CALIFORNIA WOMEN'S LAW CENTER

July 31, 2018

Alex Azar, Secretary of Health and Human Services
Attention: Family Planning
Hubert H. Humphrey Building, Room 716G
200 Independence Avenue, SW
Washington, D.C. 20201

Submitted online via http://regulations.gov

RE: Comments on Proposed Regulations Titled "Compliance with Statutory Program Integrity Requirements" Docket ID No. HHS-OS-2018-0008 [RIN: 0927-ZA00]

The California Women's Law Center (CWLC) appreciates the opportunity to submit comments on the proposed regulations titled "Compliance with Statutory Program Integrity Requirements," issued by the U.S. Department of Health and Human Services (HHS) that was published in the Federal Register on June 1, 2018 (proposed regulations).

CWLC is a statewide nonprofit law and policy center dedicated to breaking down barriers and advancing the potential of women and girls through impact litigation, advocacy and education. A vital part of CWLC's mission is fighting for reproductive health, rights, and justice by ensuring women have access to the health care opportunities they need to lead healthy and productive lives. CWLC believes that women and adolescent girls deserve the right to make choices about their bodies and it is vital to ensure that the full range of reproductive health options are accessible to all women and adolescent girls regardless of their income levels, race or residence.

Given our work on behalf of low-income women and girls in California, CWLC strongly opposes the proposed regulations, which if implemented, would significantly impede access to time-sensitive family planning and reproductive health services and disproportionately harm poor women and women of color. The proposed regulations are likely to deter patients from seeking care at Title X-funded health centers and those that do seek care will be denied their full reproductive health options. As a result, the proposed regulations will likely increase unintended pregnancies, teen pregnancies and sexually transmitted infections (STIs).

The Proposed Domestic Gag Rule is Unconstitutional and Will Force Providers to Withhold Full Information from their Patients

Title X was introduced to improve the availability of comprehensive family planning services,[1] with priority given to low-income individuals.[2] Congress restricts Title

[1] Family Planning Services and Population Research Act of 1970, Pub. L. No. 91-572, 84 Stat. 1504 (codified as amended at 42 U.S.C. §§ 300-300a-6 (2018).
[2] 42 U.S. Code § 300a–4(c)(1).

X funds from being used to fund abortions.[3] However, under the current regulatory scheme, abortion counseling must be made available if a patient requests it.[4] The counseling provided must be non-directive, comprising "neutral, factual information" on pregnancy options including prenatal care, foster care or adoption, and pregnancy termination, to help individuals make fully informed family planning decisions.[5]

In 1988, President Ronald Reagan proposed changes to Title X which included bans on abortion counseling and referrals.[6] Together, these provisions came to be known as the domestic gag rule.[7] These changes were litigated[8] and ultimately upheld by the Supreme Court in *Rust v. Sullivan*.[9] They were then reversed by the Clinton administration in 1993.[10]

The proposed regulations (1) eliminate the requirements for abortion counseling and referral[11] and (2) "prohibit Title X projects from performing, promoting, referring for, or supporting, abortion as a method of family planning."[12] This prohibition includes "disseminating materials advocating abortion as a method of family planning or otherwise

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[3] 42 U.S. Code § 300a–6 (§1008 of Title X).

[4] *Provision of Abortion-Related Services in Family Planning Services Projects*, 65 Fed. Reg. 41,281 (July 3, 2000).

[5] 42 C.F.R. § 59.5. The proposed changes remove the requirement of pregnancy counseling regarding termination as an option.

[6] *See Statutory Prohibition on Use of Appropriated Funds in Programs Where Abortion is a Method of Family Planning; Standard of Compliance for Family Planning Services Projects*, 53 Fed. Reg. 2,922, 2,928, 2,936 (Feb. 2, 1988).

[7] *See, e.g.*, Paul Houston, *Senate Votes to Lift 'Gag' on Abortion Counseling*, LOS ANGELES TIMES (July 18, 1991), http://articles.latimes.com/1991-07-18/news/mn-3370_1_gag-rule-bill.

[8] *See Planned Parenthood Fed'n v. Sullivan*, 913 F.2d 1492 (10th Cir. 1990); *Massachusetts v. Sec'y of Health & Human Servs*., 899 F.2d 53 (1st Cir. 1990); *New York v. Sullivan*, 889 F.2d 401 (2d Cir. 1989); *NY v. Bowen*, 863 F.2d 46 (2d Cir. 1988).

[9] *See Rust v. Sullivan*, 500 U.S. 173 (1991). By March of 1992, the rules had not yet been implemented. *See* David G Savage, *Abortion 'Gag Rule' Likely to Take Effect Soon: Regulations: It's been 10 months since the high court upheld the directive to federally funded clinics. Enforcement may start as early as today*, LOS ANGELES TIMES (Mar. 20, 1992), http://articles.latimes.com/1992-03-20/news/mn-4263_1_gag-rule.

[10] Memorandum on the Title X "Gag Rule," (Jan. 22, 1993), https://www.gpo.gov/fdsys/pkg/PPP-1993-book1/pdf/PPP-1993-book1-doc-pg10-2.pdf ("The Act specifies that Title X funds may not be used for the performance of abortions, but places no restrictions on the ability of clinics that receive Title X funds to provide abortion counseling and referrals or to perform abortions using non-Title X funds."); *Standards of Compliance for Abortion-Related Services in Family Planning Service Projects*, 58 Fed. Reg. 7,462, 7,462 (Feb. 5, 1993) ("[T]he Secretary suspends the 1988 rules and announces that…the agency's nonregulatory compliance standards that existed prior to February 2, 1988…will be used to administer the Family Planning Program").

[11] *Compliance with Statutory Program Integrity Requirements*, 83 Fed. Reg. 25,502, 25,507 (June 1, 2018) [hereinafter *Proposed Requirements*].

[12] *Proposed Requirements*, *supra* note 11, at 25,523. These changes mirror the 1988 regulatory changes advanced under Ronald Reagan, though the proposed changes are less absolute. *Compare Proposed Requirements*, *supra* note 11, at 25,531 ("If asked, a medical doctor may provide a list of licensed, qualified, comprehensive health service providers (some, but not all, of which also provide abortion, in addition to comprehensive prenatal care), but only if a woman who is currently pregnant clearly states that she has already decided to have an abortion.") *with Statutory Prohibition*, *supra* note 6, at 2,945 ("[A] Title X project may not provide counseling concerning the use of abortion as a method of family planning or provide referral for abortion…").

promoting a favorable attitude toward abortion."[13] Nondirective counseling, while still permitted, is limited to providing patients who have already decided to terminate a pregnancy with a "list of licensed, qualified, comprehensive health service providers, some (but not all) of which provide abortion in addition to comprehensive prenatal care."[14] Such nondirective counseling is optional[15]—providers under the proposed regulations could refuse to include providers that offer abortion services on a nondirective referral list at all.

Section 1008 of Title X already prohibits the use of Title X funds for providing abortions.[16] However, whether that ban extends to providing abortion counseling or referrals is not clear from the statute's legislative history,[17] leading to these varying interpretations by different administrations.[18] An overly strict interpretation and application of Section 1008 has been advanced to justify the proposed changes and the reinstatement of the gag rule.[19]

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[13] *Proposed Requirements, supra* note 11, at 25,519.

[14] *Id.* at 25,518. A provider may *not* provide a list exclusively composed of clinics of providers that provide prenatal care as well as abortions—providers of prenatal care that do not provide abortions must be included. *See* proposed § 59.14(e)(4), *Id*. at 25,531.

[15] *Id.* at 25,531 ("If asked, a medical doctor *may* provide a list…") (emphasis added).

[16] 42 U.S.C. § 300a–6.

[17] Loye M. Barton, *The Policy Against Federal Funding for Abortions Extends into the Realm of Free Speech After Rust v. Sullivan*, 19 PEPP. L. REV. 637, 689 n.212 (1992) ("The records of the lower courts show that the consensus was that Congress had not addressed the scope of the abortion ban in section 1008. See, e.g., *Massachusetts v. Sullivan*, 899 F.2d 53, 58-61 (1st Cir.1990); *Planned Parenthood v. Sullivan*, 913 F.2d 1492, 1497 (10th Cir. 1990); *New York v. Sullivan*, 889 F.2d 401, 407 (2d Cir.1989) (all agreeing that Congress had not addressed the scope of the abortion prohibition).").

