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July 30, 2018

Via Federal eRulemaking Portal
Secretary Alex M. Azar II
Assistant Secretary ADM Brett P. Giroir, M.D.
Deputy Assistant Secretary Diane Foley, M.D., FAAP
Office of the Assistant Secretary for Health
Office of Population Affairs
Attention: Family Planning
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 716G
200 Independence Avenue SW
Washington, DC 20201

RE: Comments on Proposed Rule: Compliance With Statutory Program Integrity, 83 Fed. Reg. 25502 (June 1, 2018), RIN 0937-ZA00

Dear Secretary Azar, Assistant Secretary Giroir & Deputy Assistant Secretary Foley:

We, the Attorneys General of California, Connecticut, Delaware, Hawai'i, Illinois, Iowa, Maine, Maryland, Minnesota, New Jersey, New Mexico, North Carolina, and the District of Columbia write today to urge the U.S. Department of Health and Human Services (HHS) to withdraw the Proposed Rule: *Compliance With Statutory Program Integrity*, 83 Fed. Reg. 25502 (June 1, 2018), RIN 0937-ZA00 (Proposed Rule). The regulation severely undermines the Title X family planning program, restricting access to affordable, life-saving reproductive healthcare. In our States alone, this Proposed Rule will impact over 1.6 million patients.

Title X has successfully provided critical care in our States for decades. As State Attorneys General, we have a duty to protect our residents, safeguard their health and safety, and defend state laws. If implemented, this Proposed Rule will have significant negative impacts on states; their residents, including women, LGBTQ individuals, and other marginalized

populations; doctors and other women's healthcare providers; and numerous entities in the states that receive federal healthcare funding.

Title X is the only national family planning program that serves low-income women and families and otherwise underserved communities. Title X provides patients with basic primary and preventive healthcare services, including well-woman exams, lifesaving cervical and breast cancer screenings, birth control, contraception education, and testing and treatment for sexually transmitted infections (STIs), including HIV. Our States collectively and uniquely are served by this program:

- California benefits from the largest Title X program in the nation, which funds providers throughout the State to support the delivery of quality preventive and reproductive healthcare. California's Title X family planning program collectively serves more than one million patients annually—over 25% of all Title X patients nationwide—through 59 healthcare organizations, operating nearly 350 health centers in 37 of California's 58 counties.

- In Connecticut, Title X clinics served over 43,000 individuals at 17 different sites in 2017. About 85% of all those served had incomes below 250% of the federal poverty level.

- In Delaware, the Delaware Health and Social Services is the Title X grantee. In 2017, the US Department of Health and Human Services' Office of Population Affairs (OPA) granted $1,135,000 to Delaware. In 2017, Delaware's 55 Title X clinics served 19,132 patients.

- In the District of Columbia, Title X funding supports access to high-quality family planning and sexual health care at 35 service sites across the District. Nine of the service sites are Federally Qualified Health Centers, and the remaining 26 service sites throughout the District include school-based health centers and mobile clinics for individuals experiencing homelessness. Title X funding enabled these service sites to serve more than 51,000 individuals in Fiscal Year 2016.

- In Hawai‘i, the Hawai‘i State Department of Health and Planned Parenthood of the Great Northwest and the Hawaiian Islands are the Title X grantees. In 2017, the OPA granted $2,987,300 to support 37 service sites across the island state. In 2016, Title X served 13,335 patients.

- In Illinois, Title X clinics served over 110,000 individuals in 2016. As of April 2018, more than 98 facilities receive Title X funding in Illinois. Illinois's Department of Public Health Family Planning Program is a Title X grantee and

funds more than 65 clinic sites that include health departments, hospital-based clinics, single service not-for-profit agencies, federally qualified health centers, and community-based organizations.

- In Iowa, Family Planning Council of Iowa and the Iowa Department of Public Health are the Title X grantees. In 2017, the OPA provided $4,077,000 to support access to high-quality family planning and sexual health care at 40 service sites across the state. In 2016, Iowa's Title X clinics served 37,607 patients.

- In Maine, Maine Family Planning is the sole Title X grantee. In 2017, it received $1,965,000 from the OPA to support access to high-quality family planning and sexual healthcare at 42 service sites across the state. In 2016, Title X served 21,911 patients in Maine.

- In Maryland, the Title X Family Planning Program serves approximately 71,000 Maryland women at more than 75 clinical sites. Maryland's Department of Health is a Title X grantee. Title X grantees in Maryland include local health departments, community health centers, Planned Parenthood clinics, and other providers.

- In Minnesota, Planned Parenthood Minnesota, North Dakota, South Dakota and St. Paul-Ramsey County Department of Public Health are the Title X grantees. In 2017, the OPA provided $3,187,000 to support access to high-quality family planning and sexual health care at 38 service sites across the state. In 2016, Title X clinics served 56,400 patients.

- New Jersey has 9 Title X sub-grantees, which operate a total of 48 clinics. New Jersey has six counties with only 1 Title X provider site: Atlantic, Burlington, Cape May, Hunterdon, Salem, and Sussex. Of those, the single county site provides abortion outside of the Title X program in 4 counties: Atlantic, Burlington, Hunterdon, and Sussex. If that one single site closed, all 4 counties would be without a Title X provider. In 2017, 72% of Title X-eligible women who received Title X services at providers in New Jersey received those services at clinics that provide abortions outside the Title X program (64,890 women out of 89,845 women). In 2017, the Title X program in New Jersey prevented 13,190 unplanned pregnancies, 6,210 unplanned births, and 4,460 abortions.

- In New Mexico, the New Mexico Department of Health is the Title X grantee. In 2017, the OPA provided $3,325,000 to support 67 service sites across the state. In 2016, Title X served 17,252 patients in New Mexico.

- In North Carolina, in 2015, there were 120 Title X-funded sites. Collectively, these Title X-funded sites delivered contraceptive care to 111,010 women in North Carolina. If all Title X funds were redirected only to federally qualified health center sites, those sites would have to increase their contraceptive client caseloads by a factor of five or more to maintain the current range of service provided by Title X.

The Proposed Rule seeks to create barriers to access to women's healthcare, including abortion. Among other things, it requires a physical and financial separation between any Title X program and any facility that provides abortion: the provider must have at a minimum separate examination and waiting rooms, office entrances and exits, phone numbers, email addresses, educational services, websites, personnel, electronic or paper-based health care records, and workstations. Providers will effectively have to open a second clinic in order to continue to provide abortions and continue to obtain Title X funding. It also undermines the standard of care by allowing Title X providers to refuse to provide medically-approved contraceptive methods, in favor of less effective methods such as abstinence only. Importantly, it eliminates nondirective options counseling and instead steers all pregnant women to be referred for prenatal care and social services, regardless of a patient's choice. It undermines the provider-patient relationship trust, instead allowing the federal government to interfere in longstanding practices aimed to advance confidence and trust. It also gags healthcare providers. The Proposed Regulation takes several steps to create barriers to women seeking abortion and the healthcare providers that provide them care, from prohibiting activities like advocacy related to abortion, making abortion counseling impossible, and gagging doctors from discussing healthcare options, including abortion, with patients.

