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

July 31, 2018

VIA ELECTRONIC SUBMISSION

Re: Comments on Notice of Proposed Rule on Compliance With Statutory Program Integrity Requirements [Docket No.: HHS–OS–2018–0008]

We are writing to express our deep concern with and full opposition to the Notice of Proposed Rulemaking ("the proposed rule" or "the NPRM") on Compliance With Statutory Program Integrity Requirements, published by the Department of Health and Human Services ("HHS" or "the Department") on June 1, 2018. HHS's proposed rule aims to limit access to reproductive health care services under the pretext of clarifying the law. The NPRM proposes a number of unnecessary and harmful restrictions on Title X funding, and it marks yet another instance in which the administration disavows medically-proven methods and services. We strongly urge HHS to withdraw this NPRM in its entirety.

As more fully described below, HHS should withdraw the NPRM in its entirety because the proposed rule would:

- Harm women's health, in particular that of low-income women and women of color, by devastating the Title X provider network;
- Reshape the program to reduce the quality of health care for the low-income patients it serves;
- Violate the Administrative Procedure Act; and
- Violate the Constitution.

Since 1992, the Center for Reproductive Rights has used the power of law to advance reproductive rights as fundamental human rights worldwide. Our litigation and advocacy over the past 26 years have expanded access to reproductive health care around the nation and the world. We have played a key role in securing legal victories in the United States, Latin America, Sub-Saharan Africa, Asia, and Eastern Europe on issues including access to life-saving obstetrics care, contraception, safe abortion services, and comprehensive sexuality information. We envision a world where every person participates with dignity as an equal member of society, regardless of gender; where every woman is free to decide whether or when to have children and whether or when to get married; where access to quality reproductive health care is guaranteed; and where every woman can make these decisions free from coercion or discrimination.

I. Title X provides critical reproductive health services to millions of individuals in underserved communities across the country

Access to family planning is central to women's health and equality. Because of birth control, women can protect their health, meet their educational and employment goals, and support their families. The ability to plan and space pregnancies also plays an important role in improving maternal health and birth outcomes, and helps women prevent unintended pregnancies that can result in higher-risk pregnancies. Avoiding closely spaced pregnancies reduces the risk of premature birth and low birth weight,[1] and preventing unintended pregnancy can help women manage certain health conditions, such as diabetes, hypertension, and heart disease.[2] Title X plays a key role in providing these critical family planning services to individuals across the country.

Enacted in 1970 under President Richard Nixon, Title X is the only federal program solely dedicated to providing family planning services in the United States and has enjoyed broad bipartisan support for decades.[3] At the core of Title X's mission is the expansion of access to reproductive health care services to low-income women and men, including communities of color, immigrants, and rural residents who may otherwise lack access to health care with family planning services and related preventive care.[4] The Title X program serves more than four million low-income, uninsured, and underserved clients.[5]

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[1] Sohni V. Dean et al., *Born Toon Soon: Care before and between pregnancy to prevent preterm births: from evidence to action*, 10 REPROD. HEALTH S3 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3828587/.

[2] *See, e.g.*, Anjel Vahratian et al., *Family-Planning Practices Among Women With Diabetes and Overweight and Obese Women in the 2002 National Survey for Family Growth*, 32(6) DIABETES CARE, 1026-31 (June 2009) ("Effective family planning, used in conjunction with glucose management for women with diabetes[. . .] may reduce the risk to the mother and fetus associated with diabetes and obesity"); American College of Obstetricians and Gynecologists, Task Force on Hypertension in Pregnancy, *Hypertension in Pregnancy* (2013), https://www.acog.org/Clinical-Guidance-and-Publications/Task-Force-and-Work-Group-Reports/Hypertension-in-Pregnancy ("Hypertensive disorders of pregnancy remain a major health issue for women and their infants in the United States. Preeclampsia, either alone or superimposed on preexisting (chronic) hypertension, presents the major risk."); Adult Congenital Heart Association, *Pregnancy in Women with Congenital Heart Disease*, https://www.achaheart.org/your-heart/health-information/pregnancy-and-chd/ ("Most women with congenital heart disease (CHD) can have a successful pregnancy. Doing so requires careful planning and management.").

[3] C.I. Fowler et al., *Family Planning Annual Report: 2016 national summary*, RTI INTERNATIONAL (Aug. 2017), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf. [Hereinafter *2016 Family Planning Annual Report*].

[4] *Id.*; *See also* National Family Planning & Reproductive Health Association, *Title X: Helping Ensure Access to High-Quality Care, Policy Brief* (Mar. 2015), https://www.nationalfamilyplanning.org/document.doc?id=514.

[5] Laurie Sobel et al., *Proposed Changes to Title X: Implications for Women and Family Planning Providers*, HENRY J. KAISER FAMILY FOUNDATION (June 28, 2018), https://www.kff.org/womens-health-policy/issue-brief/proposed-changes-to-title-x-implications-for-women-and-family-planning-providers/.

Notably, six in ten women receiving Title X services reported that a Title X-funded health center was their usual source of medical care,[6] and four in ten reported it was their only source of care.[7] For many, Title X-funded health centers provide a critical entry point—at times the only entry point—into the health care system.

Publicly funded family planning clinics are critically important resources for the twenty-four percent of U.S. residents living in rural areas—including nineteen million women.[8] Rural areas are already experiencing a significant shortage of reproductive health providers.[9] A further reduction in the number of reproductive health providers in their area would place rural women at increased risk of unwanted pregnancy, morbidity from later abortions, and obstetric complications.[10]

Title X clinics are a critical source of care for low-income communities of color.[11] Decades of racism, sexism and other social and economic barriers have contributed to stark health disparities for women of color, who are more than half of the patients in the Title X program. Black women use contraception at lower rates and have higher breast cancer mortality rates than women of

[6] Megan L. Kavanaugh et al., *Use of Health Insurance Among Clients Seeking Contraceptive Services at Title X–Funded Facilities in 2016*, 50 PERSPECTIVES ON SEXUAL AND REPRODUCTIVE HEALTH (2018), https://onlinelibrary.wiley.com/doi/epdf/10.1363/psrh.12061.

[7] *Id*.

[8] Sharon A. Dobie et al., *Family Planning Service Provision in Rural Areas: A Survey in Washington State*, FAMILY PLANNING PERSPECTIVES (June 1998), https://pdfs.semanticscholar.org/09af/d6874486e371e214d3adb67df9fc438356eb.pdf; *see* U.S. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Bureau *Women's Health USA 2013* (2013), https://mchb.hrsa.gov/whusa13/population-characteristics/p/rural-urban-women.html; *see generally* U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, *Telehealth: Mapping the Evidence for Patient Outcomes from Systematic Reviews, Technical Brief No. 26* (June 2016), https://mchb.hrsa.gov/whusa13/population-characteristics/p/rural-urban-women.html.