[18] *Compare Statutory Prohibition on Use of Appropriated Funds in Programs Where Abortion is a Method of Family Planning; Standard of Compliance for Family Planning Services Projects*, 53 Fed. Reg. 2,922, 2,922-23 (Feb. 2, 1988) ("It is important to recognize that section 1008 extends to all activities conducted by the federally funded project, not just the use of federal funds for abortions within the project… Because counseling and referral activities are integral parts of the provision of any method of family planning, to interpret section 1008 as applicable only to the performance of abortion would be inconsistent with the broad prohibition against use of abortion as a method of family planning.") *with Standards of Compliance for Abortion-Related Services in Family Planning Service Projects*, 58 Fed. Reg. 7,462, 7,462 (Feb. 5, 1993) ("[T]he original interpretation of section 1008, which prohibited the use of Title X funds in programs where abortion is a method of family planning, did not include a prohibition on non-directive counseling on abortion; moreover, Congress's repeated attempts—vetoed by President Bush—to amend Title X to eliminate the restrictions justify suspension of the Rule while the regulations are being revised to further the purposes of Title X.") *and Provision of Abortion-Related Services in Family Planning Services Projects*, 65 Fed. Reg. 41,281, 41,281 (July 3, 2000) ("In general, section 1008 prohibits Title X programs from engaging in activities which promote or encourage abortion as a method of family planning. However, section 1008 does not prohibit the funding under Title X of activities which have only a possibility of encouraging or promoting abortion; rather, a more direct nexus is required.").

[19] *Proposed Requirements, supra* note 11, at 25,505 ("[T]he Department believes that the policies outlined in this proposed regulations provide for the best interpretation of section 1008 of Title X…[T]he Department interprets section 1008 to establish a broad prohibition on funding, directly or indirectly, activities related to abortion as a method of family planning.").

The Domestic Gag Rule Violates the First Amendment

The proposed regulations seek to reinstate the domestic gag rule, which was widely challenged as unconstitutional when first introduced.[20] As stated by Justice Blackmun's dissent in *Rust*, (1) restrictions on physicians' speech constitute both content- and viewpoint-based suppression,[21] (2) it is impermissible to force a physician to give up a constitutional right to free speech as a condition of government employment,[22] and (3) Title X patients' right "to be free from affirmative governmental interference in [their] decision" concerning pregnancy is violated when "medically pertinent information" is withheld from them.[23] Ultimately, the domestic gag rule infringes on the First Amendment rights of Title X-projects' staff members[24] and the Fifth Amendment rights of Title X-projects' patients.[25]

The proposed regulations would enact content- and viewpoint-based suppression of speech. Like the 1988 rules,[26] the proposed regulations make certain information mandatory and prohibit the provision of other information entirely: any pregnant patient who has not independently decided to get an abortion will only be provided with a list of "licensed, qualified, comprehensive health service providers (including providers of prenatal care) who do not provide abortion as a part of their services, along with referrals for prenatal care and social services."[27] This constitutes a "formidable obstacle" to

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[20] *New York v. Bowen*, 690 F. Supp. 1261, 1263 (S.D.N.Y. 1988), *aff'd sub nom. New York v. Sullivan*, 889 F.2d 401 (2d Cir. 1989), *aff'd sub nom. Rust*, 500 U.S. 173 (1991); *Planned Parenthood Fed'n of Am. v. Bowen*, 687 F. Supp. 540, 542 (D. Colo. 1988), *aff'd sub nom. Planned Parenthood v. Sullivan*, 913 F.2d 1492 (10th Cir. 1990), *vacated*, 500 U.S. 949 (1991); *Planned Parenthood Fed'n of Am. v. Bowen*, 680 F. Supp. 1465, 1466 (D. Colo. 1988); *Massachusetts v. Bowen*, 679 F. Supp. 137, 140 (D. Mass. 1988), *aff'd sub nom. Massachusetts v. Secretary of Health & Human Servs.*, 899 F.2d 53 (1st Cir. 1990) (en banc), *vacated*, 500 U.S. 949 (1991).

[21] *Rust*, 500 U.S. at 209 (Blackmun, J., dissenting).

[22] *Id.* at 212-13.

[23] *Id.* at 216.

[24] *Id.* at 214-15 ("By failing to balance or even to consider the free speech interests claimed by Title X physicians against the Government's asserted interest in suppressing the speech, the Court falters in its duty to implement the protection that the First Amendment clearly provides for this important message.").

[25] *Id.* at 219 ("The manipulation of the doctor-patient dialogue achieved through the Secretary's regulations is clearly an effort "to deter a woman from making a decision that, with her physician, is hers to make." As such, it violates the Fifth Amendment.") (internal citations omitted).

[26] *See* Ann Brewster Weeks, *The Pregnant Silence: Rust v. Sullivan, Abortion Rights, and Publicly Funded Speech*, 70 N.C. L. REV. 1623, 1661 (1992) ("The language of the abortion counseling regulations themselves do not support [the *Rust*] holding, however, as they require that specific information be given to a pregnant Title X patient concerning prenatal care to protect her health and the health of the fetus, but prohibit any counseling on or referral for abortions. In addition, they contain direct references to the government's goal of reducing the incidence of abortion.")

[27] *Proposed Requirements, supra* note 11, at 25,518.

"freedom of choice" about how to handle a pregnancy, as it will mislead patients about their options and thus interfere in their decision-making.[28]

Furthermore, the government cannot enforce, as it seeks to under the proposed regulations, a *quid pro quo*, conditioning federal funding or employment on the waiver of a constitutional right, as "a government may not require an individual to relinquish rights guaranteed him by the First Amendment as a condition of public employment."[29] The proposed regulations bar providers from counseling pregnant patients on the full scope of options available to them and forces providers to provide referrals for prenatal counseling regardless of a pregnant patient's expressed wishes.[30] This is impermissible under the First Amendment[31] irrespective of the program's federal funding and the government's wish "to ensure that the limits of the federal program are observed."[32]

The government acts unconstitutionally when it manipulates a woman into continuing her pregnancy. Restricting abortion counseling and referral in Title X centers effectively coerces women to do so:[33] if a physician only informs them about prenatal care or adoption, women seeking counsel from a Title X clinic are likely to mistakenly believe that abortion is not available to them at all, despite a constitutionally-protected right to obtain one.[34] The suppression of medically pertinent information interferes with and hinders patients' ability to decide how to proceed with a pregnancy.[35]

The Domestic Gag Rule Harms Women's Ability to Make Informed Decisions about their Health by Diminishing the Quality and Availability of Unbiased Care

Separate from the constitutional issues, the proposed regulations will force current Title X funding recipients to decide if they are willing to change their practices to comply with Title X. This will undoubtedly interfere with the patient/provider relationship and clinics' ability to provide the same array of services, including comprehensive healthcare information and unbiased counseling related to family planning. This mandate is widely

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[28] *Rust*, 500 U.S. at 216 (Blackmun, J., dissenting) ("By suppressing medically pertinent information and injecting a restrictive ideological message unrelated to considerations of maternal health…").

[29] *Id.* at 212 (citing *Abood v. Detroit Bd. of Ed.*, 431 U.S. 209, 234 (1977)).

[30] *Proposed Requirements, supra* note 11, at 25,531 ("[O]nce a client served by a Title X project is medically verified as pregnant, she *must* 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.") (emphasis added).

[31] *Rust*, 500 U.S. at 209-10 (Blackmun, J., dissenting) ("Both requirements are antithetical to the First Amendment.").

[32] *Id.* at 193 (majority opinion).

[33] *See* Dorothy E. Roberts, *Rust v. Sullivan and the Control of Knowledge*, 61 GEO. WASH. L. REV. 587, 590 (1993) ("*Rust* upheld regulations that deliberately withheld from women in [poor Black] communities knowledge critical to their reproductive health and autonomy."). *Id.* at 600 ("The physician's failure to discuss abortion as a legal option is likely to lead at least some patients to conclude incorrectly that abortion is not such an option.").