Alarmingly, this Proposed Rule, if finalized, will force Title X recipients into an untenable position of deciding whether to accept program funds with mandates that restrict access to care and force a gag on clinics, or forfeit Title X funding altogether, leaving gaps in access to family planning care that the Title X program was first established to fill. The former scenario will result in the invasion of the physician-patient relationship, the trampling of the constitutional rights of patients and providers, the transmission of incomplete, misleading, and medically dangerous information to women, and the frustration of the right to make an informed, independent decision as to whether to terminate a pregnancy. The latter scenario will reduce funding available to crucial family planning providers, thereby reducing critical healthcare services available to vulnerable populations. Either decision will lead to serious public health threats, increased risk of unintended pregnancies, and gaps in care. Our States will be left to pick up the pieces. Thus, we urge that the Proposed Rule be withdrawn immediately.

HHS Secretary Azar appears to largely agree with our position that ensuring patient access to accurate information is of vital public interest. He recently stated that HHS was "[e]nding gag clauses" "to bring more transparency" to healthcare and to ensure that patients obtain necessary healthcare information. Consequently, he proposed eliminating the current gag

order on pharmacists that prevents them from educating patients about drug pricing.[1] To act to the contrary with respect to reproductive health would seem arbitrary. Like Secretary Azar, we agree that HHS should end gag clauses to ensure that patients have all necessary healthcare information to make an informed decision and to ensure transparency and honesty in the provider-patient relationship.

I. The Proposed Rule's Mandates Will Harm the States' Residents

The Proposed Rule imposes a gag on healthcare providers. It expressly prohibits a healthcare provider from providing a patient with full information, to make an informed decision, regarding her healthcare decisions. *See, e.g.*, 83 Fed. Reg. at 25531. Specifically, the Proposed Rule prohibits a Title X clinic, including all of its healthcare providers and staff, from referring, supporting, or promoting abortion even with separate, non-Title X funds unless there is both financial *and* physical separation. This gag further prohibits the healthcare provider from providing a patient with nondirective options counseling and mandates that healthcare providers give a pregnant woman a misleading referral list that does not clearly identify abortion providers.

This gag will have far-reaching consequences. It will create a barrier to the provider-patient relationship, as women will not be able to make an informed decision about their healthcare condition and options. In healthcare, information can "save lives," *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 566 (2011), permit "alleviation of physical pain," *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 763-64 (1976), and enable people to act in "'their own best interest,'" *Sorell*, 564 U.S. at 578 (quoting *Va. State Bd. of Pharmacy*, 425 U.S. at 770). Such medical information allows women to take control of their most "intimate and personal choices . . . central to personal dignity and autonomy." *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 851 (1992) (plurality op.). In the context of women's health decisions, and in particular with respect to a woman's decision about whether to carry to full term or terminate a pregnancy, obtaining complete and honest healthcare information is critical *and* time-sensitive.

a. HHS's Proposed Rule Interferes with the Provider-Patient Relationship

The provider-patient relationship inherently requires complete confidence and trust. The American Medical Association's (AMA) Counsel on Ethical and Judicial Affairs has stated that "[t]he relationship between a patient and a physician is based on trust, which gives rise to

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[1] *See* HHS: Remarks on Drug Pricing Blueprint, *available* at https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html (May 14, 2018) (visited June 12, 2018); *See also* 83 Fed. Reg. at 22695, 22699 (May 16, 2018) (discussing eliminating gag clauses to ensure that patients receive full information from their healthcare providers to make informed decisions).

physicians' ethical responsibility to place patients' welfare above the physician's . . . obligations to others."[2] The AMA's Code of Medical Ethics further states that, "[t]ruthful and open communication between physician and patient is essential for trust in the relationship and for respect for autonomy. Withholding pertinent medical information from patients . . . creates a conflict between the physician's obligations to promote patient welfare and to respect patient autonomy."[3] Indeed, "withholding information without the patient's knowledge or consent is *ethically unacceptable*."[4] This honesty is crucial because the role of a physician is not only to treat a patient's medical condition and ailments, but also to educate patients so that they can be proactive in their healthcare decisions.[5] The Proposed Rule requires physicians to disregard their Code of Medical Ethics and to tailor their speech to not provide full and accurate healthcare information. As a consequence, patients will not know whether their doctors are speaking frankly and candidly, and the quality of medical care may erode, with potentially dire consequences, such as patients forgoing care altogether. These government-imposed barriers to the physician-patient relationship interfere with the provision of medical care and will impede public health.

These same concerns extend to nurses, physician assistants, and nurses' aides. For instance, the American Nurses Association Code of Ethics states that, "[t]he nurses's primary commitment is to the patient, whether an individual, family, group, community, or population."[6] The patient-provider relationship remains the foundational responsibility of healthcare. This

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[2] Code of Medical Ethics, Current Opinions (2017); Opinion 1.1.1-Patient-Physician Relationships, available at https://goo.gl/qKXwA6.

[3] Opinion 2.1.3-Withholding Information from Patients, available at https://goo.gl/q1bpt8.

[4] Opinion 2.1.3-Withholding Information from Patients, available at https://goo.gl/q1bpt8 (emphasis added).

[5] *See* HHS: Remarks on Drug Pricing Blueprint, available at https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html (May 14, 2018) (visited June 12, 2018); *See also* 83 Fed. Reg. at 22695, 22699 (May 16, 2018) (discussing eliminating gag clauses to ensure that patients receive full information from their healthcare providers to make informed decisions).

[6] American Nurses Association, Code of Ethics for Nurses (2015); *id*. ("[t]he nurse practices with compassion and respect for the inherent dignity, worth, and unique attributes of every person."); *See also, e.g.*, Cal. Code Regs. tit. 16, § 1443.5 (outlining the standards of competent performance for nurses as including "[a]ct[ing] as the client's advocate . . . by giving the client the opportunity to make informed decisions about health care before it is provided" and "[f]ormulat[ing] a care plan, in collaboration with the client").

Proposed Rule undermines that responsibility by inhibiting all healthcare providers from providing comprehensive medical information to patients.

b. The Proposed Rule Presents Women Seeking or Considering an Abortion with Illusory Healthcare Options

The Proposed Rule provides that a "referral" for an abortion may only occur when a woman "clearly states that she has already decided to have an abortion." There are no exceptions. Even when a woman makes such a "clear" statement to her healthcare provider in order to obtain care guidance, the provider is prohibited from arranging for her appointment (83 Fed. Reg. at 25532) or providing her with a specific list of healthcare entities that perform abortions (83 Fed. Reg. at 25531-25532). Instead, the healthcare provider may only provide a referral list of "comprehensive health services providers (*some* of which also provide abortion in addition to comprehensive prenatal care)." 83 Fed. Reg. at 25531 (emphasis added). This proviso has several flaws that make it a barrier to care and forces the woman to navigate the misleading, incomplete, and unreliable information regarding her "options" alone.