[9] Annalisa Merelli, *America is running out of OB/GYNs*, QUARTZ (June 29, 2018), https://qz.com/1315458/the-link-between-medicaid-and-americas-shortage-of-ob-gyns/; Kevin J. Bennett et al., *Rural Women's Health*, NATIONAL RURAL HEALTH ASSOCIATION (Jan. 2013), https://www.ruralhealthweb.org/getattachment/Advocate/Policy-Documents/RuralWomensHealth-(1).pdf.aspx.

[10] Sharon A. Dobie et al., *Family Planning Service Provision in Rural Areas: A Survey in Washington State*, FAMILY PLANNING PERSPECTIVES (June 1998), https://pdfs.semanticscholar.org/09af/d6874486e371e214d3adb67df9fc438356eb.pdf.

[11] Sixty-four percent of Title X patients have incomes at or below the federal poverty level, earning less than $11,880 in 2016. Title X patients are disproportionately Black and Hispanic or Latino. Twenty-one percent of Title X patients self-identify as Black and thirty-two percent as Hispanic or Latino, as compared twelve and eighteen percent of the nation, respectively. *See, e.g.*, National Family Planning & Reproductive Health Association, *Title X: An Introduction to the Nation's Family Planning Program*, *Policy Brief* (Nov. 2017), https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf; C.I. Fowler et al., *Family Planning Annual Report: 2016 National Summary*, RTI INTERNATIONAL (Aug. 2017), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf.

other racial and ethnic backgrounds.[12] Latinas experience cervical cancer at twice the rate of white women and also have higher rates of sexually transmitted infections.[13] Latina youth experience pregnancies at about twice the rate of their white counterparts.[14] Asian American and Pacific Islander women use highly effective contraceptive methods at lower rates than women of other races and instead rely on inexpensive, less effective methods.[15] Without access to Title X services, existing health disparities would worsen.

Title X clinics are also an important source of care for LGBTQ people, who are disproportionately represented in the number of Americans living in poverty and homelessness. Family planning services are vital for this community because lesbian, gay, and bisexual youth experience more pregnancies than do youth who do not identify as a sexual minority.[16] Moreover, clinics in the Title X program, especially Planned Parenthood clinics, provide a trusted source of confidential, compassionate, non-judgmental health care for young people and LGBTQ individuals, who may not be able to find such care elsewhere in their area.

The Title X program is known for its high-quality and effective family planning services.[17] In fact, research shows that compared with non-Title X-funded health care providers, many Title X grantees provide higher quality, more timely care to a greater number of women.[18]

During a visit to a Title X site, patients may also receive comprehensive sexual and reproductive health services, including preconception health care, STI testing and treatment, vaccines to prevent human papillomavirus, and Pap tests for early detection of cervical cancer. In 2015, Title

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[12] Jo Jones, Mosher Williams, and Kimberly Daniels, *Current Contraceptive Use in the United States, 2006-2010, and Changes in Patterns of Use Since 1995*, 60 NATIONAL HEALTH STATISTICS REPORTS (Oct. 18, 2012), http://www.cdc.gov/nchs/data/nhsr/nhsr060.pdf.

[13] Jacqueline Corcoran et al., *Cervical Cancer Screening Interventions for US Latinas: A Systematic Review*, 37 HEALTH AND SOCIAL WORK 197-205 (2012); Centers for Disease Control and Prevention, *Health Disparities in HIV/AIDS, Viral Hepatitis, STDs, and TB, Hispanics/Latinos* (Feb. 1, 2017), https://www.cdc.gov/nchhstp/healthdisparities/hispanics.html.

[14] Centers for Disease Control and Prevention, *Reproductive Health: Teen Pregnancy, Social Determinants and Eliminating Disparities in Teen Pregnancy*, https://www.cdc.gov/teenpregnancy/about/social-determinants-disparities-teen-pregnancy.htm.

[15] Kimberly Daniels et al., *Contraceptive Methods Women Have Ever Used: United States, 1982-2010*, 62 NATIONAL HEALTH STATISTIC REPORT 1-15 (Feb. 14, 2013).

[16] Lisa L. Lindley & Katrina M. Walsemann, *Sexual Orientation and Risk of Pregnancy Among New York City High-School Students*, 105 AM. J. OF PUBLIC HEALTH 1379–86 (July 1, 2015); Karen Schantz, *Pregnancy Risk Among Bisexual, Lesbian, and Gay Youth: What Does Research Tell Us*, ACT FOR YOUTH CENTER OF EXCELLENCE (Apr. 2015), http://www.actforyouth.net/resources/rf/rf_lgb-prg_0415.pdf.

[17] Kinsey Hasstedt, *Why We Cannot Afford to Undercut the Title X National Family Planning Program*, 20 GUTTMACHER POLICY REVIEW 20 (2017), https://www.guttmacher.org/gpr/2017/01/why-we-cannot-afford-undercut-title-x-national-family-planning-program; National Family Planning & Reproductive Health Association, *Key Facts About Title X*, https://www.nationalfamilyplanning.org/title-x_title-x-key-facts.

[18] Kinsey Hasstedt, *Understanding Planned Parenthood's Critical Role in the Nation's Family Planning Safety Net*, 20 GUTTMACHER POLICY REVIEW 12 (2017), https://www.guttmacher.org/gpr/2017/01/understanding-planned-parenthoods-critical-role-nations-family-planning-safety-net.

X provided family planning services that helped women avert 822,300 unintended pregnancies.[19] In 2016, health centers used Title X funding to provide 700,000 Pap tests, more than four million STD tests, and breast exams for nearly one million women.[20] Title X grantees also provide screenings for high blood pressure and diabetes—services that can be critically important in detecting high-risk pregnancies and improving maternal and infant health outcomes.[21]

For nearly half a century, the services provided by Title X grantees have substantially improved the health and well-being of underserved populations across the country. The proposed rule would undo that progress and must be withdrawn in its entirety.

II. The proposed rule would harm women's health, in particular low-income women and women of color, by devastating the Title X provider network

a. The proposed rule would devastate the Title X network by effectively defunding many experienced and qualified Title X providers and encouraging underqualified entities to apply to the program

The NPRM proposes a myriad of funding conditions and restrictions on Title X grantees, including a prohibition on referring for abortion, a *de facto* prohibition on abortion counseling, a physical and financial separation requirement that would likely require providers to erect entirely separate facilities and staff for Title X services and abortion care, and strict limitations on the use of Title X funds.

The Title X program provides an irreplaceable source of funding that allows many independent clinics to pay for critical infrastructure costs other funding sources will not cover. The proposed rule's revised requirements would force many long-time, experienced Title X providers to leave the program.

