where pregnancy termination is a method of family planning and related statutory requirements.

The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 154,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

Over the course of their lifespans women face unique challenges regarding their physical health, interactions with the health care system, and roles in society. A policy paper published by the American College of Physicians on June 19, 2018, “Women's Health Policy in the United States,”¹ addresses these issues, including access to reproductive health care.

In 1970, Congress enacted the Title X statute that authorized the Secretary of Health and Human Services (HHS) to make grants to public or nonprofit private entities to establish and operate “voluntary family planning projects.”

The earliest Title X regulations made clear that under Congress’ directive, Title X projects are required to provide “medical services related to family planning including physician’s

¹ <http://annals.org/aim/fullarticle/2682682/women-s-health-policy-united-states-american-college-physicians-position>

consultation, examination, prescription, continuing supervision, laboratory examination, contraceptive supplies” and “for use of a broad range of **medically approved** methods of family planning.”² Current federal law does prohibit the use of Title X funds in programs where abortion is a method of family planning—a grantee’s abortion activities must be “separate and distinct” from the Title X project activities. Title X funded programs currently provide non-directive counseling (e.g., via shared decision-making) to pregnant women on prenatal care and delivery, infant or foster care, adoption, and abortion. Pregnant women seeking an abortion must be provided a referral to those services, but abortion cannot be promoted or scheduled by the Title X-funded provider. Participating programs must also offer a broad range of FDA-approved contraceptive methods and follow U.S. Centers for Disease Control (CDC) and Office of Population Affairs (OPA) guidelines for provision of their family planning services.³ Title X-funded clinics are open to all and especially provide care to the most vulnerable, those living in a nonmetropolitan area, who may be black or Hispanic/Latina, who live below the poverty level, and/or are uninsured. The Title X program funds clinics that keep families well by providing a number of preventive health services, such as patient education and counseling; breast and pelvic examinations; screenings for cervical cancer and sexually transmitted diseases

The following ACP recommendations will be discussed in greater detail within this letter:

- Definition of “family planning” services:
 - **The College asserts that women should have sufficient access to evidence-based family planning and sexual health information and the full range of medically accepted forms of contraception.**
- Prohibition of referrals for abortion:
 - **ACP believes in respect for the principle of patient autonomy on matters affecting patients' individual health and reproductive decision-making rights, including types of contraceptive methods they use and whether or not to continue a pregnancy as defined by existing constitutional law.**
 - **Accordingly, ACP opposes government restrictions that would erode or abrogate a woman's right to continue or discontinue a pregnancy.**
 - **Further, ACP opposes any legislation or regulations that limits access to comprehensive reproductive health care by putting medically unnecessary restrictions on health care professionals or facilities.**
- Federal oversight and maintenance of physical and financial separation of facilities:
 - **In line with ACP’s “Patients Before Paperwork” initiative,⁴ the College calls on HHS to analyze the financial, time, and quality-of-care impacts these new administrative tasks will have and eliminate or streamline any that will increase costs, decrease the quality of patient care, or unnecessarily question a physician’s or clinician’s judgment.**
- Confidentiality:

² “Part 59—Grants for Family Planning Services,” 36 Federal Register 179 (September 15, 1971), p. 18465, § 59.5.

³ <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

⁴ Erickson, Shari M., Brooke Rockwern, Michelle Koltov, and Robert M. McLean. "Putting patients first by reducing administrative tasks in health care: a position paper of the American College of Physicians." *Annals of internal medicine* 166, no. 9 (2017): 659-661.

- **The College strongly contends that information should not be disclosed to others without the patient's permission.⁵ In such cases, the physician should be guided by the minor's best interest in light of the physician's conscience and responsibilities under the law.**
- The College also is concerned about the proposed rule's potential impact on access to care and exacerbation of racial and economic disparities.