1. Doesn't Meet the Federal Quality Family Planning Guidelines on Referrals. The Proposed Rule is contradictory to the Centers for Disease Control and Prevention's (CDC) Quality Family Planning Guidelines—the quality standard of recommendations for providers on what to offer during a family planning visit and how to provide such services.[7] Among other things, the Guidelines provide that pregnancy testing and counseling services are a "core part of family planning services, in accordance with recommendations of major professional medical organizations, such as the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP)."[8] To that end, the CDC specifically instructs that after a Title X provider administers a pregnancy test, the "test results should be presented to the client, followed by a discussion of **options and appropriate referrals**." *Id*. at 14 (emphasis added). The CDC Guidelines continue that "[r]eferral to appropriate providers of follow-up care should be made at the request of the client, as needed," and "[e]very effort should be made to expedite and follow through on all referrals." *Id*. In terms of providing a referral list, the CDC Guidelines instruct that Title X providers "provide a resource listing or directory of providers to help the client identify options for [pregnancy] care." *Id*. This instruction is not limited to only those women who choose to continue with their pregnancy. *Id*. Rather, the CDC instruction is

[7] HHS continues to refer Title X providers to the Quality Family Planning Guidelines. *See* HHS Office of Population Affairs, https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html (last visited June 19, 2018).

[8] Providing Quality Family Planning Services, Recommendations of CDC and the U.S. Office of Population Affairs, Centers for Disease Control and Prevention, at 14 (Apr. 25, 2014), https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf.

broad and instructs that providers give referrals, "at the request of the client," including for termination of pregnancy.

2. Limits Which Healthcare Providers Can Be on "Referral List." The Proposed Rule inexplicably mandates that the referral list only contain abortion providers that also provide "comprehensive prenatal care." 83 Fed. Reg. at 25531. This means that a stand-alone healthcare provider who provides abortions and other healthcare services, but not "comprehensive prenatal care" would be ineligible to be placed on the referral list. HHS fails to provide any justification for this additional requirement. This is likely to leave out many qualified abortion providers, providing women with even less information and fewer choices.

3. Compels Medical Providers to Give Incomplete Healthcare Information. The Proposed Rule not only mandates that Title X doctors give a misleading referral list, but it does not permit the doctor to inform the patient—who has requested a referral for an abortion—that the referral list includes healthcare facilities that do not provide abortions. Thus, in some circumstances, the patient will not even know that her healthcare provider—whom she has turned to for honest healthcare information—has knowingly provided her with an intentionally deceptive referral list. Because the patient has been given a misleading list, and because her physician is prohibited from providing her the necessary referral, she will be forced to investigate on her own, without her physician's guidance, which providers in the referral list provide the necessary and time-sensitive medical care she requires. This inserts a cruel and useless obstacle that is specifically targeted to women who have sought medical advice for the purpose terminating a pregnancy.

4. Limits Who Can Provide "Referral List," Excluding Advanced Practice Providers. Without any justification, this limited permission to provide a referral list, if asked, is only available to "doctors." 83 Fed. Reg. at 25531 (providing that "a *doctor*, may, if asked, provide" a referral list to a pregnant woman). In practice, this doctor-only limitation unnecessarily restricts who may provide this information. Counselling regarding medical options can be, and is, safely and effectively provided by clinicians with a variety of credentials, with no evidence of complications. Thus, the doctor-only requirement means that several qualified, licensed medical providers could not provide a referral list. In practice, if an Advanced Practice Provider is present in a medical clinic, but a doctor is not, the patient would not be able to receive any referral list.

5. Directs Counseling Against Abortion. This misleading referral list mandated by the Proposed Rule runs contrary to Congress's express instruction—an instruction that HHS relies upon (83 Fed. Reg. at 25502)—that Title X providers give "nondirective" counseling.[9] The current Title X regulation requires nondirective counseling to offer "pregnant women the

[9] *See* Omnibus Consolidated Rescissions and Appropriations Act, 1996, Public Law 104-134, Title II, 110 Stat. 1321, 1321-221 (1996).

opportunity to be provided information and counseling regarding…prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination." 42 C.F.R. § 59.5(a)(5)(i). The current regulation further requires that such information and counseling "provide neutral, factual information and nondirective options counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling." 42 C.F.R. § 59.5(a)(5)(ii). The Proposed Rule deletes all references to nondirective options counseling. It instead mandates that Title X healthcare providers give a woman who has "clearly state[d]" that she wants an abortion a referral list with both abortion providers and non-abortion providers, forcing her to call each entity. By doing so, the Title X provider has given her "directive" counseling, steering her away from abortion despite her stated decision. Indeed, in contrast to the limited exception for a woman who has "clearly state[d]" that she intends to terminate her pregnancy, the regulation mandates that Title X clinics give "assistance with setting up a referral appointment" for prenatal care for *all* women who have been "medically verified as pregnant," including those who express a desire to terminate. 83 Fed. Reg. at 25531. Thus, when a woman comes to a Title X clinic and learns that she is pregnant, the clinic is mandated to steer a woman towards a prenatal care appointment, *even if* the woman "clearly state[d]" her intention to terminate her pregnancy. This is "directive" counselling. It gags a healthcare provider from informing a woman as to all of her healthcare options and instead directs her towards a single option: prenatal care. It pushes women away from pregnancy termination in favor of carrying a pregnancy to full-term. Under the regime of this Proposed Rule, if a woman in fact exercises her constitutional right to safe, legal abortion, the Title X clinic is forced to abandon her, providing zero guidance or worse, misdirecting her away from her decision to terminate a pregnancy.