[34] *Rust*, 500 U.S. at 216 (Blackmun, J., dissenting) (citing *Roe v. Wade*, 410 U.S. 113 (1973)) ("The Fifth Amendment right asserted by petitioners is the right of a pregnant woman to be free from affirmative governmental interference in her decision.").

[35] *See Id.* at 218-19; Weeks, *supra* note 26, at 1642 (describing the regulations as "creat[ing] an obstacle to Title X patients' exercise of their Fifth Amendment rights").

opposed, as it was in 1988. In the past, Congressional action in both houses to overturn the previously-passed gag rule indicated broad opposition to the ban on abortion counseling and referral.[36] Currently, more than 200 members of Congress oppose the changes.[37]

The proposed changes are detrimental to the scope and quality of family planning services available under Title X. First, restricting the counseling healthcare providers are able to provide patients goes against accepted standards of informed consent.[38] Second, the proposed regulations would bar providers from giving information about abortion even in *medically necessary* situations.[39] Third, the regulations would place poor and uninsured women at a disproportionate risk of decreased access to comprehensive family planning health care.

The proposed changes restrict health care providers' speech and require them to act contrary to accepted standards of informed consent.[40] The American Medical Association, for example, considers "[t]ruthful and open communication between physician and patient" to be "essential," and "withholding information without the patient's knowledge or consent" to be "ethically unacceptable."[41] The American College of Obstetricians and Gynecologists requires "accurate and unbiased information" as well as "appropriate

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[36] H.R. 2707, 102nd Cong., 1st Sess. (1991) (bill summary indicates that it "Prohibits the use of funds to enforce or otherwise implement regulations prohibiting abortion counseling and referral services and limiting program services to family planning."); Family Planning Amendments Act of 1992, S. 323, 102nd Cong., 1st Sess. (1992) ("The Secretary may not make an award of a grant or contract under this section unless the applicant for the award agrees that the family planning project involved will provide to individuals information regarding pregnancy management options upon request of the individuals…For purposes of this subsection, the term 'information regarding pregnancy management options' means nondirective counseling and referrals regarding-- (A) prenatal care and delivery; (B) infant care, foster care, and adoption; and (C) termination of pregnancy.").

[37] Letter from Members of Congress to Alexander M. Azar , Secretary, U.S. Dept. of Health & Human Services (May 15, 2018), https://www.plannedparenthood.org/uploads/filer_public/85/d9/85d98a81-2b43-4520-a41b-b301a8fb1c95/final_house_title_x_domestic_gag_letter111.pdf; Letter from U.S. Senators to Alexander M. Azar , Secretary, U.S. Dept. of Health & Human Services (May 14, 2018), https://www.plannedparenthood.org/uploads/filer_public/cc/2e/cc2ed355-0308-4a59-9535-71a9c81474a3/20180514_letter_to_hhs_opposing_domestic_gag_on_title_x212111.pdf.

[38] *See Rust v. Sullivan*, 500 U.S. 173, 218 (1991) (Blackmun, J., dissenting) ("The substantial obstacles to bodily self-determination that the regulations impose are doubly offensive because they are effected by manipulating the very words spoken by physicians and counselors to their patients.").

[39] *See* Proposed § 59.14(d): "Nothing in this subpart shall be construed as prohibiting the provision of information to a project client that is medically necessary to assess the risks and benefits of different methods of contraception in the course of selecting a method, provided that the provision of such information does not otherwise promote abortion as a method of family planning." *Proposed Requirements*, *supra* note 11, at 25,531.

[40] *See* Kinsey Hasstedt, Unbiased Information on and Referral for All Pregnancy Options Are Essential to Informed Consent in Reproductive Health Care, GUTTMACHER INSTITUTE (Jan. 10, 2018), https://www.guttmacher.org/gpr/2018/01/unbiased-information-and-referral-all-pregnancy-options-are-essential-informed-consent.

[41] Withholding Information from Patients, Code of Medical Ethics Opinion 2.1.3, AMERICAN MEDICAL ASSOCIATION, https://www.ama-assn.org/delivering-care/withholding-information-patients (last visited June 29, 2018).

referrals," under the broad statement that "[i]nformed consent includes freedom from external coercion, manipulation, or infringement of bodily integrity."[42]

If enforced, the proposed Title X regulations will require medical providers to withhold information from, infringe the bodily integrity of, and refuse to make referrals for abortions to pregnant patients. As stated in the recent *Nat'l Inst. of Family & Life Advocates v. Becerra* decision,

> [T]his Court has stressed the danger of content-based regulations "in the fields of medicine and public health, where information can save lives…[R]egulating the content of professionals' speech poses the inherent risk that the Government seeks not to advance a legitimate regulatory goal, but to suppress unpopular ideas or information…and the people lose when the government is the one deciding which ideas should prevail.[43]

Here, although the administration might disagree with the practice of abortion, and although it may refuse to fund the procedure, preventing healthcare providers from informing patients of the availability of abortion interferes with these individuals' personal decisions and views.

As written, the proposed changes do not allow for abortion counseling or referral even in *medically urgent* situations. There are numerous situations in which an abortion may be medically necessary: placental abruption, bleeding from placenta previa, preeclampsia or eclampsia, and cardiac or renal conditions.[44] Ectopic pregnancies similarly endanger a woman's life and require termination.[45] In these instances, it is possible that a referral for abortion would be permissible.[46] However, there are additional situations in which an abortion may be medically recommended, such as where a pregnancy endangers a woman's health, but not life. For example, pregnancy may exacerbate existing medical conditions such as heart disease, hypertension, diabetes, sickle cell anemia, cancer, and AIDS.[47] The proposed regulations may force women in these

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[42] ACOG Committee Opinion No. 439: Informed Consent, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS 1, 6 (August 2009), https://www.acog.org/-/media/Committee-Opinions/Committee-on-Ethics/co439.pdf?dmc=1&ts=20180629T1827414484 (reaffirmed 2015).

[43] *Nat'l Inst. of Family & Life Advocates v. Becerra*, No. 16-1140, 2018 WL 3116336, at *10-11 (U.S. June 26, 2018).

[44] ACOG Committee Opinion No. 613: Increasing Access to Abortion, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS 1, 2 (November 2014), https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co613.pdf?dmc=1&ts=20180706T2151258054 (reaffirmed 2017).

[45] *Ectopic Pregnancy*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/ectopic-pregnancy/symptoms-causes/syc-20372088 ("An ectopic pregnancy can't proceed normally. The fertilized egg can't survive, and the growing tissue may cause life-threatening bleeding, if left untreated.") (last visited July 6, 2018).

[46] *See Proposed Requirements, supra* note 11, at 25,531 ("A Title X project discovers an ectopic pregnancy in the course of conducting a physical examination of a client. Referral arrangements for emergency medical care are immediately provided. Such action complies with the requirements of paragraph (b) of this section."); *see also Rust*, 500 U.S. at 195 ("On their face, we do not read the regulations to bar abortion referral or counseling in such circumstances. Abortion counseling as a "method of family planning" is prohibited, and it does not seem that a medically necessitated abortion in such circumstances would be the equivalent of its use as a "method of family planning." Neither § 1008 nor the specific restrictions of the regulations would apply.").

[47] Roberts, *supra* note 33, at 594 (Additionally, "a woman with diabetic retinopathy who becomes pregnant may go blind.").

situations to forgo medication that would damage the fetus, at risk to their own health, or proceed with treatment and risk endangering the fetus.[48] Health care providers at Title X-funded clinics should not be prevented from counseling patients on the full scope of options in these situations.

Protections for medically necessary abortions often arise: numerous cases at the state level following *Harris v. McRae* asserted that their state Medicaid programs must provide *medically necessary* abortions despite the federal government's refusal to provide Medicaid reimbursements for such procedures under the Hyde Amendment.[49] Barring providers from even counseling women about abortion, or providing a referral, in these medically necessary situations exposes women in the care of Title X facilities to great risk.