Definitions of "Family Planning"

Under the proposed regulations, "family planning" would be redefined as the voluntary process of identifying goals and developing a plan for the number and spacing of children and the means by which those goals may be achieved. The means to achieve the goals of "family planning" include a broad set of acceptable and effective choices, which may range from choosing not to have sex to the use of other family planning methods and services to limit or enhance the likelihood of conception (including contraceptive methods and other fertility awareness-based methods), and the management of infertility (including adoption).

Further, as per Section 59.5 of this proposed rule, this new definition would change the methods and services of Title X programs in the following ways:

- It would remove the words "medically approved" from the longstanding regulatory requirement that projects provide "a broad range of acceptable and effective medically approved family planning methods";
- It would specify adoption as a type of service that can be offered, along with the existing requirement of basic family planning management of infertility services and services for adolescents); and
- It would further add "Such projects are not required to provide every acceptable and effective family planning method or service. A participating entity may offer only a single method or a limited number of methods of family planning as long as the entire project offers a broad range of such family planning methods and services."

ACP Comments:

These changes may limit a patient's ability to make an informed patient care decision because limited options may be provided without consideration to the patient's clinical need. This violates the accepted principles of clinical shared-decision making where the clinician and the patient communicate together and discuss the best available clinical evidence.

The College asserts that women should have sufficient access to evidence-based family planning and sexual health information and the full range of medically accepted forms of contraception. Limiting access to evidence-based medicine greatly affects a woman's ability to make her own health care choices. Reproductive care is a key component of women's health, and limiting access can have lasting repercussions on a woman's physical and mental health, economic well-being, and social mobility. ACP opposes any regulation of reproductive health care services that is not focused on patient safety or based in accepted science. Public health

⁵ <https://www.acponline.org/clinical-information/ethics-and-professionalism/acp-ethics-manual-sixth-edition/acp-ethics-manual-sixth-edition#ref-19>

policy about women's reproductive health and health care services should first and foremost be based in clinical research, with an emphasis on health promotion, prevention of unintended pregnancy, and access to reproductive health services.

It is critically important to note that Title X is the only federal program exclusively dedicated to providing low-income and adolescent patients with essential family planning and preventive health services and information. Evidence-based sexuality education programs help young women achieve their educational and professional goals by educating them about sexual health, including preventing unintended pregnancy and family planning. This federal program must continue to provide non-directive, comprehensive, medically accurate information.

Supporting access to family planning services and all forms of contraception is essential to reducing the rate of unintended pregnancy and demand for abortion services. As outlined in ACP's recent policy paper, "Women's Health Policy in the United States,"⁶ evidence shows that rather than seeking care elsewhere when access to family planning services is limited, some women forego preventive care or their usual contraceptive methods. Therefore, restricting access to care and information will increase rates of unplanned pregnancy, pregnancy complications, and undiagnosed medical conditions. It will reverse decades of progress that have brought our nation to a 30-year low for unplanned pregnancy and record low teen pregnancy rates. These public health victories are due in large part to the good work of the Title X program and qualified providers who offer high-quality patient care. The administration should advance policies that continue this positive trend, not undermine it.

Since the proposed regulations will likely lead to a reduction in the number of Title X-funded women's health clinics low-income women who have typically relied on these clinics for family planning care would need to seek out alternative affordable and accessible care options, such as community health centers (CHC). However, there is a concern that an influx of this size may strain the capacity of remaining CHCs; a survey of CHCs that provide family planning services found that a majority would be unable to accept a major increase in new patients.⁷ The lack of affordable alternatives could be compounded by the fact that many community health centers may choose to no longer participate in Title X due to the requirements of participation that would result in censored communication, the dissemination of non-evidence-based information, and increased administrative burden.