6. Does Not Require that Providers on Referral List Be Publicly Funded or Accessible to Low-Income Patients. Last, there is no requirement that the providers on the referral list be publicly-funded or make available no- or low-cost healthcare, or even identify such providers. Title X clinics serve low-income patients that are underinsured or uninsured. Providing a referral list to patients without designating which options will provide no- or low-cost healthcare services will result in women paying an exorbitant amount of out-of-pocket fees, wasting precious time trying to find a provider to perform the time-sensitive service at no- or low-cost, or having to forego the healthcare services altogether.[10] This is in direct conflict with

[10] In 2011-2012, the median cost of an abortion was $495. The Cost of Abortion, When Providers Offer Services and Harassment of Abortion Providers All Remained Stable Between 2008 and 2012, Guttmacher Institute (July 2, 2014), available at https://www.guttmacher.org/news-release/2014/cost-abortion-when-providers-offer-services-and-harassment-abortion-providers-all.

the Title X statute, which directs program funds for "services to persons from low-income families."[11]

c. The Proposed Rule Creates Barriers for Young People to Obtain Care

The Proposed Rule imposes several new—yet ironically antiquated—requirements on providing care to minors. The Proposed Rule mandates that Title X clinics conduct a "screening" of any adolescent who has an STD or is pregnant. 83 Fed. Reg. at 25533. It further mandates that Title X clinics "[e]ncourage family participation in the decision of minors to seek family planning services and ensure that the record maintained with respect to each minor document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged)." 83 Fed. Reg. at 25530. The Proposed Rule will cause confusion for providers about their obligations, is not in line with the CDC Quality Guidelines, and runs afoul of the Title X regulation which requires a patient-centered approach in providing services in a manner that protects patient dignity and ensures patient choices are entirely voluntary. 42 C.F.R. § 59.5. It also conflicts with state and local regulations that allow minors to consent to confidential health services for the prevention, diagnosis, or treatment of pregnancy, its lawful termination, or sexually transmitted diseases. *See, e.g.*, D.C. Mun. Reg. 22-B600.7. These new requirements impede the ability of providers to care for their patients and would have a deleterious effect on public health in states as young people forgo care to avoid the pressure of refusing requests to involve unwanted family involvement in decisionmaking.

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II. If Implemented, the Proposed Rule Would Decrease Access to Care Throughout the Country

The Proposed Rule puts current Title X clinics in an untenable predicament: either give up their crucial Title X funds or incur devastating costs by complying with the physical separation mandate, violating their ethical obligations by imposing gags on all their doctors, nurses, and staff, and surrendering their constitutional First Amendment rights to associate with other entities and organizations that provide or advocate for abortion. Given the Proposed Rule's unnecessary and dangerous mandates, several Title X clinics will likely forgo Title X funding or will apply, but will be denied. The consequences will be devastating to the providers and patients alike.

For providers, Title X is "literally keeping the lights on" at several clinics in rural parts of the country. For example, without Title X funds, "six or seven health centers, including four rural sites" will close in Wisconsin "within three to six months, as they already operate at a loss and cannot be sustained with Medicaid and private reimbursement alone." Decl. Atkinson (ECF

[11] 42 U.S.C. § 300, Section 1006 (c)(1).

No. 18-1) at ¶ 48, *Planned Parenthood of Wisconsin, et al. v. Azar*, No. 18-cv-01035-TNM (05/08/2018). In addition, "two or three additional sites throughout Milwaukee" will close. *Id.* If these health centers close, employees will be laid off. *Id*. at ¶ 49. This will also have a devastating impact in our States. For example, numerous clinics in California will be forced to decide whether to embrace the Proposed Rule's mandates and requirements that are contrary to the most effective family planning practices, diverting resources from their core mission of patient care, or face major losses of funding that will dramatically impair their ability to provide family planning services. Connecticut's Title X providers will face the same decision for their 17 sites. In the District of Columbia, 36 healthcare facilities and clinics will have to decide whether to accept the unconstitutional conditions on Title X funding, or lose a major source of funding that helps prevent thousands of unintended pregnancies and helps educate tens of thousands of people about their reproductive health. In North Carolina, more than 110 healthcare providers will have to make a substantially similar choice. Furthermore, other Title X clinics will also have to shut their doors to patients as a result of the Proposed Rule's gag or colocation of services ban.

For patients, without clinics providing life-saving care, many will go without needed medical services. As HHS's 2016 Title X Family Planning Annual Report notes, "[f]or many clients, Title X providers are their only ongoing source of health care and health education."[12] For example, 47% of Title X patients go to a Title X clinic for general health information and 49% of patients go to a Title X clinic for a physical exam.[13]

a. The Proposed Rule Will Have a Disparate Impact on Low-Income Families, Women, Women of Color, and Rural Communities

1. Disparate Impact on Women and Low-Income Families. Title X clinics are crucial for low-income families and women. They provide no-cost family planning services to people with very low incomes, and services on a sliding fee scale for others. For example, in California, 91% of Title X patients had incomes at or below 250% of the federal poverty level, and nearly

[12] Title X Family Planning Annual Report: 2016 National Summary, HHS-Office of Population Affairs, at 1 (Aug. 2017), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf (citing Jennifer J. Frost, U.S. Women's Use of Sexual and Reproductive Health Services: Trends, Sources of Care and Factors Associated with Use, 1995-2010, New York: Guttmacher Institute (May 2013) https://www.guttmacher.org/report/us-womens-use-sexual-and-reproductive-health-services-trends-sources-care-and-factors).

[13] Oglesby, Willie, Perceptions of and preferences for Federally-Funded Family Planning Clinics, Reprod. Health (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4086278/pdf/1742-4755-11-50.pdf.

60% were uninsured in 2016.[14] Title X clinics act as a "one stop shop" where a patient can seamlessly see medical providers, get screened and tested as necessary for disease, and access any needed prescription or medical supplies, without having to travel offsite to a pharmacy, additional medical facility, or lab testing facility. Women comprise 89% (3.6 million out of 4 million) of Title X family planning users.[15] A U.S. woman spends more than 30 years trying to avoid becoming pregnant, but still, approximately "2.8 million women have an unintended pregnancy" each year with approximately 42% resulting in abortions.[16] Because the Proposed Rule will effectively force some Title X clinics to shut down, and deprive others of crucial resources, the consequences will be disproportionately felt by low-income families and women. A recent report from the United Nations highlighted that placing barriers for low-income women to access healthcare "traps many women in cycles of poverty."[17] This Proposed Rule accentuates this consequence as it will decimate our nation's family planning network, which is why it is opposed by a majority of Americans.[18]

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[14] Similarly, in Vermont, 47% of patients had incomes at or below 100% of the federal poverty level, while 77% of patients had incomes at or below 250% of the federal poverty level. In Connecticut, 37% of patients had incomes at or below 100% of the federal poverty level, 28% more are below 150% of the federal poverty level, 13% more had incomes below 200% of the federal poverty level, and 7% more had incomes below 250% of the federal poverty level. In the District of Columbia, 60% of Title X patients had incomes 100% of the federal poverty level, while 85% of patients had incomes at or below 250% of the federal poverty level. In North Carolina, 66% of patients had incomes at or below 100% of the poverty line and 87% of patients earned less than 250% of the federal poverty line.

[15] Title X Family Planning Annual Report: 2016 National Summary, HHS-Office of Population Affairs, at 9 (Aug. 2017), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf.

[16] Susan Moskosky, U.S. Department of Health and Human Services, Office of Population Affairs, Public Health Reports (2016), http://journals.sagepub.com/doi/full/10.1177/0033354916662638.

[17] Report of the Special Rapporteur on Extreme Poverty and Human Rights on his Mission to the United States of America, United Nations General Assembly, at 15 (May 4, 2018), https://documents-dds-ny.un.org/doc/UNDOC/GEN/G18/125/30/PDF/G1812530.pdf.