Defunding health care providers who perform or refer for abortion, such as Planned Parenthood, would have grave implications for low-income individuals across the country. Planned Parenthood is an irreplaceable provider of Title X services. While Planned Parenthood health centers make up just thirteen percent of Title X centers, they serve forty-one percent of all Title X patients.[22] In effect, the proposed rule could prevent up to 1.6 million women who obtain contraceptive care from Title X-funded Planned Parenthood sites each year from seeing their

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[19] Jennifer J. Frost et al., *Publicly Funded Contraceptive Services at U.S. Clinics, 2015*, GUTTMACHER INSTITUTE (Apr. 2017), https://www.guttmacher.org/report/publicly-funded-contraceptive-services-us-clinics-2015 ("The U.S. unintended pregnancy rate would have been 31% higher without the services provided by Title X-funded clinics.").

[20] Planned Parenthood Action Fund, *Title X: The Nation's Program for Affordable Birth Control and Reproductive Health Care*, https://www.plannedparenthoodaction.org/issues/health-care-equity/title-x.

[21] Kinsey Hasstedt, *Why We Cannot Afford to Undercut the Title X National Family Planning Program*, 20 GUTTMACHER POLICY REVIEW 20-21 (2017), https://www.guttmacher.org/gpr/2017/01/why-we-cannot-afford-undercut-title-x-national-family-planning-program.

[22] Planned Parenthood Action Fund, *Title X: The Nation's Program for Affordable Birth Control and Reproductive Health Care*, https://www.plannedparenthoodaction.org/issues/health-care-equity/title-x.

trusted provider, and in many cases, the only source of care they receive.[23] In order to provide contraceptive coverage to the women who currently obtain care at Title X-supported Planned Parenthood health centers, other Title X providers would be required to increase their patient caseloads, on average, by seventy percent.[24]

Federally Qualified Health Centers (FQHCs), which would need to take up the bulk of new patients, do not have the capacity to serve the patients who would be displaced by this rule. To maintain Title X's current capacity would require FQHCs to double their contraceptive client caseloads in forty-one states, and triple them in twenty-seven states.[25] And, although some FQHCs provide contraception, they do not specialize in reproductive health care. In thirty-three percent of the counties served by Title X providers, FQHCs do not provide any contraceptive services. Instead, FQHC's provide patients with a broad range of services, including vaccinations, dental, vision, and mental health services. In 2015, only sixty percent of FQHCs reported providing contraceptive services to ten or more women.[26]

In addition, the proposed rule radically revises Title X funding criteria in a way that would encourage underqualified providers to flood the program. Crisis pregnancy centers, or "fake women's health centers," pose as full-service women's health clinics, but specifically target pregnant women who are considering abortion to dissuade or outright prevent them from obtaining abortion care.[27] Fake women's health centers, which often do not have qualified medical providers on staff and refuse to provide or refer for appropriate medical services, would dilute the quality of the Title X network. Fake women's health centers are known to provide false and misleading information about abortion and contraception, including the false claims that there is a link between abortion and breast cancer, that abortion causes future infertility, and that abortion increases suicide risks.[28] Some fake women's health centers have falsely claimed

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[23] Kinsey Hasstedt, *Trump Administration Looks to Impose "Domestic Gag Rule," Continuing Its Assault on Reproductive Health and Rights*, GUTTMACHER INSTITUTE (June 20, 2018), https://www.guttmacher.org/article/2018/06/trump-administration-looks-impose-domestic-gag-rule-continuing-its-assault.

[24] Kinsey Hasstedt, *Beyond the Rhetoric: The Real-World Impact of Attacks on Planned Parenthood and Title X*, 20 GUTTMACHER POLICY REVIEW 86, 89 (2017), https://www.guttmacher.org/gpr/2017/08/beyond-rhetoric-real-world-impact-attacks-planned-parenthood-and-title-x.

[25] Kinsey Hasstedt, *Federally Qualified Health Centers: Vital Sources of Care, No Substitute for the Family Planning Safety Net*, 20 GUTTMACHER POLICY REVIEW 67, 70 (2017), https://www.guttmacher.org/gpr/2017/05/federally-qualified-health-centers-vital-sources-care-no-substitute-family-planning ("Nationwide, this would add up to an additional 3.1 million clients.").

[26] *Id.* at 68.

[27] *See, e.g.*, *Reproductive FACT Act: Hearing on AB 775 Before the Assemb. Comm. On Health*, 2015-16 Leg. 3 (Cal. 2015); Brief for 51 Reproductive Rights, Civil Rights, and Social Justice Organizations as Amici Curiae Supporting Respondents at 9, NIFLA v. Becerra, 138 S. Ct. 2361 (2018).

[28] Amy G. Bryant & Jonas J. Swartz, *Why Crisis Pregnancy Centers are Legal but Unethical*, 20 AMA J. ETHICS 269 (2018); Jennifer Ludden, *States Fund Pregnancy Centers that Discourage Abortion*, NPR (Mar. 9, 2015), https://www.npr.org/sections/health-shots/2015/03/09/391877614/states-fund-pregnancy-centers-that-discourage-abortion; Kelly Mcevers, *California Law Adds New Twist to Abortion, Religious Freedom Debate*, NPR (Nov. 4,

that condoms are not effective and provided misinformation about hormonal contraception.[29] Fake women's health centers are dangerous for women's health—but the proposed rule could allow them to take Title X dollars for their harmful practices. This is discussed in greater detail below.

b. A cautionary tale: Texas' exclusion of family planning providers who offer abortion from family planning programs undermined its family planning program

Experience shows that excluding providers who also offer abortion services from family planning programs is devastating to women's health. The Department would be wise to look to Texas as an example of the detrimental effects of such measures. In 2011, the Texas legislature barred all health care entities that "perform or promote" abortion or their affiliates from participating in the state's family planning program, which administers federal Title X and Medicaid funding. For decades, women had relied on family planning clinics near or in their communities as a trusted source of contraception, annual exams, and other forms of preventive care—but no more. Texas' Rio Grande Valley demonstrates the harmful impact of defunding these clinics.

In 2012, the Center, in partnership with the National Latina Institute for Reproductive Health, conducted interviews and focus groups with nearly 200 women in the Rio Grande Valley of Texas to document the impact of the loss of health care services. The women we spoke with articulated widespread violations of Latinas' human rights to life and health, non-discrimination and equality, autonomy, and privacy in reproductive decision-making.

Over one third of the Valley's population lives in poverty, and residents face numerous barriers to health care, including a crushing inability to afford health care services and a severe shortage of health care providers. Until the 2011 policy changes, family planning services were the exception, as the state family planning program provided low- or no-cost services within their communities. Two years after the defunding measures took effect, many of the Valley's clinics had lost funding. Twenty-eight percent of state-funded family planning clinics in the Rio Grande Valley were forced to shut their doors, and many others had to reduce services while raising fees.[30] As a result, the demand for health care services increased at the remaining clinics. Booking an appointment typically meant several months of wait time at one of the few remaining health centers that could still afford to offer reduced-rate services.

The impact of the defunding had far-reaching consequences for women's health:

2015), https://www.npr.org/sections/health-shots/2015/11/04/454589142/california-law-adds-new-twist-to-abortion-religious-freedom-debate.