Prohibition on Referral for Abortion:

This proposed rule interprets counseling and referral for abortion to be activities that are equivalent to providing "abortion as a method of family planning." This would serve to prohibit Title X programs from providing, promoting, referring to, supporting, or presenting abortion services to patients. There would be a limited exception for when a pregnant Title X patient has

⁶ <http://annals.org/aim/fullarticle/2682682/women-s-health-policy-united-states-american-college-physicians-position>

⁷ Wood, Susan F., Julia Strasser, Jessica Sharac, Janelle Wylie, Sara Rosenbaum, Caroline Rosenzweig, Laurie Sobel, and Alina Salganicoff. "Community Health Centers and Family Planning in an Era of Policy Uncertainty." The Henry J. Kaiser Family Foundation. March 15, 2018. Accessed July 25, 2018. <https://www.kff.org/womens-health-policy/report/community-health-centers-and-family-planning-in-an-era-of-policy-uncertainty/>.

determined she will have an abortion and explicitly seeks a referral for that purpose. A physician (and no other clinical staff member) then may provide a list of comprehensive qualified providers (of which some, but not all, may also provide abortion in addition to prenatal care). However, this list shall not identify which providers perform abortions. Pregnant patients who do not explicitly declare their intention to seek an abortion also must receive a list of providers of prenatal care, but this list would not include providers of abortion services.

ACP Comment:

ACP believes in respect for the principle of patient autonomy on matters affecting patients' individual health and reproductive decision-making rights, including types of contraceptive methods they use and whether or not to continue a pregnancy as defined by existing constitutional law. Accordingly, ACP opposes government restrictions that would erode or abrogate a woman's right to continue or discontinue a pregnancy. A woman has the right to make her own decisions, in consultation with her physician or health care professional, on matters affecting her individual health. Reproductive decision-making rights should be based on the ethical principle of respect for patient autonomy. Women should have access to the health care services they may need in their lifetimes, including reproductive health care and contraception. They should feel empowered to make decisions around pregnancy that are grounded in evidence-based information and reflect their own circumstances, which may result in a woman delivering and raising a child, choosing adoption, or choosing abortion.

Along these lines, ACP opposes any legislation or regulations that limits access to comprehensive reproductive health care by putting medically unnecessary restrictions on health care professionals or facilities. “Laws and regulations should not mandate the content of what physicians may or may not say to patients or mandate the provision or withholding of information or care that, in the physician's clinical judgment and based on clinical evidence and the norms of the profession, are not necessary or appropriate for a particular patient at the time of a patient encounter.”⁸ These laws may interfere with the relationship between physicians and patients or make access to reproductive health care services or abortion extremely difficult or impossible. Physicians may personally choose not to provide certain reproductive services or information about these services if it conflicts with their moral or personal standards. However, they still have a duty to inform patients about care options and alternatives or refer them for information (so that patient rights are not constrained) and provide information that is evidence-based and free of personal bias.⁹

As any referral lists provided would be limited to a list of prenatal care physicians, of which only some can also provide abortion services, the facilities listed would mainly include hospitals and doctor's offices. Directing those seeking health care services towards hospitals and doctor's offices and away from abortion and other nonspecialized clinics can create financial and other barriers for women seeking care. Evidence suggests that care provided in a hospital setting is typically more expensive than that provided in a clinical setting. Patients seeking care from private doctor's offices may also find that Medicaid and uninsured patients are not accepted.

⁸ https://www.acponline.org/acp_policy/policies/patient_physician_relationship_2012.pdf

⁹ Snyder L. American College of Physicians Ethics, Professionalism, and Human Rights Committee. American College of Physicians ethics manual: sixth edition. Ann Intern Med, 2012, vol. 156 (pg. 73-104)

Further, it is possible that women would have to travel further distances to access hospital-based care than clinic-based care, resulting in foregone wages and added travel expenses.

Federal Oversight and Maintenance of Physical and Financial Separation

Existing regulations enacted under 42 CFR 59 essentially eliminated provisions (a) prohibiting Title X projects from counseling or referring project clients for abortion as a method of family planning; and (b) requiring grantees to separate their Title X project physically and financially from any abortion activities. While a contemporaneous notice stated that more than separate bookkeeping entries and allocation of funds were necessary to separate Title X project activities from non-Title X abortion activities, it discussed and approved shared facilities, staff, and records, as long as costs were pro-rated and properly allocated. These regulations also affirmatively required that Title X providers counsel on, and refer for, abortion at the request of a Title X client.