Forcing health care organizations to choose between providing abortion counseling and referral or receiving Title X funding will be most damaging to poor and uninsured women who rely on federally-funded health care.[50] The gag rule will result in clinics either providing incomplete care to vulnerable patients or the existence of fewer accessible Title X-funded care centers. Poor women relying on the federally funded clinics will be denied complete information from Title X projects, whereas women with access to private medical care will not.[51]

Health care centers that wish to continue providing abortion counseling and referral would be forced to forgo Title X funding, diminishing the availability of family planning clinics accessible to poor women.[52] This makes women more vulnerable to experiencing delayed care. For women who undertake to get an abortion, first-trimester abortions are significantly safer than later abortions,[53] making prompt counsel and referral

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[48] Cynthia Soohoo, *Hyde-Care for All: The Expansion of Abortion-Funding Restrictions Under Health Care Reform*, 15 CUNY L. REV. 391, 412-13 (2012).

[49] *See Harris v. McRae*, 448 U.S. 297 (1980) (upholding restrictions on federal funding of abortions); Soohoo, *supra* note 48, at 410 ("After the Harris decision, challenges to abortion funding restrictions moved to the state level. Courts in thirteen states--Alaska, Arizona, California, Connecticut, Illinois, Massachusetts, Minnesota, Montana, New Jersey, New Mexico, Oregon, Vermont, and West Virginia--held that their state constitutions required that their state Medicaid programs cover medically necessary abortions even if the federal government would not provide reimbursement for services.").

[50] *See, e.g., Comm. To Defend Reprod. Rights v. Myers*, 29 Cal. 3d 252, 275 (1981) ("[B]y definition . . . the only women affected by the restrictions at issue are those who lack the money or resources to pay for medically supervised abortion on their own.").

[51] *Myers*, 29 Cal. 3d at 285 ("[The] practical effect is to deny to poor women the right of choice guaranteed to the rich."); Barton, *supra* note 17, at 680 ("Women who must rely on federally funded programs because of their indigence receive incomplete information while women who can afford private medical care generally receive complete information.").

[52] *See* Barton, *supra* note 17, at 679 ("Immediately after the announcement of the Rust v. Sullivan decision, clinics around the country announced their intent to give up their Title X federal funds and continue to provide abortion counseling and referral.").

[53] *Induced Abortion in the United States*, GUTTMACHER INSTITUTE (Jan. 2018), https://www.guttmacher.org/fact-sheet/induced-abortion-united-states ("A first-trimester abortion is one of the safest medical procedures and carries minimal risk: Major complications (those requiring hospital care, surgery or transfusion) occur at a rate of less than 0.5%…The risk of death associated with abortion increases with the length of pregnancy, from 0.3 for every 100,000 abortions at or before eight weeks to 6.7 per 100,000 at 18 weeks or later."); *See also* Kari White et al., *Complications from First-Trimester Aspiration Abortion: A Systematic Review of the Literature*, 92 CONTRACEPTION, no. 5, 2015, at 422-438,

pivotal. The danger of decreased availability is exemplified by the reinstatement of the global gag rule,[54] which has in the past led to the closure of family planning and women's health clinics and reduced access to contraception,[55] and also contributed to a rise in unsafe abortions.[56] In the domestic context, women who rely on government-funded medical care may remain unaware that abortion is an option available to them or receive that information too late in their pregnancy.[57] Some states have gone farther to impose restrictive time constraints on when a woman can seek an abortion, making timely information all the more urgent.[58]

The proposed regulations will cause severe harm to poor and uninsured women, especially because patients seek far more than just contraceptive care from Title X clinics: the sites offer breast and cervical cancer screening as well as testing, referral, and prevention education for STIs and HIV.[59] Many patients' only access to health care or health education comes from their Title X provider.[60]

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https://www.ncbi.nlm.nih.gov/pubmed/26238336; Zane S et al., Abortion-Related Mortality in the United States, 1998–2010, 126 OBSTETRICS & GYNECOLOGY, no. 2, 2015, at 258-265.

[54] *See, e.g.*, Press Release, Office of the Spokesperson, Protecting Life in Global Health Assistance (May 15, 2017), https://www.state.gov/r/pa/prs/ps/2017/05/270866.htm.

[55] Andrea Montes, *Reinstatement of the Global Gag Rule in 2017: Playing Politics with Women's Lives Around the World*, 42 NOVA L. REV. 285, 293-94 (2018).

[56] *Breaking the Silence: The Global Gag Rule's Impact on Unsafe Abortion*, Center for Reproductive Rights 5, https://www.reproductiverights.org/sites/default/files/documents/bo_ggr.pdf; *See also* Anika Rahman et al., A Global Review of Laws on Induced Abortion, 1985-1997, 24 INT'L FAM. PLAN. PERSPECTIVES 56 (1998), available at http://www.guttmacher.org/pubs/journals/2405698.html.

[57] Barton, *supra* note 17, at 684; Roberts, *supra* note 33, at 594 ("Some pregnant women would interpret the clinic's failure to discuss abortion to mean that abortion is not a safe and legal alternative. This obfuscation of referrals would mean dangerous delays in obtaining an abortion") (citations omitted); *Id*. at n.30 ("36% of American adults believe that, during the first three months of pregnancy, abortion is allowed only under "extreme circumstances" or not at all.").

[58] *20-Week Bans*, REWIRE.NEWS (last updated Jan. 1, 2018), https://rewire.news/legislative-tracker/law-topic/20-week-bans/ ("Twenty-week abortion bans with varying exceptions have been enacted in 21 states: Alabama, Arkansas, Arizona, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Nebraska, North Carolina, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, West Virginia and Wisconsin. Laws banning abortion at 20 weeks have been blocked in two states: Arizona and Idaho."). Many contest these abortion bans as unconstitutional. *See* Bebe J. Anderson, Litigating Abortion Access Cases in the Post-Windsor World, 29 Colum. J. Gender & L. 143, 146–47 (2015) ("Opponents of reproductive rights have enacted increasingly extreme bills in the past few years. For example, they have gone so far as to pass a number of bans on pre-viability abortions--even as early as approximately six weeks of pregnancy, twelve weeks, twenty weeks-- although under both Roe and Casey it is absolutely clear that pre-viability bans are unconstitutional.") (internal citations omitted).

[59] *Program Requirements for Title X Funded Family Planning Projects*, Office of Population Affairs, 2014 at 5, 15, available at https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf.

[60] C. I. Fowler et al., *Family Planning Annual Report: 2016 National Summary*, Office of Population Affairs, August 2017, at ES-1, available at https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf.

The Elimination of the Requirement that Family Planning Options be "Medically Approved" Will Endanger Women and Disproportionately Harm Low-Income Women

Title X requires that funding be distributed to family planning projects that "offer a broad range of acceptable and effective family planning methods and services."[61] Current regulations also stipulate that the broad range of acceptable and effective methods be "medically approved," without further defining the phrase.[62] As of 2016, Title X granted support family planning services in almost 4,000 sites, primarily serving young, low-income women.[63]

The proposed regulations will reduce the quality and range of services that a project must provide to be eligible for funding. HHS proposes that the requirement that projects offer "medically approved" family planning options be eliminated, opening the door for funding of ineffective forms of family planning over medically approved methods.[64] The proposed regulations emphasize that natural family planning methods, such as fertility based-awareness methods and abstinence, are acceptable and effective methods that will be funded.[65] HHS also added a provision that Title X-funded projects are not required to provide every type of family planning available,[66] and that individual facilities need only provide a single service if they are part of a project that provides a broad range of services.[67]

Taken together, these changes indicate a dangerous shift away from comprehensive family planning, to the detriment of low-income women. As funding is diverted from comprehensive care towards non-medically approved single-service facilities and projects, low-income women will have reduced access to information and family planning options. There are three key issues that arise from these proposed changes: (1) women may lose access to the family planning method they previously used under Title X, (2) if their family planning method is no longer available, women may choose other family planning methods that are less effective for them, and (3) if women must resort to less effective family planning methods, it is possible that unintended pregnancies will result. The results will be harmful and costly. Each of these potential effects also contravenes Title X's stated purpose to provide individuals with the resources to "determine the number and spacing of their children."[68]

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[61] 42 U.S.C. § 300(a).
[62] 42 C.F.R. § 59.5.
[63] Fowler, *supra* note 60, at ES-1.
[64] *Proposed Requirements*, *supra* note 11, at 25,515.
[65] *Id.* at 25,529. The proposed definition of family planning (a proposed addition to 42 C.F.R. § 59.2) says that "acceptable and effective" methods for planning the number and spacing of children, include a "broad range 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 natural family planning or other fertility awareness-based methods) and the management of infertility (including adoption)."
[66] *Proposed Requirements*, *supra* note 11, at 25,515. The proposed change to 42 C.F.R. § 59.5 adds that "projects are not required to provide every acceptable and effective family planning method or service." This is not stated in the current version of 42 C.F.R. § 59.5.
[67] *Id.* at 25,515; 42 C.F.R. § 59.5.
[68] 42 C.F.R. § 59.1.