[29] Katelyn Bryant-Comstock et al., *Information about Sexual Health on Crisis Pregnancy Center Web Sites: Accurate for Adolescents?*, 29 JOURNAL OF PEDIATRIC & ADOLESCENT GYNECOLOGY 22 (Feb. 2016); Joanne D. Rosen, *The Public Health Risks of Crisis Pregnancy Centers*, 44 PERSPECTIVES ON SEXUAL AND REPRODUCTIVE HEALTH 201-205 (Sept. 2012), https://www.guttmacher.org/journals/psrh/2012/09/public-health-risks-crisis-pregnancy-centers.

[30] Center for Reproductive Rights & National Latina Institute for Reproductive Health, *Nuestra Voz, Nuestra Salud, Nuestro Texas: The Fight for Women's Reproductive Health in the Rio Grande Valley* 6 (Nov. 2013), http://www.nuestrotexas.org/wp-content/uploads/2015/03/NT-executive-summary-EN1.pdf.

> Nearly all women consulted for this report live on incomes below the federal poverty level—in many cases, far below—and any extra health care expense requires compromising on other necessities such as food or clothing. The cost of one month's supply of contraception, as well as the fee for an annual exam, has increased by three to four times since 2010. Specialty tests such as ultrasounds and mammograms that women used to be able to receive at local clinics at subsidized rates are now no longer available from many clinics. Clinics now refer women to private doctors who charge rates far beyond what women can afford, and the referrals expire long before women can save enough to use them. Some women who received abnormal results years ago from Pap tests or breast exams have yet to be able to afford necessary follow-up tests to obtain more information about the status of their health. . . . Problems that could have been diagnosed and treated early become much more serious, as in the case of women with chronic reproductive conditions or early signs of cancer.[31]

Additional research found that women in Texas had reduced access to the full range of contraceptive methods and likely experienced higher rates of unintended pregnancy. Specifically, researchers found a thirty-five percent decline in women using the most effective methods of birth control and a dramatic twenty-seven percent spike in births among women who had previously used injectable contraception.[32] After funding was cut off to providers who offer abortion in 2011, eighty-two family planning clinics closed in the state, a third of which were Planned Parenthood affiliates. The Texas Women's Health Program served 30,000 fewer women after family planning providers were defunded.[33] As the Heidi Group, a large anti-abortion group that was called upon to fill the gap, conceded: "It's not as easy as it looks because we are not Planned Parenthood."[34]

As described in detail above, the Title X network currently is not equipped to absorb the additional patients that would be displaced by this rule. In addition, due to the geographic distribution of Title X clinics, many patients would be unable to obtain care in or near their communities, making it unlikely that they would be able to obtain care at all. The Department must not follow Texas' lead in abandoning the women who most need access to care.

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[31] *Id.* at 7.

[32] Amanda J. Stevenson et al., *Effect of Removal of Planned Parenthood from the Texas Women's Health Program*, 374 NEW ENGLAND JOURNAL OF MEDICINE 853-60 (2016).

[33] Paul J. Weber, *Get by without Planned Parenthood? One Texas effort stumbles*, ASSOCIATED PRESS (Mar. 14, 2017), https://apnews.com/f7645d59944d47228f2eb195a35a19a4.

[34] *Id.*

III. The Proposed Rule Should be Withdrawn Because It Reshapes the Title X Program to Lower the Quality of Health Care for Low-Income Individuals

For decades, high-quality care has been a hallmark of the Title X family planning program.[35] Since its inception nearly five decades ago, Title X has provided millions of low-income and uninsured women and men with affordable, high-quality birth control and reproductive health care. In fact, Title X-funded centers are much more likely to provide a broader variety of contraceptive services and follow the evidence-based best practices for high-quality family planning care than the Title X program currently requires.[36] Research shows that compared with non-Title X-funded health care providers, many Title X grantees provide higher quality, more timely care to a greater number of women.[37]

The proposed rule claims to only clarify compliance requirements and enforce the law; however, its impact will almost certainly be to make abortion inaccessible for many patients, pushing an essential health service out of reach. In addition, the proposed rule's revised application criteria would encourage underqualified providers to participate in the program, putting the high-quality care the program is known for at risk.

a. The proposed rule directs health care providers to withhold comprehensive health care information from their patients

The NPRM proposes to rescind existing requirements that health care providers offer nondirective counseling on abortion, prenatal care, and adoption. The proposed rule also would ban health care providers from "presenting" abortion as a family planning method, even while claiming to permit counseling on abortion. These changes create confusion that would likely deter providers from providing any counseling on abortion care.

Pregnancy testing is a common and frequent reason for women to visit Title X sites.[38] As a result, a significant number of Title X patients seek out and need pregnancy counseling. Options

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[35] *See, e.g.*, C.I. Fowler et al., *Family Planning Annual Report: 2015 National Summary*, RTI INTERNATIONAL (2015), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2015.pdf; Kinsey Hasstedt, *Title X: An Essential Investment, Now More than Ever*, 16 GUTTMACHER POLICY REVIEW (Sept. 13, 2013), https://www.guttmacher.org/gpr/2013/09/title-x-essential-investment-now-more-ever; Kiersten Gillette-Pierce & Jamila Taylor, *The Threat to Title X Family Planning: Why it Matters and What's at Stake for Women*, CENTER FOR AMERICAN PROGRESS (Feb. 9, 2017), https://www.americanprogress.org/issues/women/reports/2017/02/09/414773/the-threat-to-title-x-family-planning/.

[36] Henry J. Kaiser Family Foundation, *New Survey Examines the Provision of Family Planning Services by Community Health Centers* (Mar. 15, 2018), https://www.kff.org/womens-health-policy/press-release/new-survey-examines-the-provision-of-family-planning-services-by-community-health-centers/.

[37] Kinsey Hasstedt, *Understanding Planned Parenthood's Critical Role in the Nation's Family Planning Safety Net*, 20 GUTTMACHER POLICY REVIEW 12 (2017), https://www.guttmacher.org/gpr/2017/01/understanding-planned-parenthoods-critical-role-nations-family-planning-safety-net.

[38] Illinois Department of Human Services, *Guidelines for Client Services and Clinic Management, Section 8.6: Pregnancy Diagnosis and Counseling* (2008), http://www.dhs.state.il.us/page.aspx?item=40642; *see also* Jennifer J. Frost et al., *Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in*

counseling is an important service for many when they first discover their pregnancy. Depending on the age and education level of the patient, they may not be aware of all their pregnancy options. Like with any other medical condition, medical counseling on all available options is required for informed consent, and consistent with medical standards put forth by leading medical associations such as the American College of Obstetricians and Gynecologists and the American Medical Association. Medical ethics require health care providers to ensure there is informed consent.[39] Informed consent is a necessary principle of patient-centered decision-making intended to help balance the power dynamics between health care providers and patients. It also ensures patients have full autonomy over what is to happen to their bodies. Informed consent requires providers to disclose relevant and medically accurate information about treatment choices and alternatives so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.[40]

Under current regulations, providers are required to offer nondirective counseling services with respect to abortion, adoption, and prenatal care. This requirement has been in place for many years and, as the Department has previously recognized, it has "been considered to be a necessary and basic health service of Title X projects."[41] Nonetheless, the proposed rule rescinds this requirement. Importantly, since 1996, Congress has annually passed a requirement that all pregnancy counseling must be "nondirective." This statutory requirement remains in place. At the same time, the proposed rule would ban "present[ing]" abortion "as a family planning method."