[18] Ashley Kirzinger, et al., Further Findings from Kaiser's June Health Tracking Poll: Women's Issues, Kaiser Family Foundation, at 14 (June 29, 2018), http://files.kff.org/attachment/Topline-Kaiser-Health-Tracking-Poll–June-2018-9212. The same poll also found that eight in 10 (80%) of the public say federal funding for family planning and other reproductive health services to low-income women is "very important" or "somewhat important" to them, including most Republicans and the overwhelming majority (94%) of women 18-44. *Id.* And, one-third of

2. Disparate Impact on Communities of Color. This Proposed Rule also fails to account for the harm that will come to the disproportionately high number of minority patients who rely on these Title X clinics as their primary source of healthcare. Nationwide, 21% of Title X patients self-identify as black or African-American and 32% as Hispanic or Latino/a.[19] For women of color, access to these services is crucial. Women of color already face disparities in healthcare. For example, black women with cervical cancer—a disease that can easily be prevented or cured—have lower survival rates than white women, due to later diagnosis and treatment differences, owing to a lack of health insurance and regular access to healthcare.[20] The United States also has the highest rate of maternal mortality among wealthy countries and black women are three to four times more likely to die during childbirth than white women.[21] HHS's mandates will only further harm minority communities by reducing access to essential health care.

3. Disparate Impact on Rural, Non-Urban Communities. Title X family planning clinics are especially critical in rural areas, where reproductive health access is often limited by healthcare provider shortages, lack of transportation, and other factors. In seven rural California counties, a Title X clinic is the only publicly funded clinic offering a full range of contraceptive methods. Likewise, in New Jersey, eight of its Title X clinics are sole providers in rural areas.

In the event that clinics decide to comply with the Proposed Rule's unlawful and harmful mandates, including the gag rule, the impacted patients who will receive partial, misleading information are from the same disadvantaged communities: women and low-income families, communities of color, and rural, non-urban communities. The Proposed Rule's mandate of

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women of reproductive age, who are more likely to have direct experience, say it is "too difficult" to access reproductive healthcare services. *Id.*

[19] *See* Title X Family Planning Annual Report: 2016 National Summary, HHS-Office of Population Affairs, at 12 (Aug. 2017), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf. These statistics are consistent with States' Title X patient populations. For example, in the District of Columbia, more than 60% of Title X patients identified as black or African-American and 32% identified as Hispanic or Latino/a.

[20] Wonsuk Yoo, et al., "Recent trends in racial and regional disparities in cervical cancer incidence and mortality in United States", *PLOS ONE*, vol. 12, No. 2 (Feb. 2017).

[21] *Focus on Infants During Childbirth Leaves U.S. Moms in Danger*, NPR (May 12, 2017), https://www.npr.org/2017/05/12/527806002/focus-on-infants-during-childbirth-leaves-u-s-moms-in-danger; *Black Mothers Keep Dying After Giving Birth*, NPR, https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irvings-story-explains-why; Pregnancy Mortality Surveillance System, CDC, https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pmss.html.

providing slanted and misleading information will undermine rather than promote a woman's right and ability to make an informed reproductive healthcare decision, and that impact will be felt by these patient populations.

b. Current Title X Clinics Cannot Be Replaced

Title X clinics that will be forced to shut their doors due to this Proposed Rule cannot easily be replaced. A recent report by the Guttmacher Institute concluded that although federally qualified health centers are vital sources for healthcare, they cannot fill the shoes of safety-net Title X clinics.[22] Specifically, the report found that Title X family planning sites, like Planned Parenthood locations, each serve 2,950 contraceptive patients per year, whereas federally qualified health centers (community health centers) serve only 320 contraceptive patients per year. If Title X's mandates take effect and force safety net clinics like Planned Parenthood to close, community health centers would be severely impacted. *Id.* In 27 states, they would have to double their caseloads and in nine states, they would have to triple them. *Id.* Even if current community health centers could handle the massive influx of new patients, there would still be huge gaps in service. For example, 13% of the 415 U.S. counties with Planned Parenthood health centers, do not have a community health center site that provides contraceptive care. In addition, while there are over 2,000 U.S. counties with Title X sites, in 33% of these counties no community health centers provide contraceptive services, meaning that women in these areas could simply lose access to this coverage. This will impact will be felt most acutely by poor women, rural communities, and communities of color that rely on these services. In many instances, the women, men, and adolescents served by the program will have no alternative source of care. In many cases, women will go without preventive care such as family planning care or sexually transmitted infection screenings, leading to increased unintended pregnancies as well as increased risks for public health outbreaks of diseases. Further, if women are not able to get their full range of care through Title X-funded clinics, they are more likely to seek care at other state-funded providers that are not gagged and will provide them with complete and truthful medical information, increasing the burden on state resources. However, because many state programs will be unable to fill this gap, inevitably, fewer women will receive family planning services, and as a result, unintended pregnancies will increase and government costs for medical treatment and social services will rise.

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

c. The Loss of Title X Funding and Closure of Clinics Will Harm the States' Public Health and Public Fisc

The availability of publicly funded family planning services will be sacrificed as a result of this Proposed Rule. Title X clinics play an indispensable role in improving a State's public health and ensuring access to care for the State's most vulnerable residents. States know from experience that restricting access to reproductive healthcare also burdens the public at large. For instance, Title X clinics play a major role in preventive healthcare, such as providing screenings and early treatment to prevent the spread of communicable, preventable diseases. Indeed, between 2006 and 2010, 18% of all women who were tested, treated, or received counseling for an STD did so at a Title X clinic, as did 14% of women tested for HIV and 10% of those receiving a Pap test or pelvic exam.[23]

During public health crises, such as the Zika outbreak, Title X providers play an important role in providing contraceptive methods to prevent the transmission of the disease and collaborating with the CDC.[24] The Proposed Rule could not come at a worse time: the CDC recently reported that in 2016, there were more than 2 million cases of chlamydia, gonorrhea, and syphilis reported—the highest number of reported cases ever.[25] The states and their residents need reliable and comprehensive Title X programs now more than ever to help address this public health crisis.

Finally, Title X providers and the comprehensive care they provide have a huge fiscal impact on the states. In helping women avoid unplanned pregnancies and investing in early detection and treatment of disease, Title X providers play a role in protecting the public fisc. For example, the United States has the highest maternal mortality rate in the developed world—17 to 28 per 100,000 live births—which is more than double the rate three decades ago. In the District of Columbia, the rate is 39 women per 100,000 live births—the highest in the Nation. For black

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[23] Kinsey Hasstedt, *Title X: An Essential Investment, Now More than Ever*, 16 GUTTMACHER POLICY REVIEW 14, 15 (Summer 2013), https://www.guttmacher.org/sites/default/files/article_files/gpr160314.pdf.