HHS's removal of the "medically approved" requirement, emphasis on natural family planning methods, and statement that facilities need not provide a broad range of family planning methods, will limit the availability of medically-approved family planning resources and comprehensive family planning care. First, the proposed changes eliminate the current regulations' requirement that Title X-funded projects provide "medically approved" family planning methods.[69] HHS claims that the current language in the regulation is confusing because it does not define "medically approved" and there is no agreed upon professional standard.[70] It also notes that the statutory language of 42 USC § 300 does not require that family planning methods be medically approved, concluding that "the statutory language of 'acceptable and effective family methods or services' provides better guidance for the types of methods and services that Congress sought to fund."[71]

In addition to shifting away from medically approved methods, HHS's proposal places emphasis on natural family planning methods that are not effective. It lists "choosing not to have sex" and "other family planning methods and services to limit or enhance the likelihood of conception (including contraceptive methods and natural family planning or other fertility awareness-based methods)" as examples of "acceptable and effective" family planning options.[72] While the current regulations also mention "natural family planning methods" as examples of "acceptable and effective medically approved family planning method[s]," they do not refer to fertility awareness-based methods (FABMs).[73] The addition of FABM language in the proposed regulations suggests the HHS's increased prioritization of natural family planning methods that have high rates of failure and are not effective compared to medically approved methods.[74]

The proposed regulations also reduce the number of family planning options that a project as a whole must provide.[75] HHS states that the proposed regulations "would … make it more explicit that the requirement to provide a 'broad range' of acceptable and effective family planning methods and services does not require a project to provide every acceptable and effective family planning method or service."[76] Further, an individual

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[69] Current 42 CFR § 59.5(a)(1) requires that each project supported by Title X funding "[p]rovide a broad range of acceptable and effective *medically approved* family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents)" (emphasis added). *Compare with Proposed Requirements*, *supra* note 11, at 25,530.

[70] *Proposed Requirements* at 25,515 ("Medical doctors and professional organizations can differ on which methods of health care they approve, including different methods of family planning. Such differences may be based on differing areas of expertise, or differing views of the health care method."

[71] *Proposed Requirements*, *supra* note 11, at 25,515.

[72] *Id.* at 25,529.

[73] 42 C.F.R. § 59.5(a)(1).

[74] Center for Disease Control and Prevention (CDC), *Effectiveness of Family Planning Methods*, https://cdc.gov/reproductivehealth/unintendedpregnancy/pdf/contraceptive_methods_508.pdf; Cf. American College of Obstetricians and Gynecologists, *Fertility Awareness-Based Methods of Family Planning*, https://www.acog.org/-/media/For-Patients/faq024.pdf?dmc=1&ts=20180629T2210108938 (citing that 12 to 24 percent of women will become pregnant during the first year of typical FABM use, and which perfect use only 1 to 5 percent will become pregnant during the first year) [hereinafter *Fertility Methods*].

[75] *Proposed Requirements*, *supra* note 11, at 25,515.

[76] *Id*. at 25,515. Each project as a whole would still be required to offer contraceptives, natural family planning methods, infertility services, and services for adolescents. *Id.* at 25,516 ("[L]imited family planning service offering is permissible as long as the overall Title X project offers a broad range of family planning services, including contraceptives." "[I]ncluded in the

facility that only provides one method of family planning would still be eligible for funding if it were part of a project that provided a permissible range of family planning methods.[77]

Taken together, these changes will restrict access to comprehensive family planning care, including access to medically approved options. Funding will be diverted from facilities that provide comprehensive family planning options to those that provide only a single service or limited services, and these limited services may not be medically approved. Women, especially those who already find themselves traveling for low-cost family planning services, will be burdened by the limited methods of family planning offered near them. They will likely resort to methods that are less effective for them than the one(s) they are currently using or would have chosen.

Comprehensive family planning care is necessary to ensure that individuals can exercise their autonomy and make appropriate family planning decisions. The Family Planning Services and Population Research Act of 1970 (from which Title X comes) declares that one of its purposes is "to assist in making comprehensive voluntary family planning services readily available to all persons desiring such services."[78] The current Title X regulations state "these projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children."[79] The Act and the current regulations prioritize the individual's autonomy in making his or her family planning decisions. However, autonomy is undermined when there is a limited number of available services and choices.

Comprehensive care is also a necessity as it the only way to fully address well-documented reproductive health needs among Americans. Family planning cannot be satisfied in the United States by a single method. American women express diverse interests and needs in family planning services, including among contraceptive methods.[80] Contraceptive methods range from daily birth control pills, to inserted IUDs, to male and female condoms that must be used at the time of intercourse, to irreversible sterilization.[81] In 2014, 25% of female contraceptive users relied on oral contraceptives, 22% relied on female sterilization, 15% relied on condoms, 12% relied on IUDs, 8% relied on withdrawal, 7% relied on a patch, ring, or injectable, 3% relied on an implant, 2% relied on FABMs, and 1% relied on other methods as their most effective method.[82] Moreover, women often use multiple methods at the same time,[83] and switch between methods

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broad range of acceptable and effective family planning methods and services that each Title X project must offer are natural family planning methods, infertility services, and services for adolescents").

[77] This is also permissible under current regulations.

[78] Family Planning Services and Population Research Act of 1970, Pub. L. No. 91-572, 84 Stat. 1504 (codified as amended at 42 U.S.C. §§ 300-300a-6 (2018)).

[79] 42 C.F.R. § 59.1.

[80] Adam Sonfield, *Policy and Practice Must Guarantee a True Choice of Contraceptive Methods*, Guttmacher Institute (Nov. 2017). ("U.S. women and couples rely on a broad mix of contraceptive methods").

[81] *Contraceptive Use in the United States*, GUTTMACHER INSTITUTE (Sept. 2016), https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.

[82] *Id*.

[83] *Id.* (A 2017 study found that 17% of female contraceptive users used two or more methods the last time they had sex).

depending on their life circumstances and family goals.[84] Eighty-six percent of women have used three or more methods by their 40s.[85]

These family care methods range in effectiveness, side effects, and vigilance required by the individual using the method.[86] A woman's choice of contraceptive often reflects her experiences with side effects, drug interactions, and hormones.[87] It may also reflect the "ability to use the method confidentially or without [her] partner's permission."[88]

Comprehensive care is essential in order to address the health concerns of women who have a wide range of family planning and health needs. Without a full range of options from which to choose, women may lose access to the method they previously used and prefer. They may resort to a method that is less effective for them. If the proposed regulations are implemented, women may resort to pregnancy avoidance methods that are less effective for them than the methods they would have chosen had they had more options, resulting in an increased number of unintended pregnancies.