The ban on "presenting" abortion as a family planning service would likely create a chilling effect on providers who want to provide high-quality care and counsel their patients consistent with the prevailing standard of care and medical ethics. Even if, as the administration claims in the preamble, counseling on abortion is permitted, the controlling regulatory text in the proposed rule does not expressly permit counseling, and the ban on "presenting" abortion appears to

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Meeting Women's Health Care Needs, 22(6) WOMEN'S HEALTH ISSUES e519-e525 (2002) ("Ten percent of respondents were primarily at the clinic for a pregnancy test").

[39] *See, e.g.*, American College of Physicians, *Ethics Manual* (6th Ed. 2012), https://www.acponline.org/clinical-information/ethics-and-professionalism/acp-ethics-manual-sixth-edition/acp-ethics-manual-sixth-edition#informed ("The ethical duty to disclose relevant information about human reproduction to the patient may conflict with the physician's personal moral standards on abortion, sterilization, contraception, or other reproductive services. A physician who objects to these services is not obligated to recommend, perform, or prescribe them. As in any other medical situation, however, the physician has a duty to inform the patient about care options and alternatives, or refer the patient for such information, so that the patient's rights are not constrained. Physicians unable to provide such information should transfer care as long as the health of the patient is not compromised."); American Nurses Association, *Code of Ethics for Nurses with Interpretive Statements, Section 1.4* (2015) ("Patients have the moral and legal right to determine what will be done with their own person; to be given accurate, complete and understandable information in a manner that facilitates an informed decision.").

[40] *See* American Medical Association, *Code of Medical Ethics Opinion 2.1.1: Informed Consent*, https://www.ama-assn.org/delivering-care/informed-consent ("Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making.").

[41] 65 Fed. Reg. 41273 (July 3, 2000).

eliminate a provider's ability to even *offer* counseling on abortion services. As a result, patients who are unaware of the option and do not expressly request counseling on the topic may be unable to make an informed decision about their pregnancy. With the amount of money that is at stake, the rescission of the counseling offer requirement, the ban on "presenting" abortion as a family planning method and the lack of an explicit permission to counsel on abortion would operate to chill providers' speech and prevent patients from accessing comprehensive information about their health care options.

The statutory requirement that pregnancy counseling be nondirective[42] creates additional confusion for providers. Nondirective counseling is "the provision of information on *all* available options without promoting, advocating, or encouraging one option over another" (emphasis added).[43] The proposed rule would force providers to omit information about abortion. By definition, this forced omission steers patients away from abortion and is directive counseling, and thus is in violation of the law—a fact that this Department has recognized in the past.[44] Given this confusing and contradictory set of restrictions, a health care provider could be deterred from providing *any* pregnancy counseling so as not to violate the law.

Finally, even where the preamble suggests that nondirective counseling on abortion would be permitted in some undefined circumstances, the preamble seems to confine this permission to physicians. Since the vast majority of medical services and counseling in Title X is provided by non-physician clinicians, such as nurse practitioners, few Title X projects could engage in the even limited opportunity for counseling seemingly contemplated by the preamble.[45]

The proposed counseling requirements are confusing, in conflict with existing law, and harmful for women's health and must be withdrawn.

b. The ban on referrals for abortion care directs Title X grantees to withhold or obfuscate full and accurate medical information, endangering women's health and undermining the patient-provider relationship

The proposed rule makes sweeping changes that compromise a provider's ability to comply with medical ethics when referring a patient for care outside the Title X program, putting women's health at risk.

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[42] A statutory provision passed annually in the Title X appropriation since 1996 would remain in place requiring that "all pregnancy counseling shall be nondirective." *See, e.g.*, Consolidated Appropriations Act, 2018, Public Law 115-141, Div. H, Title II, 132 Stat. 348, 716-717 (2018).

[43] *See* 83 Fed. Reg. 25512 fn. 41 (June 1, 2018).

[44] *See* 65 Fed. Reg. 41273 (July 3, 2000) ("Totally omitting information on a legal option or removing an option from the client's consideration necessarily steers her toward the options presented and is a directive form of counseling.").

[45] According to the *2016 Family Planning Annual Report*, of the 3,550 full-time equivalent (FTE) clinical services providers responsible for the provision of family planning and sexual health services in Title X-funded health centers, 71% (2,511.8) were mid-level clinicians (physicians assistants, nurse practitioners, and certified nurse midwives).

Under current regulations, Title X recipients must provide abortion referrals if requested by the patient. The proposed rule would rescind this requirement, instead banning direct abortion referrals entirely except in medical emergencies. If a patient requests a referral for an abortion, a provider may give only a mixed list of health care providers who offer prenatal care, of which some, but not all also offer abortion.[46] The list may not identify which providers on the referral list offer abortion care.[47] All other pregnant patients *must* be referred to prenatal care providers, regardless of their wishes.[48] These changes would reduce the quality of health care for pregnant Title X patients who want or need abortion care by obfuscating their health care choices and directing them towards unwanted services.

The ban on referrals disrupts the continuum of care and puts an undue burden on patients, who must expend additional time and money in order to obtain the care they need—if they are able to obtain care at all. Where a Title X clinic might have been able to refer to services provided outside the Title X program but within their own facility and begin the health care service on the same day, a patient now would have to first research which providers even provide abortion. She may not know that she was given a mixed list, trusting her doctor to provide her with accurate information. As a result, patients would have to spend valuable time and money, including travel costs and co-pays, on appointments for providers who would not provide the requested service—wasting time and money for a population that often has neither to spare. The additional time and expense falls most heavily on the low-income individuals that make up the Title X program, including those without the job flexibility to take paid sick time. Even if the patient is made aware that the list is mixed, she may not have the time or resources to research which provider performs the requested service, making it more likely that she is unable to obtain needed care or her care is significantly delayed.

This burden is especially troubling given the time-sensitive nature of obtaining abortion care. As pregnancy progresses, abortion care becomes more expensive and more difficult to obtain.[49] Seemingly minor delays may push a patient into a later stage of pregnancy, where fewer providers may be available and procedures may be more complex. The proposed rule would result in medically unnecessary and inappropriate delays in care, which are never in the best interest of the patient.