[24] Ctrs. for Disease Control & Prevention, *The Importance of Pregnancy Planning in Areas with Active Zika Transmission*, (June 2, 2016), at 23, https://www.cdc.gov/zika/pdfs/postzap-familyplanning.pdf; *see also* Office of Population Affairs, U.S. Health & Human Servs. Dep't: Providing Family Planning Care for Non-Pregnant Women and Men of Reproductive Age in the Context of Zika (Nov. 2016), https://www.hhs.gov/opa/reproductive-health/zika/toolkit/index.html (providing a toolkit, based on CDC guidance, for Title X clinics).

[25] STDs at Record High, Indicating Urgent Need for Prevention, Centers for Disease Control and Prevent (Sep. 26, 2017), https://www.cdc.gov/media/releases/2017/p0926-std-prevention.html.

women, this rate is three times that of white women.[26] The Proposed Rule will result in less access to critical preventive care, leading to increased unintended pregnancies, and in some cases, lead women to providers that are not medical providers, delaying access to prenatal care and increased maternal mortality outcomes. Yet the Proposed Rule makes no exceptions when necessary to protect the life of the mother. In addition, the loss of Title X funding will result in increased costs to states due to unintended pregnancies. Nationally, 68% of unplanned births are paid for with public funds. The average cost of an unintended pregnancy is $15,364 and of a miscarriage is $4,249. Further, many states will see increased usage of state-funded family planning and public health programs, which will face increased patient load and financial burdens if patients are not able to seek care at their trusted provider under Title X.

III. The Proposed Rule Is Not Supported by Evidence

HHS's gag rule and additional mandates in the Proposed Rule are arbitrary and capricious. Although HHS may change its policies within limits set by the Title X statute, the agency must "provide a reasoned explanation for the change." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). Here, the Proposed Rule fails to provide the necessary "satisfactory explanation" for its proposed changes to the Title X regulations. *See Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

The Proposed Rule rejects scientific, evidence-based policies, favoring unscientific ideologies. The Proposed Rule is opposed by all leading healthcare experts, including the American Medical Association, the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Nurse-Midwives, the American College of Physicians, the Association for Physician Assistance in Obstetrics and Gynecology, the National Association of Nurse Practitioners in Women's Health, Nurses for Sexual and Reproductive Health, and the Society for Adolescent Health and Medicine. Women and children's health providers warn that the Proposed Rule puts "more than 40 percent of Title X patients [] at risk of losing access to critical primary and preventive care services."[27] Moreover, "[r]estricting access to care and information will increase rates of unplanned pregnancy, pregnancy complications, and undiagnosed medical conditions," reversing decades of progress that have brought our nation to a 30-year low for unplanned pregnancy and teen pregnancy. *Id*.

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[26] https://www.nejm.org/doi/full/10.1056/NEJMp1709473.

[27] America's Women's Health Providers Oppose Efforts to Exclude Qualified Providers from Federally-Funded Programs (May 23, 2018), available at https://www.acog.org/About-ACOG/News-Room/Statements/2018/Health-Providers-Oppose-Efforts-to-Exclude-Qualified-Providers-from-Federally-Funded-Programs.

The Proposed Regulation alters and eliminates longstanding standards for reproductive healthcare without evidentiary support. These changes are not rooted in law or based on medical-evidence and drastically undermine the Title X program and access to care:

1. **Disregards Medically-Approved Definition**: The Proposed Rule eliminates the requirement that a Title X family planning project offer "medically approved" family planning methods. 83 Fed. Reg. at 25515; 83 Fed. Reg. at 25530. Rather than deferring to the federal agency charged with determining what is medically appropriate (the Food and Drug Administration (FDA)), HHS instead opens the door to non-experts to decide what is acceptable and effective reproductive healthcare. This new position is entirely unsupported by evidence, and is inconsistent with the position that HHS has taken in several other healthcare areas. For instance, HHS's Health Resources and Services Administration (HRSA) commissioned the Institute of Medicine (IOM) to study what should be considered women's preventive services and to make evidence-based recommendations. 42 U.S.C. § 300gg-13(a)(4).[28] The IOM responded by assembling a panel of independent experts to survey the relevant literature and peer reviewed research, and produced a report that ultimately recommended that preventive services for women include all FDA-approved "contraceptive methods, sterilization procedures, and patient education and counseling." IOM, Clinical Prevention Services for Women: Closing the Gaps 110 (2011) (IOM Report).[29] HRSA adopted the IOM Report's recommendation, and the three federal agencies responsible for implementing the Affordable Care Act (ACA) (Treasury, HHS, and Labor) promulgated regulations that gave them legal effect. *See* 76 Fed. Reg. 46,621 (Aug. 3, 2011); 77 Fed. Reg. 8,725 (Feb. 15, 2012). Although the Proposed Rule acknowledges its own FDA as the entity with "regulatory jurisdiction over drugs, biologics, and medical devices," including contraceptives, it disregards the FDA's role in setting standards for reproductive healthcare because the FDA does not recognize "non-drug and non-device fertility awareness-based methods of family planning" such as the rhythm method or abstinence only. Thus, the Proposed Rule changes the definition of "medically approved," despite FDA's guidance and expertise. HHS's new position that it need not defer to experts, including its own regulators such as the FDA or HRSA, is entirely inconsistent with HHS's prior position, and HHS provides no reasonable explanation for disregarding medical science when it comes to

[28] "The IOM is an arm of the National Academy of Sciences, an organization Congress established 'for the explicit purpose of furnishing advice to the Government.'" *Hobby Lobby*, 134 S. at, 2789 n.3 (Ginsburg, J., dissenting).

[29] *available at* https://www.nap.edu/read/13181/chapter/1.

reproductive health. It is also inconsistent with Secretary Azar's own public statements emphasizing the important of "evidence-based guidance on public health issues."[30]

2. **Undermines Family Planning to Allow Abstinence Only and Non-Approved Methods**: The Proposed Rule seeks to change the definition of "family planning" to "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." 83 Fed. Reg. at 25529. Such "means" include "choosing not to have sex" and "natural family planning." *Id*. This definition conflicts with the CDC's own definition of family planning services as well as the World Health Organization and United Nation's definitions.[31] The Proposed Rule concedes that its definition does not meet these other longstanding definitions, but gives little by way of justification or support for the change. 83 Fed. Reg. at 25513 n.44.

3. **Provides Women Refused Birth Control Under the ACA an Illusory and Inadequate Accommodation**: The Proposed Rule changes the definition of "low income family" to include "women who are unable to obtain certain family planning services under their employer-sponsored health insurance policies due to their employer's religious beliefs or moral convictions." 83 Fed. Reg. at 25514. This change is premised on the Administration's Interim Final Regulations, "Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act" [32] and "Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act"[33] (Birth Control Refusal Regulations), both of which are currently enjoined by two U.S. District Courts.[34] But, the Proposed Rule provides women and families with an illusory option. First, because the Title X family planning program is a discretionary government program funded by Congress, there is no guarantee the annually appropriated Title X funding will cover this

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[30] *See* https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/hhs-secretary-alex-azar-world-health-assembly-plenary-remarks.html.