The proposed regulations state that a specialized, single-method natural family planning service site (such as one that provides fertility awareness-based methods of planning) would be a permissible component of a larger Title X project.[89]

Fertility awareness-based methods (FAMBs) track a woman's fertility cycle. Women trying to avoid conception will avoid sexual intercourse during the fertile period or use a barrier method of birth control, such as a condom.[90] There is limited research on the effectiveness of these methods, and the data that exists is complicated by the fact that women sometimes use a FABM in conjunction with a contraceptive.[91] The CDC reports that with typical use 24% of women become pregnant in a year when using FABMs, while 9% become pregnant with typical use of the birth control pill, and .02 to .08% become pregnant with typical use of an IUD.[92]

While suitable for some individuals, FABMs do not fit everyone's lifestyle and are therefore ineffective for many women. Only a small percentage of contraceptive-using women use FABMs as their primary form of contraception.[93] FABMs require education

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[84] *Id.*
[85] *Id.*
[86] *See, e.g., Fertility Methods*, *supra* note 74 (explaining the variations between different types of FABMs).
[87] *Contraceptive Use in the United States*, *supra* note 81.
[88] *Id.*
[89] *Proposed Requirements*, *supra* note 11, at 25,516.
[90] The American College of Obstetricians and Gynecologists, *FAQ Contraception: Fertility Awareness-Based Methods of Family Planning*, https://www.acog.org/-/media/For-Patients/faq024.pdf?dmc=1&ts=20180629T2210108938.
[91] Michael D. Manhart et al., *Fertility awareness-based methods of family planning: A review of effectiveness for avoiding pregnancy using SORT*, Osteopathic Family Physician (5) (2013) at 6 ("[T]here have been about 30 studies of FABM conducted in more than 30 years, and only about one-third of them have been of high quality"); *See generally* Chelsea B. Polis and Rachel K. Jones, *Multiple contraceptive method use and prevalence of fertility awareness based method use in the United States, 2013-2015*, Guttmacher Institute (2018).
[92] CDC, *supra* note 90; *Cf. Fertility Methods*, *supra* note 74 (citing that 12 to 24 percent of women will become pregnant during the first year of typical FABM use, and with perfect use only 1 to 5 percent will become pregnant during the first year).
[92] CDC, *supra* note 74.
[93] *Contraceptive Use in the United States*, *supra* note 81.

and counseling, and they involve detailed tracking of fertility cycles and cooperation from sexual partners.[94] The difficulties associated with this method likely account for the high percentage of unintended pregnancies that occur with typical use.

The proposed regulations also recommend abstinence as an effective method of family planning.[95] Although theoretically abstinence is the most effective measure for preventing pregnancy, its user failure rate is high.[96] Significant evidence from the past 20 years "has found that [Abstinence-Only-Until-Marriage] programs [in schools] are not effective at preventing pregnancy or STIs, nor do they have a positive impact on age at first sexual intercourse, number of sexual partners or other behaviors."[97] In addition to being ineffective, promoting primarily an abstinence-only message in Title X facilities completely ignores the needs of individuals who are already engaged in sexual activity, or those who do not wish to follow an abstinence-only program. Abstinence as a family planning method also ignores the reality that sexual activity is not always a choice: such as for victims of sexual abuse, rape, and intimate partner violence.[98]

The prioritization of abstinence and fertility awareness-based methods that are less effective than other methods with typical use, will increase the rate of unintended pregnancies, contrary to the stated goal of Title X.[99] Unintended pregnancies that result in birth have health impacts on mothers and children[100] and are also costly.[101] The cost of providing family planning services is less than the cost associated with unintended pregnancies; Title X family planning services saved $15.7 billion in gross public savings in 2010 by reducing unintended pregnancies.[102]

Unintended pregnancies are associated with harmful conditions for both mothers and infants, as they often are not accompanied by prenatal care. Prenatal care is essential to reduce complications during birth and promote fetal health and development.[103] Mothers whose pregnancies were unintended "are more than twice as likely to report an inadequate consumption of folic acid prior to their pregnancy, putting their newborn at

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[94] Manhart et al., *supra* note 91.
[95] *See Proposed Requirements* at 25,529.
[96] John S. Santelli et al., *Abstinence-Only-Until-Marriage: An Updated Review of U.S. Policies and Programs and Their Impact,* 61 Adolescent Health 273, 276 (2017).
[97] Rebecca Wind, *Abstinence-Only-Until-Marriage Programs Are Ineffective and Harmful to Young People, Expert Review Confirms,* Guttmacher Institute (Aug. 2017), https://www.guttmacher.org/news-release/2017/abstinence-only-until-marriage-programs-are-ineffective-and-harmful-young-people.
[98] *See* Santelli, *supra* note 96, at 277.
[99] *Unintended Pregnancy in the United States*, GUTTMACHER INSTITUTE (Sept. 2016).
[100] *Id.* ("Births resulting from unintended or closely spaced pregnancies are associated with adverse maternal and child health outcomes, such as delayed prenatal care, premature birth, and negative physical and mental health effects for children.")
[101] Adam Sonfield and Kathryn Kost, *Public Costs from unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy Related Care: National and State Estimates for 2010,* Guttmacher Institute (Feb. 2015) (Two thirds of unplanned births in 2010 were paid for by public insurance programs).
[102] Jennifer J. Frost, et al., *Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the US Publicly Funded Family Planning Program*, MILBANK QUARTERLY 667, 668 (15 Oct. 2014).
[103] *See generally What is prenatal care and why is it important,* US Department of Health and Human Services: National Institutes of Health (nichd.nih.gov), https://www.nichd.nih.gov/health/topics/pregnancy/conditioninfo/prenatal-care.

risk of developing neural tube effects."[104] There is also a greater risk that fetuses will be exposed to alcohol during the first trimester, increasing the risk of abnormal growth and morphogenesis.[105] Lack of neonatal care "is associated with a 40% increase in the risk of neonatal death."[106]

Further, women who unintentionally become pregnant may not realize it in a timely manner because of misinformation about the effectiveness of contraceptive and other family planning methods, such as abstinence and FABMs. In addition to the matter of prenatal care, this raises concerns regarding timely access to abortion. For women who decide to get an abortion, first-trimester abortions are significantly safer than later abortions.[107]

Therefore, women will be harmed by the proposed regulations because they will be deprived of access to comprehensive health care if clinics are allowed to offer family planning options that are not "medically approved."

The Proposed Regulations Harm Minors by Removing Important Confidentiality Protections

Congressional intent to provide confidential family planning access to teenagers through Title X programming is unambiguous.[108] Although the Title X statute did not name them in its initial version, adolescents were drawn to Title X services from the program's onset, in large part because of the confidentiality Title X clinics provided.[109] Concerned about the number of sexually active teenagers whose family planning needs were unmet,[110] in 1978, Congress amended the statute to explicitly include services for adolescents.[111] Further, Congress recognized that much of the program's success within

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[104] Elizaveta Oulman, et al., *Prevalence and predictors of unintended pregnancy among women: an analysis of the Canadian Maternity Experiences Survey*, BMC Pregnancy and Childbirth (2015) at 1-2.
[105] *Id.* at 2.
[106] *Neonatal Death Risk: Effect of Prenatal Care Is More Evident After Term Birth,* Guttmacher Institute (2002).
[107] *Induced Abortion in the United States,* Guttmacher Institute (Jan. 2018) ("A first-trimester abortion is one of the safest medical procedures and carries minimal risk: Major complications (those requiring hospital care, surgery or transfusion) occur at a rate of less than 0.5%…The risk of death associated with abortion increases with the length of pregnancy, from 0.3 for every 100,000 abortions at or before eight weeks to 6.7 per 100,000 at 18 weeks or later."); *See also* Kari White et al., *Complications from First-Trimester Aspiration Abortion: A Systematic Review of the Literature*, 92 Contraception, no. 5, 2015, at 422-438, https://www.ncbi.nlm.nih.gov/pubmed/26238336; Zane S et al., *Abortion-Related Mortality in the United States, 1998–2010,* 126 Obstetrics & Gynecology, no. 2, 2015, at 258-265.
[108] *See Id.* at 662.
[109] Stephanie Bornstein, *The Undue Burden: Parental Notification Requirements for Publicly Funded Contraception*, 15 Berkeley Women's L.J. 40, 46 (2000) ("In 1970, the year the statute was passed, approximately 380,000 adolescent girls visited Title X clinics.")
[110] *Heckler* at 562 ("certain population groups requiring these services are not being reached … include[ing] teenagers" (quoting H.R. Rep. No. 1161, 93d Cong., 2d Sess. 14 (1974)).
[111] *See* Bornstein, *supra* note 109, at 47. The current version of 42 U.S.C. § 300(a) specifically mentions adolescents.

the adolescent community was due to the confidential nature of Title X services, and urged HHS not to "overlook" this.[112]

The current Title X regulatory scheme reflects the importance of confidentiality to the success of the program. Section 59.11 of the regulations provides in part: "all information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must 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."[113] Title X project staff is not permitted to notify a parent that a minor has requested or received family planning services, and projects may not require parental consent.[114] These stipulations protect the health needs of adolescents, who otherwise would avoid needed services.[115]

Contrary to Congressional intent in enacting Title X, the proposed regulations stigmatize adolescent sexual activity and will discourage adolescents from seeking Title X services. The first relevant change will require that Title X providers take action encouraging minors to involve their parents in family planning services and document these actions.[116] Providers will also be required to record their reasons for not encouraging family participation, if applicable. This new regulation is intended to enforce Section 300(a) of the Title X statute, which stipulates: "To the extent practical, entities which receive grants or contracts under this subsection shall encourage family participation in projects assisted under this subsection."[117]

The proposed regulations also require that records be kept documenting minors' ages and the ages of their sexual partners.[118] This requirement, which is likely to deter adolescents from seeking Title X services, has no public health purpose and is not narrowly tailored to achieve any particular state goal. Finally, Title X providers will be required to conduct mandatory victimization screenings of any adolescent who is pregnant or has contracted a sexually transmitted infection (STI).[119] Each of these proposed changes raises issues regarding privacy and the First Amendment.