When women face delays in obtaining an abortion, the logistical and financial burdens they face multiply. On average, a woman must wait at least a week between when she attempts to make an appointment and when she receives an abortion.[50] Delays also have the effect of increasing the

[46] 83 Fed. Reg. 25531 (June 1, 2018).

[47] *Id.*

[48] *Id.*

[49] Rachel K. Jones et al., *Differences in Abortion Service Delivery in Hostile, Middle-Ground and Supportive States in 2014,* WOMEN'S HEALTH ISSUES 215-16 (2018), http://www.whijournal.com/article/S1049-3867(17)30536-4/abstract.

[50] The median is seven days, while the average is 10 days. Moreover, poorer women wait two to three days longer than the typical woman. *See* Lawrence B. Finer et al., *Timing of Steps and Reasons for Delays in Obtaining Abortions in the United States,* 74 CONTRACEPTION 334, 338-43 (2006).

cost of an abortion. Abortion in the first trimester is substantially less expensive than in the second trimester: the median price of a surgical abortion at ten weeks is $508, while the cost rises to $1,195 at week twenty.[51] The rising cost of abortion as gestational age increases poses a profound challenge to the affordability of the procedure for lower-income women. As one Utah woman explained: "I knew the longer it took, the more money it would cost . . . We are living paycheck to paycheck as it is, and if I [had] gone one week sooner, it would have been $100 less."[52] Moreover, delays raise the cost of each step of obtaining an abortion—not just the cost of the procedure. For example, one recent study found that Utah's mandatory waiting period caused forty-seven percent of women having an abortion to miss an extra day of work.[53] More than sixty percent were negatively affected in other ways, including increased transportation costs, lost wages by a family member or friend, or being required to disclose the abortion to someone whom they otherwise would not have told.[54] And because many clinics do not offer second-trimester abortions, a woman who has been delayed into the second trimester will typically be required to travel farther to obtain an abortion, thereby incurring additional travel and related costs, such as lost wages.[55] As a result, indirect referrals that result in a delay in care can significantly drive up the cost of care for a woman seeking abortion care.

The proposed rule contravenes key and well-established principles of quality care: that care must be timely, in the best interest of the patient, and according to medical need.[56] With regards to abortion specifically, the World Health Organization has stated that:

> Information, counselling and abortion procedures should be provided as promptly as possible without undue delay . . . The woman should be given as much time as she needs to make her decision, even if it means returning to the clinic later. However, the advantage of abortion at earlier gestational ages in terms of their greater safety over abortion at later ages should be explained. Once the decision is made by the woman, abortion should be provided as soon as is possible to do so.[57]

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[51] Rachel K. Jones et al., *Differences in Abortion Service Delivery in Hostile, Middle-Ground and Supportive States in 2014,* WOMEN'S HEALTH ISSUES 215-16 (2018), http://www.whijournal.com/article/S1049-3867(17)30536-4/abstract.

[52] Sarah C.M. Roberts et al., *Utah's 72-Hour Waiting Period for Abortion: Experiences Among a Clinic-Based Sample of Women*, 48 PERSPECTIVES ON SEXUAL & REPRODUCTIVE HEALTH 179, 184 (2016).

[53] Jessica N. Sanders et al., *The Longest Wait: Examining the Impact of Utah's 72-Hour Waiting Period for Abortion*, 26 WOMEN'S HEALTH ISSUES 483, 485 (2016).

[54] *Id.*; Deborah Karasek et al*., Abortion Patients' Experience and Perceptions of Waiting Periods: Survey Evidence Before Arizona's Two-Visit 24-hour Mandatory Waiting Period Law*, 26 WOMEN'S HEALTH ISSUES 60 (2016).

[55] Rachel K. Jones & Jenna Jerman, *How Far Did US Women Travel for Abortion Services in 2008*?, 22 J. WOMEN'S HEALTH 706 (2013).

[56] Institute of Medicine (now the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine), *Crossing the Quality Chasm: A New Health System for the 21st Century* (Mar. 2001), http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf.

[57] World Health Organization, *Safe Abortion: Technical and Policy Guidance for Health Systems* (2nd ed.) 36 (2012), http://apps.who.int/iris/bitstream/10665/70914/1/9789241548434_eng.pdf.

The proposed rule's ban on abortion referrals exemplifies how the Department seeks to relegate low-income pregnant patients who rely on Title X services to lower-quality health care. While the proposed rule would continue to permit grantees to provide "necessary referral to other medical facilities when medically indicated," it would prohibit referrals for medically necessary abortions unless the patient requires emergency care.[58] Then, a direct referral to an "appropriate provider of emergency medical services" is permitted. For other medically necessary and even life-saving abortions that are not an immediate emergency, a health care provider may not give a direct referral, or even any referral information except the mixed list, and only upon request. This could deny pregnant patients who may need to make difficult decisions about a wanted pregnancy, but have not yet made up their mind about an abortion, the opportunity to be referred to a specialist for a consultation. Because of the limitations on counseling, it is also unclear whether the provider would be able to discuss abortion as a medical treatment option.

A footnote in the preamble suggests that it would not be a violation of the ban on abortion referrals to refer directly to an abortion provider in cases of rape or incest—but only if the referring provider has complied with all laws requiring reporting to, or notification of, relevant authorities and documents the report in the patient's record.[59] Conditioning a health care referral on reporting laws is a violation of key liberty and privacy principles. Forcing providers to report survivors could also put the survivor in harm's way, and could deter them from identifying themselves as survivors or seeking care at all. A patient should never be forced to choose between obtaining needed care and her privacy.

The ban on abortion referrals is also an attempt to entice fake women's health centers to join the ranks of Title X providers. The Department expressly states that the referrals ban would "promote grantee diversity by expanding the number of qualified entities that would be willing and able to apply to provide Title X services, since potential grantees and subrecipients that refuse to provide abortion referrals may have been ineligible or discouraged from applying for Title X grants […] by the requirements of the current regulations."[60] As described in detail below, many of these centers provide little to no licensed health care, much less high-quality reproductive care.

The proposed counseling and referral requirements would undermine the trust integral to the patient-provider relationship and force providers to violate medical ethics. As the American Medical Association explains:

> High-quality medical care relies on honest, unfiltered conversations between patients and their physicians. Gag orders that restrict the ability of physicians to explain all options to their patients and refer them—whatever their health care

[58] 83 Fed. Reg. 25530 (June 1, 2018).

[59] This language, while instructive, is not controlling because the exception is only in the preamble and not in the actual regulatory text. Accordingly, in practice, providers would not be able to make such a referral even under these limited conditions without fear of violating the referral ban. 83 Fed. Reg. 25518 (June 1, 2018).

[60] 83 Fed. Reg. 25518 (June 1, 2018).