This proposed regulation would require that Title X projects be physically and financially separated from activities prohibited under this Act, namely the provision, promotion, or referral of abortion services. This separation must go beyond bookkeeping separation permitted under the previous administration. There must be separate accounting records; separate facilities in which activities occur (including waiting room, consultation, treatment); separate records/electronic health records (EHRs) and workstations; and separate signage and informational materials.

ACP Comment:

The College believes that requiring the physical and financial separation of abortion services provided by entities receiving Title X funding would create immense administrative burden and excessive operating costs for reproductive health and family planning facilities that also offer abortion services. Separate recordkeeping would add to the crushing administrative burden physicians and clinicians already face and would result in physicians and clinicians either spending less time with their patients or having to hire more staff. Further, obtaining additional space to maintain separate waiting rooms, consultation areas, treatment facilities, workstations, EHR systems, signage, and informational materials may prove to be impossible for providers either due to availability of real estate, limitations in the structure of the existing building, or excessive costs. **In line with ACP's "Patients Before Paperwork" initiative,¹⁰ the College calls on HHS to analyze the financial, time, and quality-of-care impacts these new administrative tasks will have and eliminate or streamline any that will increase costs, decrease the quality of patient care, or unnecessarily question a physician's or clinician's judgment.**

The College also is concerned about the requirement that Title X grantees report on the services provided by and be accountable for the quality and effectiveness of subrecipients and referral agencies. Grantees may not be familiar with the policies, referral practices, or services

¹⁰ Erickson, Shari M., Brooke Rockwern, Michelle Koltov, and Robert M. McLean. "Putting patients first by reducing administrative tasks in health care: a position paper of the American College of Physicians." *Annals of internal medicine* 166, no. 9 (2017): 659-661.

offered by subrecipients and referral agencies. Requiring physicians and clinicians to track down and constantly monitor this information would add significant additional administrative burden.

As the U.S. health care system evolves to focus on value, stakeholders should conduct research on the effect of administrative tasks on our health care system in terms of quality, time, and cost; physicians, other clinicians, their staff, and health care provider organizations; patient and family experience; and, most important, patient outcomes.

Confidentiality

Under existing regulation, all information, such as personal facts and circumstances, obtained by the project staff about individuals receiving services must be held confidential and not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. The proposed regulation clarifies that confidentiality of information may not be used as a rationale for noncompliance with laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

Additionally, the proposed regulation requires clinicians to encourage minors who seek family planning services to engage their parents or guardians in the process. Physicians and clinicians would have to keep a detailed record for each minor patient of this encouragement, including the specific actions taken to encourage family participation or the reason why actions were not taken. However, clinicians are not required to document these efforts if they suspect the minor is a victim of child abuse or incest and have reported the situation to the proper authorities as permitted or required by state or local law.

Further, per the proposed rule, if a Title X clinician does not encourage and document this encouragement of such minors to involve their parents or guardian in their decision to seek family planning services, then unemancipated minors could be prevented from receiving confidential services for free.

ACP Comment:

If a patient who is a minor requests termination of pregnancy, advice on contraception, or treatment of sexually transmitted diseases without a parent's knowledge or permission, the physician may wish to attempt to persuade the patient of the benefits of having parents involved, but should be aware that a conflict may exist between the legal duty to maintain confidentiality and the obligation toward parents or guardians. **However, the College strongly contends that information should not be disclosed to others without the patient's permission.¹¹ In such cases, the physician should be guided by the minor's best interest in light of the physician's conscience and responsibilities under the law.**

¹¹ <https://www.acponline.org/clinical-information/ethics-and-professionalism/acp-ethics-manual-sixth-edition/acp-ethics-manual-sixth-edition#ref-19>

Confidentiality, like other ethical duties, is not absolute. It may have to be overridden to protect individuals or the public or to disclose or report information when the law requires it. However, confidentiality is a fundamental tenet of medical care. Physicians must follow appropriate security protocols for storage and transfer of patient information to maintain confidentiality, adhering to best practices for electronic communication and use of decision-making tools.