The changes will discourage adolescents from seeking family planning assistance and are likely to result in increased rates of STIs and pregnancy among teenagers. Rates of STIs and pregnancy among U.S. adolescents is already high. The Centers for Disease Control (CDC) estimates that in the U.S., youth aged 15 to 24 account for half of the 20

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[112] *Heckler*, 712 F.2d at 659-660 ("The Committee believes HEW [now HSS] must not overlook the preference of many individuals, particularly the teenage target group, for family planning clinics as the initial entry point to family planning information and services. This preference is due partially to the greater degree of teenage confidence in the confidentiality which can be assured by a family planning clinic..." (quoting the Senate report accompanying the 1977 reauthorization of Title X (S. Rep. No. 102, 95th Cong., 1st Sess. 26 (1977))).

[113] 42 C.F.R. § 59.11.

[114] *OPA Program Policy Notice 2014-01—Confidential Services to Adolescents*, U.S. Department of Health & Human Services (HHS.gov), https://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/program-policy-notices/confidential-services-adolescents.html.

[115] *See generally* Liza Fuentes et al., *Adolescents' and Young Adults' Reports of Barriers to Confidential Health Care and Receipt of Contraceptive Services*, 62 Adolescent Health 36, 38 (Jan. 2018) (demonstrating the confidentiality concerns that adolescents have).

[116] *Proposed Requirements*, *supra* note 11, at 25,525.

[117] 42 U.S.C. § 300(a)

[118] *Proposed Requirements*, *supra* note 11, at 25,532 (proposed amendment to 42 C.F.R. § 59.17).

[119] *Id.*

million new sexually transmitted diseases that occur each year, despite the fact that they make up just over a quarter of the sexually active population.[120] Moreover, the CDC estimates that 1 in 4 sexually active adolescent females has an STI.[121]

While U.S. adolescents continue to have sex at a high rate,[122] societal attitudes towards teenage sexual activity often inhibits them from planning effectively for sexual intercourse. Confidentiality concerns are also a significant reason that adolescents are hesitant to visit facilities offering family planning services and obtain contraceptives or other family planning assistance.[123] Requiring Title X providers to record the age of patients and their sexual partners, and to perform mandatory victimization screenings on minors who are pregnant or have contracted STIs is likely to deter adolescents, who are already nervous to seek family planning care,[124] from seeking assistance. The mandatory screenings are particularly troublesome because they suggest that pregnancy and STIs are usually a result of victimization.

The chilling effect that these requirements will have on adolescent participation in Title X programming is both harmful and costly, as there will likely be a rise in untreated STIs and teenage unintended pregnancies. Delaying treatment of STIs increases the risk of acquiring further infection and can cause serious health problems.[125] Left untreated, chlamydia, a common STI among adolescents (particularly females),[126] can result in pelvic inflammatory disease, infertility, and even fatal ectopic pregnancy.[127] Untreated HIV puts an individual at risk for cancer, including lymphomas, sarcomas, and cervical cancer.[128] Further, adolescents who delay treatment may risk spreading STIs to others. Unintended pregnancies can be harmful to mothers' mental health[129] and are also costly. In 2006, "64% of the 1.6 million births resulting from unintended pregnancies … were

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[120] *Adolescents and Young Adults,* Centers for Disease Control and Prevention, https://www.cdc.gov/std/life-stages-populations/adolescents-youngadults.htm.

[121] *STDs in Adolescents and Young Adults,* Centers for Disease Control and Prevention, https://www.cdc.gov/std/stats14/adol.htm#foot2.

[122] *Adolescent Sexual and Reproductive Health in the United States, supra* note 18 ("In 2011-2013, among unmarried 15-19-year-olds, 44% of females and 49% of males had had sexual intercourse. These levels have remained steady since 2002").

[123] *See generally* Fuentes et al., *supra* note 115.

[124] *Id.* ("When asked if they would ever not go for sexual or reproductive health care because their parents might find out, 18% of 15- to 17-year-olds and 9% of 18- to 25-year-olds said yes").

[125] Angela M. Malek, et al., *Delay in Seeking Care for Sexually Transmitted Diseases in Young Men and Women Attending a Public STD Clinic,* The Open AIDS Journal (2013), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3785038/.

[126] *STDs in Adolescents and Young Adults, supra* note 121 ("For some STDs, such as chlamydia, adolescent females may have increased susceptibility to infection because of increased cervical ectopy. "In 2016, among all individuals aged 15 to 19, there were 1,854.2 to 1,929.2 reported cases of chlamydia per 100,000 population. For women aged 15-19 there were 3,070.0 cases per 100,000).

[127] *Just Diagnosed? Next Steps After Testing Positive for Gonorrhea or Chlamydia,* Centers for Disease Control and Prevention (CDC.gov), https://www.cdc.gov/std/prevention/NextSteps-GonorrheaOrChlamydia.htm.

[128] Edgar P. Simard, et al., *Cumulative Incidence of Cancer among People with AIDS in the United States,* Cancer, 1089, 1089-90 (March 2011) ("Kaposi sarcoma (KS), non-Hodgkin lymphoma (NHL), and cervical cancer are considered AIDS-defining cancers (ADCs)").

[129] *See* Oulman, *supra* note 104, at 1-2 ("Unintended pregnancies are adverse to the health of the mother as they put the mother at risk of developing mental health problems (*i.e.* depression) post partum").

paid for by public insurance programs" and "government expenditures on births resulting from unintended pregnancies nationwide totaled $11.6 billion."[130]

These proposals do not further Congressional intent or serve a public health purpose. The age of an adolescent's sexual partner does not have a bearing on the family planning services she or he needs, and the mandatory screening requirement is unnecessary where Title X grantees are already required to adhere to federal and state notification requirements.[131] These regulations undermine Title X's goal of providing care for adolescents, and are, in fact, likely to result in harm to adolescents, increasing the rate of teenage pregnancies and STIs.

The Proposed Requirements Related to Referral Information Are Burdensome and Will Prevent Women from Receiving Their Full Health Options

Title X family planning services may be offered by the grantee itself or by subrecipients operating under the umbrella of the grantee. Under the current regulatory scheme, grantees are responsible for the "quality, cost, accessibility, acceptability, reporting, and performance" of Title X-funded activities provided by subrecipients.[132]

In its proposed regulations, HHS argues that it does not have a sufficient understanding of the role each subrecipient plays in the current Title X projects because current regulations do not require Title X grantees to submit information related to their subrecipients and other partners. In order to allegedly increase transparency, it proposes changes to the regulations that would require grantees to provide specific and detailed information regarding, and a description of their collaboration with, subrecipients, referral agencies, and other partners in their communities.[133]

The proposed requirement that grantees provide this information, particularly as it pertains to referrals, will be overly burdensome to already underfunded Title X programs. Title X grantees will be responsible for providing oversight and reporting this information as it pertains to the referrals of all of their subrecipients. A single grantee could be responsible for providing oversight for hundreds of agencies.[134] The sheer number of agencies for which a single Title X grantee will be responsible is enough to make these requirements burdensome. Moreover, many referral agencies do not even provide Title X services; they provide ancillary services that the Title X grantees do not necessarily have experience with. Grantees will be put in the impossible position of having to provide oversight and accountability for these ancillary services. The requirements will certainly force Title X grantees to curtail their referrals, and some may have to opt out of the Title X program altogether.

HHS claims that these requirements are necessary to increase transparency. However, HHS fails to address the extent of the burden the requirements will have on grantees or the fact that recipients of comparable federal funding programs do not have

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[130] Adam Sonfield, et al., *The Public Costs of Births Resulting from unintended Pregnancies: National and State-Level Estimates,* Perspectives on Sexual and Reproductive Health 94, 97-98 (2011).