> needs—compromise this relationship and force physicians and nurses to withhold information that their patients need to make decisions about their care.[61]

Patients must be able to trust that their health care providers are giving them complete, transparent information about their health care options—and medical ethics obligate providers to do so.[62] Forcing providers to withhold critical information about a patient's care undermines that trust. This is especially true for minors, who, under the proposed rule, would be subject to additional invasive questioning about their sexual partners[63]—but given only evasive or incomplete answers when requesting abortion referrals or family planning counseling. For communities of color, who make up a large portion of the Title X program, the proposed rule piles on to a historic distrust of the medical community as a result of centuries of abuse, including forced sterilization and medical experiments without patient consent.[64] Especially for these underserved populations, building patients' trust in health care providers is essential to realizing the promise of the Title X program:

> Mistrust can cause a patient to refuse treatment or comply poorly with medical advice, which in turn can cause providers to become less engaged—leading to a vicious cycle. These obstacles are difficult enough to surmount in cases where a patient is ill and presumably motivated to receive some kind of treatment. In the case of a prevention intervention such as birth control, however, where the need for

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[61] American Medical Association, *Press Release: AMA Response to Administration's Attack on Family Planning Services* (May 23, 2018), https://www.ama-assn.org/ama-response-administrations-attack-family-planning-services.

[62] The AMA code of ethics states that "withholding information without the patient's knowledge or consent is ethically unacceptable." American Medical Association, *Withholding Information from Patients, Code of Medical Ethics Opinion 2.1.3*, https://www.ama-assn.org/delivering-care/withholding-information-patients; The American College of Obstetricians and Gynecologists recommends that all patients "should be counseled about [their] options: continuing the pregnancy to term and raising the infant, continuing the pregnancy to term and placing the infant for legal adoption, or terminating the pregnancy." *See* Kinsey Hasstedt, *Unbiased Information on and Referral for All Pregnancy Options Are Essential to Informed Consent in Reproductive Health* Care, 21 GUTTMACHER POLICY REVIEW 2 (2018), https://www.guttmacher.org/gpr/2018/01/unbiased-information-and-referral-all-pregnancy-options-are-essential-informed-consent.

[63] The proposed rule requires providers to document the age of minors' sexual partners. 83 Fed. Reg. 25533 (June 1, 2018).

[64] *See, e.g.*, Susan A. Cohen, *Abortion and Women of Color: The Bigger Picture*, 11 GUTTMACHER POLICY REVIEW 2, 5 (2008) ("The [Institute of Medicine] also noted a level of mistrust for the health system in general that exists in minority communities. Mistrust can cause a patient to refuse treatment or comply poorly with medical advice, which in turn can cause providers to become less engaged—leading to a vicious cycle."); Willie M. Abel & Jimmy T. Efird, *The Association between Trust in Health Care Providers and Medication Adherence among Black Women with Hypertension*, 1 FRONT. PUBLIC HEALTH (2013) ("The historical legacy of Blacks in the U.S. provides insight as to why distrust in the medical profession exists. [. . .] Frequently, [Black people] were used in experiments by White doctors to perfect medical and surgical techniques before attempting procedures on Whites. [. . .] Examples of experiments included: unanesthetized gynecological experiments on slave women; Tuskegee syphilis study that withheld treatment to plot disease progress in men; eugenic-inspired involuntary sterilizations of welfare mothers with multiple children; unconsented high dose radiation experiments; and hazardous dermatological research on prison subjects.").

> 'treatment' may seem less pressing, the cumulative effect of these obstacles could be daunting.[65]

The proposed rule could undermine the patient-provider relationship, and with it, the care patients need. We urge the Department to withdraw this harmful rule.

c. *The proposed rule's physical separation requirement and additional restrictions on use of funds would detrimentally impact Title X's trademark high-quality care*

Under current regulations, Title X providers who also perform abortion are required to maintain financial separation of abortion services from their Title X programs. Any shared costs are strictly prorated to prevent the misuse of Title X funds, which by statute may not go towards programs that provide abortion.[66] The NPRM would change this system radically by requiring health care providers that also perform abortion to demonstrate both physical and financial separation of the Title X project from abortion services. The proposed rule would essentially reinstate a near-identical Reagan-era policy that grants the Secretary unchecked power to determine whether the programs are sufficiently separate, based on a set of factors including whether there are separate waiting rooms, entrances and exits, staff, workstations, and health care records. The NPRM also proposes that at least fifty percent of Title X funds be used exclusively for direct services, and prohibits the use of any of the funds on infrastructure costs shared with programs that provide abortion. Together, the physical separation requirement and proposed restrictions on the use of Title X funds would increase operating costs and limit funding for critical infrastructure purposes that ensure quality care, in addition to directly impacting the quality of care for a woman seeking an abortion.

The physical separation requirements would likely raise the cost of care. As described in detail below, the proposed requirements will effectively require grantees that also provide abortion care outside the Title X program to engage in a complete physical separation of Title X services from services prohibited by the program. This would essentially require the grantees to operate separate facilities, hire a second set of staff and duplicate structural necessities, including medical records systems, websites, and work stations. Such a scheme would be extremely costly and could deplete a health facility's funds, forcing it to close or raise the cost of care.[67]

Restrictions on the use of Title X funds would have a similar effect. Many clinics would be unable to use Title X funding to prorate costs that are critical for both programs, such as facility updates, staff salaries or staff training. It would also raise the cost of medical supplies, as it would reduce or eliminate grantees' ability to make cost-effective bulk purchases of supplies,

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[65] Susan A. Cohen, *Abortion and Women of Color: The Bigger Picture*, 11 GUTTMACHER POLICY REVIEW 2, 5 (2008).

[66] 42 U.S.C § 300a-6.

[67] Commenters on the 1988 rule noted that many small and rural clinics, which provide services to some of the most underserved populations, "cannot afford to operate separate facilities or to employ separate staff for these services without substantially increasing the prices of *** services." 65 Fed. Reg. 41275 (July 3, 2000).

including contraceptives. The increased costs would greatly reduce the number of patients that can be served through Title X and other funding sources.

The physical separation requirement, especially when coupled with the referral ban, goes against the principle of integrated care. By removing the option of seamless referrals within a facility, the proposed rule would force patients to make multiple appointments and trips—contrary to the proposed rule's emphasis on funding grantees who can provide on-site primary care to "decrease the overall cost and transportation challenges related to access for vital health care services that may be discovered"[68] at the family planning visit. Further, the separation requirement effectively removes "one of the most opportune time[s] to facilitate the entry of the abortion patent *(sic)* into family planning counseling, which is at the post-abortion check-up"[69]—undermining Title X's mission to provide high-quality family planning services.