[31] *See* World Health Organization: Family planning/contraception, available at http://www.who.int/news-room/fact-sheets/detail/family-planning-contraception; United Nations: Guidelines on Reproductive Health, available at http://www.un.org/popin/unfpa/taskforce/guide/iatfreph.gdl.html.

[32] *See* 82 Fed. Reg. 47838 (Oct. 13, 2017).

[33] *See* 82 Fed. Reg. 47792 (Oct. 13, 2017).

[34] *Pennsylvania v. Trump*, 281 F. Supp. 3d 553 (E.D. Pa. 2017); *California v. Health & Human Services*, 281 F. Supp. 3d 806 (N.D. Cal. 2017).

> potentially massive increase in patients who will need contraceptives. Second, the Proposed Rule requires Title X providers to provide women—but not their families—with care. This is problematic because the Administration's harmful Birth Control Refusal Regulations affect not just the employed woman, but her covered dependents and family, as well. But, even modifying the Proposed Rule to encompass the impacted women and their families will result in an untenable situation because Title X providers are already at capacity with their ability to serve low-income patients, and this definition change does not come with increased annual funding (while simultaneously leaving the program with fewer providers as a result of the gag). Third, because this Proposed Rule and the accompanying Title X Funding Opportunity Announcement favor entities that do not provide comprehensive family planning, including all 18-FDA approved methods of contraceptives, the Rule is directing women who are harmed by the Administration's Birth Control Refusal Regulations to healthcare providers that cannot provide them with the Affordable Care Act required coverage, creating further barriers to care for these women. Finally, this aspect of the Proposed Rule is clearly contrary to law, as defining "low income family" to include people who are not necessarily "low income," and based on characteristics independent of their income, is nowhere contemplated, or permitted, by the statute.

These definitional changes, in addition to the numerous other changes outlined *infra*, do not result from any new developments in the healthcare field, nor are they supported by any new report. In contrast to the Reagan-Era regulatory changes, no congressional reports support these new changes. Indeed, the Proposed Rule relies largely on a 1988 rule and its subsequent litigation history. As HHS acknowledges, however, the 1988 rule was preceded by a 1982 report by HHS's Office of Inspector General (OIG) finding instances of non-compliance with existing rules. 83 Fed. Reg. at 25503. There is no such report here. In fact, several audits of Title X providers have been conducted by several different HHS agencies (and other federal agencies) and *none* have concluded that there is malfeasance or non-compliance by Title X providers in terms of federal dollars being used for abortion. The Proposed Rule cites a handful of examples, but those examples rely exclusively on *Medicaid* overbilling. As such, the "evidence" upon which the Proposed Rule relies utterly fails to actually justify the new mandates on Title X grantees. Furthermore, the Proposed Rule relies primarily on evidence from an anti-abortion group, the Lozier Institute, as a reason for the Proposed Rule, in place of an actual government Report or neutral scientific or medical evidence.

The Proposed Rule also ignores the numerous safeguards already in place to monitor Title X funds and activities. For example, HHS carefully reviews grant applications to ensure applicants have the capacity to comply with requirements, including the financial separation requirement; there are independent financial audits to analyze and account for program funded activities and prohibited activities, yearly comprehensive reviews of grantees financial status and budget reports, and periodic and comprehensive program reviews and site visits by Office of

Population Affairs regional offices. These oversight and monitoring measures ensure that there is no misuse of Title X funds. HHS provides no evidence otherwise.

IV. The Proposed Rule is Unconstitutional

The Proposed Rule is itself unconstitutional and undermines constitutional rights in several ways. The gag rule prevents healthcare providers from giving patients comprehensive information regarding medical options. The Proposed Rule requires dissemination of information about prenatal services and even requires Title X providers to arrange for a prenatal follow-up visit, but censors speech about the option of legally terminating a pregnancy. Thus, on its face, the Proposed Rule is a content-based restriction on speech related to a controversial topic of public importance. It also prohibits Title X grantees from using other funds to pay dues to any organization that advocates on behalf of abortion rights unless the dues are paid by an entity that is both financially *and* physically separate from the Title X project. 83 Fed. Reg. at 25519, 25532. Because it is viewpoint motivated, it is the purest example of a law abridging the freedom of speech.[35]

The Proposed Rule also violates a woman's constitutional right to procreative choice. American women possess a constitutional right to be free of impermissible government interference when they seek to make choices about their own bodies. This applies when they seek reproductive healthcare services, including healthcare information, contraceptives, and/or referrals for abortion.[36] This also applies to adolescents of child-bearing age.[37] The Proposed Rule

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[35] *See FCC v. League of Women Voters of Cal.*, 468 U.S. 364, 383-384 (1984) ("A regulation of speech that is motivated by nothing more than a desire to curtail expression of a particular point of view on controversial issues of general interest is the purest example of a law abridging the free of speech."); *NIFLA v. Becerra*, No. 16-1140, Slip Op. at 6-7 (2018) (reiterating the "fundamental principle that governments have 'no power to restrict expression because of its message, its ideas, its subject matter, or its content'").

[36] *See, e.g. Akron v. Akron Center for Reproductive Health, Inc.*, 462 U.S. 416 (1983) (invalidating city ordinance requiring all physicians to make specific statement to the patient prior to performing abortion); *Thornburgh v. American College of Obstetricians and Gynecologists*, 476 U.S. 747 (1986) (invalidating a governmental intrusion into the patient-doctor dialogue where statute mandated that a list of agencies offering alternative to abortion be provided to every woman).

[37] Twenty-six states and the District of Columbia allow minors to consent to contraceptive services, and all states and the District of Columbia permit minors to consent to services for sexually transmitted infections. *See* Guttmacher Inst., *An Overview of Minors' Consent Law*, https://www.guttmacher.org/state-policy/explore/overview-minors-consent-law.

impermissibly interferes with a woman's ability to choose abortion, in violation of the federal constitution.

The Proposed Rule forces Title X healthcare providers and family planning clinics to abandon their constitutional rights in order to obtain federal funding. Such a regulation squarely violates the unconstitutional conditions doctrine.[38] The doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Id*. Here, the regulation impermissibly and unlawfully penalizes those who choose to exercise a constitutionally-protected right by denying them benefits. Both the Title X healthcare physician and the Title X facility must abandon their speech as it relates to providing full and complete medical care and information to women patients to obtain federal benefits, and the entity must abandon its membership in outside organizations unless the Title X grantee is both financially and physically separate. In contrast to the Reagan-era regulation, this regulation is not limited to the Title X project—to which the Title X funding is attached—but extends to the personnel and staff at the Title X project and the activities and statements they make outside of the Title X project.