[131] *Four Big Threats to the Title X Family Planning Program: Examining the Administration's New Funding Opportunity Announcement*, Guttmacher Institute (March 2018), https://www.guttmacher.org/article/2018/03/four-big-threats-title-x-family-planning-program-examining-administrations-new.

[132] *Program Requirements*, *supra* note 59, at 11.

[133] *Proposed Requirements*, *supra* note 11, at 25,530.

[134] *See* Fowler, *supra* note 60, at A-2.

these same requirements. The proposed requirements will burden grantee entities with tracking and relaying information on potentially hundreds of subrecipients and their referrals agencies. The proposed addition to Section 59.5 of the regulations (42 C.F.R. § 59.5) would require that grantees provide the following information:

i. Subrecipients and referral agencies and individuals by name, location, expertise and services provided or to be provided;[135]
ii. Detailed description of the extent of the collaboration with subrecipients, referral agencies and individuals, as well as less formal partners within the community;[136] and
iii. Clear explanation of how the grantee will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients and those who serve as referrals for ancillary or core services.[137]

Notably, the proposed regulation requires grantees to provide this information for individuals and agencies with whom they may not have a formal relationship. A subrecipient, according to the proposed regulation is "any entity that provides family planning services with Title X funds under a written agreement with a grantee or another subrecipient."[138] In contrast, a referral agency or individual "is a person or entity which is a specialist in a certain field of service and to whom the Title X project refers patients for additional services not available at the Title X clinic site, or not adequately available at the site, to serve the immediate needs of the patient."[139]

Referral agencies sometimes do not receive Title X funding. According to the proposed regulations, if a woman came into a Title X-funded clinic for contraceptives and also revealed that she was in an unhealthy relationship she wanted to end, a referral could be made to "an entity that has expertise in relationship counseling beyond what is available in this Title X clinic."[140] This relationship counseling agency would be a referral even though it does not receive Title X funding. Therefore, under the proposed regulations, the grantee would be required to collect and report information about its relationship to this agency.

The burden of these proposed requirements will lead many Title X grantees to curtail referrals, and cause some to opt out of the program. In 2016, Title X funds were allocated to 91 grantees in support of 3,898 service sites.[141] These service sites were operated by the grantees' 1,117 subrecipients.[142] In the same year, in Region IX,[143] which includes California, there were 18 grantees, 99 subrecipients, and 469 service sites.[144] Under the proposed regulations, these 18 grantees would be responsible for providing oversight for all of these sites, and all of the sites to which the 99 subrecipients refer

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[135] *Proposed Requirements*, *supra* note 11, at 25,530 (proposed addition to 42 C.F.R. § 59.5(a)(13)(i)).
[136] *Id.* (proposed addition to 42 C.F.R. 59.5(a)(13)(ii)).
[137] *Id.* (proposed addition to 42 C.F.R. 59.5(a)(13)(iii)).
[138] *Id.* at 25,529 (proposed addition to the 42 C.F.R. 59.2 definitions).
[139] *Id.* at 25,514.
[140] *Ibid.*
[141] Fowler, *supra* note 60 at ES-1.
[142] *Id.* at A-2.
[143] Region IX includes Arizona, California, Hawaii, Nevada, American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Republic of the Marshall Islands, and Republic of Palau. *Id.* at 3.
[144] *Id.* at A-2.

patients. Notably, these referral sites do not have formal relationships with the Title X grantees and their subrecipients. They do not receive any money from Title X.

Further, the Department does not address how truly costly the requirements will be. In order to comply, it will not be enough for grantees to simply hire a health manager to "complete reports" as the Department suggests.[145] To provide oversight is more than simple data collection. Further, many of these ancillary services, such as the example of the relationship counseling service, are not part of the Title X program. It will be all the more costly and time consuming because Title X grantees will be required to hire and train staff in non-Title X areas.

These requirements put Title X grantees, and in particular those programs with larger referral networks, in the impossible position of having to provide oversight for programs that provide non-Title X services. Title X programming is already underfunded. Capacity to serve patients has declined since 2010 due to funding decreases, staffing shortages, and increased costs of medical care.[146] These programs cannot afford to take on new staff and expend more resources associated with data collection, training, and oversight. Region IX of the Title X program will be disproportionately impacted. The region is already underfunded: in 2016, Region IX served 28% of all Title X patients, but only received 8% of Title X funding.[147] The burden of this proposal will disparately impact Region IX. Where resources are already stretched thin, the burden may force Title X grantees to close service sites or opt out of the program altogether. At the very least, it will force them to greatly reduce their referral network.

The result of these overly burdensome requirements will be reduced access for low-income women to family planning services. The regulations themselves recognize the importance of comprehensive care and require Title X service providers to make referrals: "In order to promote holistic health and provide seamless care, Title X service providers should offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site."[148] Yet, these burdensome requirements will undoubtedly prevent these agencies from providing access to comprehensive care.

These proposed regulations overburden family planning clinics with reporting requirements compared to the reporting requirements of other government-funded health clinics. Federally Qualified Health Centers (Centers) that receive government funding through the HRSA (Health Resources and Services Administration) Health Center Program, do not have the same reporting requirements proposed for Title X programs. FQHCs provide primary care services, including mental health and oral health, in underserved areas.[149] Some also receive Title X funding and provide family planning

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[145] *Proposed Requirements*, *supra* note 11, at 25,528 ("The labor cost would also include a medical and health services manager spending an average of four hours each year to complete reports regarding information related to subrecipients, and referral agencies and individuals involved in the grantee's Title X project at each grantee and subrecipient. The labor cost will be $243,000 each year ($52.58 per hour x 4 x 1,208 grantees and subrecipients)").

[146] Angela Napili, *Family Planning Program Under Title X of the Public Health Service Act* at 3 (April 2018), available at https://fas.org/sgp/crs/misc/R45181.pdf.

[147] Fowler, *supra* note 60, at 2, 59.

[148] *Proposed Requirements*, *supra* note 11 at 25,530 (proposed addition to 42 C.F.R. § 59.5(a)(12)).

[149] HRSA: Health Center Program, *Eligibility*, May 2018, available at https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc/index.html.

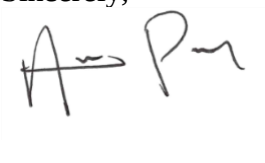
services.[150] These Centers receive government funding and, with HRSA approval, can also allocate this funding to subrecipients through formal agreements.[151]

Notably, while Centers are required to monitor the ongoing activities of subrecipients and retain records pertaining to formal referrals, they are not required to provide oversight or documentation on informal referrals. The program distinguishes between informal referrals and written formal referrals, with many more reporting requirements regarding formal referrals.[152] Information from an informal referral visit should only be provided back to the Center for the patient's record and for follow-up care. The "referral and the service and any follow-up care provided by the [informal referral], are considered outside of the health center's scope of project."[153] This differs from the proposed Title X requirements, where grantees are required to provide oversight over referrals with whom they have no formal relationship.

Therefore, we oppose the proposed reporting regulation because providers will be unfairly and unjustifiably burdened if they have to submit detailed and unnecessary information about agencies they work with or refer patients to, leading to less available service providers for low-income women in California.

For all these reasons, the California Women's Law Center respectfully requests that HHS withdraw the proposed regulations from consideration.

Sincerely,



Senior Staff Attorney
California Women's Law Center

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[150] Kinsey Hasstedt, *Federally Qualified Health Centers: Vital Sources of Care, No Substitute for the Family Planning Safety Net*, Guttmacher Institute, May 17, 2017, available at https://www.guttmacher.org/gpr/2017/05/federally-qualified-health-centers-vital-sources-care-no-substitute-family-planning.

[151] HRSA: Health Center Program, *Glossary,* available at https://www.bphc.hrsa.gov/programrequirements/compliancemanual/glossary.html#subrecipient (definition of "Pass-Through Entity" and "Subrecipient).

[152] HRSA: Health Center Program, *Service Delivery Methods,* available at https://bphc.hrsa.gov/programrequirements/scope/form5acolumndescriptors.pdf.

[153] *Id.*