Confidentiality is a matter of respecting the privacy of patients, encouraging them to seek medical care and discuss their problems candidly, and preventing discrimination on the basis of their medical conditions. The physician should not release a patient's personal medical information (often termed a "privileged communication") without that patient's consent.

Additionally, the College supports community- and school-based programs that address the growing social and economic consequences of teenage pregnancy, which is a cause for concern both nationally and in underserved areas. Support should be increased for federal, state, and local family-planning grants that provide important educational and clinical services.

Additional ACP Comments Regarding Access to Care and Racial and Economic Disparities

Physical and financial separation requirements and the restrictions on counseling and referrals would result in the targeting of specific qualified providers of care, such as Planned Parenthood, which provides care for 41 percent of all Title X users. If a loss of Title X funding would force a facility to close, it would impact access to care throughout the entire health care system for both Title X and non-Title X users. For example, after the state of Texas imposed similar restrictions to state funding of family planning services, the number of Title X providers in the state fell from 48 to 36 between implementation in 2011 and 2015, while the number of patients served dropped from 259,600 to 166,500.¹² This reduced access to care would exacerbate the existing racial and economic disparities in the American health system as nearly 30 percent of individuals who receive care under Title X are non-White and 64 percent have incomes under the Federal Poverty Level.¹³

The College also is concerned about the impact that requiring facilities to offer comprehensive primary health services onsite or have a robust referral network in close proximity would have on access to care. While we appreciate HHS' recognition of the importance of comprehensive primary care, we feel these requirements are inappropriate in serving the intent and goals of the Title X program and would decrease access to Title X services. Some Title X providers, especially specialized clinics which offer a wider range of contraceptive methods and higher quality family planning services, do not offer comprehensive primary care services, even if they do offer numerous preventive services, as Title X funds are not permitted to be used on primary care under current law. Under the proposed Regulation, these requirements would exclude these standalone clinics from receiving funding and leave women without any reproductive health or preventive care at all. Additionally, "close physical proximity" is undefined, and

¹² Katch, Hannah. "Excluding Qualified Family Planning Providers from Offering Care to Low-Income Women Will Restrict Access and Cause Harm." Center on Budget and Policy Priorities. May 30, 2018. <https://www.cbpp.org/blog/excluding-qualified-family-planning-providers-from-offering-care-to-low-income-women-will>.

¹³ Fowler, C. I., Gable, J., Wang, J., & Lasater, B. (2017, August). Family Planning Annual Report: 2016 national summary. Research Triangle Park, NC: RTI International.

standalone family planning clinics located in rural areas could be particularly at risk of losing funding as they may not be in close proximity to other primary care physicians and clinicians. Proximity is also not necessarily the best determining factor for quality patient care.

Conclusion

The American College of Physicians is strongly opposed to changes that would make it more difficult for patients seeking contraception and reproductive health care services to find care. We oppose changes that would restrict federal funding from physicians and other health care professionals who are providing legally permitted health care services. This is the case whether the funds come from Title X, Medicaid reimbursements, or other programs.

The expected changes from the Administration would prohibit any Title X funds from going to an entity that provides even basic information about all of the legal and evidence-based options available for pregnant women. Such a policy change was first attempted by the Reagan administration in the 1980s. Bringing back the idea is outdated and out of touch.

Not only that, the policy change would significantly impact access to care overall for millions of individuals, with a disproportionate number of those impacted being women who are seeking access to contraception and reproductive health care, as well as general preventive services. These patients then may not have an alternative source of care available in their area—or within a reasonable distance, may be uncertain as to where they could go for care, or may simply no longer seek out preventive care or other services. Further, the alternative sources of care are largely community health centers, which are already strained in terms of their resources.

Thank you for considering ACP's comments. Please contact Shari Erickson by phone at 202-261-4551 or e-mail at serickson@acponline.org if you have questions or need additional information.

Sincerely,

A handwritten signature in black ink that reads "Ana María López". The signature is written in a cursive, flowing style.

Ana María López, MD, MPH, FACP
President
American College of Physicians