V. HHS Has Not Conducted an Adequate Analysis of Federalism Impacts

As the Proposed Rule acknowledges, Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on state and local governments or has federalism implications. 83 Fed. Reg. at 25521-25523. HHS concludes that the Proposed Rule "does not contain policies that have federalism implications, as defined in Executive Order 13132 and, consequently, a federalism summary impact statement is not required." *Id*. This conclusion is erroneous.

The Proposed Rule, if implemented, will impose substantial costs on state and local governments. As a threshold matter, several states and local entities are either direct Title X grantees or are sub-recipients that will be affected by the rule.[39] Indeed, HHS recognized this fact in its 2016 Regulation, when it included a federalism impact statement and invited states not

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[38] *See Koontz v. St. Johns River Water Mgmt. Dist.*, 133 S. Ct. 2586, 2594 (2013) (government ordinarily "may not deny a benefit to a person because he exercises a constitutional right" (quoting *Regan v. Taxation with Representation of Wash.*, 461 U.S. 540, 545 (1983)).

[39] *See, e.g.* HHS Title X Planning Directory (April 2018), https://www.hhs.gov/opa/sites/default/files/OPA_Title_X_Family_Planning_Directory_April2018_508.pdf (Title X directory including several state and local government entities).

only to comment but to "consult with them" in promulgating the final rule. 81 Fed. Reg. 61646 (Sep. 7, 2016).[40] There is no justification for this deviation in HHS's practice.

Notably, states engage in several federal partnerships, which are not subject to as broad restrictions as this Proposed Rule. For instance, the Temporary Assistance to Needy Families Block Grant Program (Title IV), the Maternal and Child Health Services Block Grant Program (Title V), and the Social Services Block Grant Program (Title XX) permit states to administer these grants in a manner that reflect state policy, provided that the implementation is congruent with federal requirements. Nothing in the statutes and implementing regulations for these other programs prohibits State partners from directing grants to particular providers to maximize the effective delivery of preventive healthcare services.[41] In fact, the comment letter from the "chief legal officers and/or governors from nine States," relied upon by HHS in its Proposed Rule, made this same argument with respect to the 2016 Regulation. 83 Fed. Reg. at 25504. And, HHS in this 2018 Proposed Rule, citing that comment letter, laments that the 2016 Regulation would have "denied States and other grantees the freedom to choose subrecipients as they saw fit." 83 Fed. Reg. at 25504. Yet, this Proposed Rule does exactly that. It prevents states and other grantees from freely selecting subrecipients—as has been done since the Title X program came into existence. We are extremely concerned about the overreach reflected in this Proposed Rule and the clear intent to override state laws and policy choices that are legal, supported by Congress, and overwhelmingly supported by the citizens of the states in which such legislative priorities are in place.

VI. HHS's Economic Impact Analysis is Wholly Inadequate

Executive Orders 12866 and 13562 require agencies to "assess all costs and benefits of available regulatory alternatives and, if regulation is necessary to select regulatory approaches that maximize net benefits." 83 Fed. Reg. at 25521. Executive Order 12866 requires that a "significant regulatory action" comply with additional regulatory requirements. This Proposed Rule meets all the definitions of a "significant regulatory action" because it will (1) have an annual effect on the economy of $100 million or more and will also "adversely and materially affect" a sector of the economy and public health; (2) create a serious inconsistency and interfere with an action taken or planned by another agency; (3) materially alter budgetary impacts of

[40] We note that California attempted to schedule a meeting with the Office of Management and Budget, writing a letter on May 29, 2018, but never received a response and the agency never scheduled a meeting.

[41] *See* generally 42 U.S.C. §§ 401, 403, 404 (purpose of and limitations on TANF grants); 42 U.S.C. § 704 (purpose of and limitation on Maternal and Child Health service grants); and 42 U.S.C. §§ 1397, 1397d (purpose of and limitations of Social Services grant).

entitlement grants or the right and obligations of recipients thereof; and (4) raise novel legal or policy issues arising out of legal mandates.

While the Proposed Rule outlines the "Benefits and Protections" to providers and patients, it totally neglects an economic analysis of the burdens and harms to patients and providers. This one-sided economic analysis entirely ignores the steep costs to the patients trying to obtain healthcare and to the providers trying to comply with the new mandates. For patients, if a woman obtains a "referral list" from her Title X provider, she must then call each provider on the list to determine whether the provider actually provides abortion and at what cost, then make an appointment and then once again seek out necessary medical care, taking time off work or school, and finding childcare. Many women will be unable to weave their way through this intricate set of government barriers to obtain lawful healthcare, resulting in an unintended birth, which of course carries severe physical, emotional, and financial consequences for the patient. For providers, the Proposed Rule fails to account for the cost of complying with the physical separation requirement, and ensuring compliance by sub-grantees, while ensuring providers can exercise their First Amendment right to provide patients with complete medical information. To comply with the separation requirement, the provider must have at a minimum separate examination and waiting rooms, office entrances and exits, phone numbers, email addresses, educational services, websites, separate personnel, electronic or paper-based health care records, and workstations. The Proposed Rule claims that abiding with the physical separation requirements will only cost $10,000-$30,000; however, such an assertion is wholly unsupported. Many providers will effectively have to open a second clinic for every site to obtain Title X funding. Many Title X grantees, including federally qualified health centers, will not be able to separate both financially and physically their Title X projects from the "prohibited activities," including membership in advocacy organizations. Additionally, to comply with the new mandate that Title X providers maintain records to demonstrate compliance with the new requirements for minor patients, Title X clinics will need to make massive changes to their electronic health records. Conservative estimates provide that this will cost $10,000 for development and installation, depending on the number of sites across which the updates needs to be installed and the extent of the changes, and this amount does not include staff time to implement changes.[42]

Additionally, the Proposed Rule does not provide an economic analysis for its proposed definition change to "low income family" to include any woman, regardless of income, who is unable to receive contraceptive coverage as a result of the Administration's Birth Control Refusal Regulations. This will inevitably increase costs for Title X providers as they shoulder

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[42] Robin Summers, *Analysis of 2018 Proposed Title X Regulation*, Nat'l Family Planning & Reproductive Health Ass'n, at 18 n. 69 (July 5, 2018), available at https://www.nationalfamilyplanning.org/file/documents---policy--communication-tools/NFPRHA-Title-X-NPRM-Analysis-FINAL.pdf.

the patients that should be receiving seamless coverage through their employer-sponsored health insurance. The burden on these patients is also unaccounted for.

We have significant concerns with this regulation, its impact in our States, and consequence to our States' residents constitutionally protected rights, and for the reasons set forth above, the States strongly oppose the Proposed Rule and urge that it be withdrawn.

Sincerely,

Xavier Becerra
California Attorney General

George Jepsen
Connecticut Attorney General

Matthew P. Denn
Delaware Attorney General

Karl A. Racine
Attorney General for the District of Columbia

Russell A. Suzuki
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Lisa Madigan
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