Finally, the proposed restriction to require the majority of funds to be used for direct services could limit a clinic's ability to conduct outreach to new patients who need publicly funded health services. Many individuals who are eligible for Title X services do not know that they would be eligible for free or low-cost health care, so encouraging them to visit the clinic for the first time can be the greatest challenge to serving that population.[70] Because other public funding sources may not be used for outreach activities, Title X funds can be critical in establishing that connection and providing eligible individuals with a much-needed entry point into the health care system. The proposed restrictions on the use of funds would curtail outreach efforts and almost certainly reduce access to Title X services contrary to the underlying statute.[71]

d. The proposed rule would have a chilling effect on the provision of abortion care outside of the Title X program

The restrictions described above would have a chilling effect on the provision of abortion care even outside of the Title X program by forcing many clinics to give up their abortion program. Because the proposed requirements would generate sometimes insurmountable costs in order to separate abortion services from Title X services and limit the use of Title X funds where there are shared infrastructure costs, many clinics would likely be unable to comply if they continue to provide abortion services. As a result, they would have to stop providing abortion services to avoid incurring the cost of physical separation, exacerbating the existing abortion provider shortage. As of 2014, eighty-nine percent of counties in the United States did not have a single

[68] 83 Fed. Reg. 25516 (June 1, 2018).

[69] 65 Fed. Reg. 41275 (July 3, 2000).

[70] Rachel Benson Gold, *Stronger Together: Medicaid, Title X Bring Different Strengths to Family Planning Effort*, 10 GUTTMACHER POLICY REVIEW 13, 17 (2007) https://www.guttmacher.org/sites/default/files/article_files/gpr100213.pdf ("meeting the unmet need for publicly subsidized family planning is first and foremost an outreach challenge [. . .] the intensive outreach required to reach special populations often falls to Title X.").

[71] The Department misreads the research it cites as justification for the restriction on the use of Title X funds, and appears to imply that clinics are using Title X funding to attract clients for non-Title-X services. To the contrary, the research shows that the Title X funds allow populations that likely would otherwise have no access to health care at all to obtain services.

abortion clinic.[72] Even in counties that do have one or more clinics, abortion services might be available only on certain days. In several states, only one clinic offers abortion care.[73]

An increased shortage of providers would be the direct result of the proposed rule, but that result would go against the congressional intent of the program. Congress clearly stated that the abortion prohibition in the Title X program "does not and is not intended to interfere with or limit programs conducted in accordance with State or local laws and regulations which are supported by funds other than those authorized under this legislation."[74] The proposed rule, however, would do just that.

e. The proposed rule threatens patient confidentiality, particularly for minors, in ways that could cause many patients to avoid seeking care

Family planning services address some of the most sensitive and personal issues in health care and therefore require strong confidentiality protections. Patients seeking family planning services encompass a broad spectrum of patient populations. Certain groups, including adolescents, young adults, and people at risk of domestic or intimate partner violence, have special privacy concerns that require strong protections. But the proposed rule undermines patient confidentiality and access to care by exerting increased and inappropriate pressure on adolescent patients and their Title X providers to involve family members including parents or guardians in virtually all cases.

Congress requires that Title X providers encourage family participation "to the extent practicable."[75] Title X providers, guided by their expertise, training, and experience, as well as extensive practice standards and recommendations, already assist adolescents to involve their families in decisions about family planning services and other key health care matters when realistic and appropriate.

As a consequence, most adolescents already involve their families in decisions about family planning, or seek family planning services with their parents' or guardians' knowledge.[76] However, when taking a health history, clinicians sometimes learn of circumstances (short of abuse) in a minor's family that can make it not "practicable," or even harmful, to encourage the

[72] Rachel K. Jones & Jenna Jerman, *Abortion incidence and service availability in the United States, 2014*, 49(1) PERSPECTIVES ON SEXUAL AND REPRODUCTIVE HEALTH 17–27 (Mar. 2017).

[73] Allison McCann, The Last Clinics, VICE NEWS (May 23, 2017), https://news.vice.com/story/last-clinics-seven-states-one-abortion-clinic-left.

[74] 116 CONG. REC. 39871 (1970).

[75] 42 U.S.C. § 300.

[76] Diane M. Reddy et al., *Effect of Mandatory Parental Notification on Adolescent Girls' Use of Sexual Health Care Services*, 288(6) JAMA 710 – 714 (2002); Rachel K. Jones et al., *Adolescents' Reports of Parental Knowledge of Adolescents' Use of Sexual Health Services and Their Reactions to Mandated Parental Notification for Prescription Contraception*, 293(3) *JAMA* 340 – 348 (2005); Liza Fuentes et al., *Adolescents' and Young Adults' Reports of Barriers to Confidential Health Care and Receipt of Contraceptive Services*, 62(1) JOURNAL OF ADOLESCENT HEALTH 36-43 (2018).

participation of a minor's parents or guardians. In these situations, clinicians should not be required to take and document "specific actions" to encourage the minor to do so as the NPRM requires. The requirement is not only contrary to medical ethics, but it also undermines the relationship between the minor and the health care professional and is likely to deter some minors from returning for critical health care services, including family planning and testing and treatment for sexually transmitted infections.[77]

f. The proposed rule's encouragement of fake women's health centers' participation in the Title X program demonstrates a blatant disregard for women's health and the program's intended purpose

The proposed rule encourages fake women's health centers and religious entities that do not provide medically appropriate care to participate in the Title X program, putting women's health at risk and undermining the fundamental purpose of the Title X program. As described in greater detail throughout this comment, the proposed rule facilitates the participation of these entities by loosening the standards for the range of family planning methods and services to be provided, rescinding counseling requirements and banning referrals to which religious entities object, encouraging the participation of "non-traditional" Title X partners, and encouraging abstinence-only education. In effect, the proposed rule would restructure the Title X program to shift away from scientifically-proven health care. In its place, it would elevate unscientific behavioral approaches to family planning, including through clinics that stigmatize sex, abortion and medically-proven family planning methods and refuse to provide or refer for abortion or contraceptive services. By moving the Title X program away from these medically-proven family planning methods and other comprehensive health services, the proposed rule would substantially reduce the quality of care for many patients under the Title X program.

Fake women's health centers have a well-documented history of engaging in deceptive and fraudulent tactics to attract pregnant women and deter or prevent them from accessing abortion care. Many of these centers advertise their services by suggesting—explicitly, implicitly, or by omission—that they are full-spectrum reproductive health clinics, while actively concealing that they do not provide or refer for abortion or contraception.[78] Many of these centers also train their staff and volunteers to convince women to make an appointment, regardless of whether the center provides the services they are seeking.[79] Once a pregnant woman comes through their doors, she may be forced to watch anti-choice films, view slideshows and photographs, and hear biased lectures. The fake women's health centers would not only refuse to refer women to an abortion provider—some may refuse even to provide information about or referrals for birth control.[80] The refusal to refer for an abortion is especially insidious under this proposed rule,

[77] *Id.*

[78] Brief for 51 Reproductive Rights, Civil Rights, and Social Justice Organizations as Amici Curiae Supporting Respondents at 9, NIFLA v. Becerra, 138 S. Ct. 2361 (2018).

[79] *Id.* at 12.

[80] Joanne D. Rosen, *The Public Health Risks of Crisis Pregnancy Centers*, 44 PERSPECTIVES ON SEXUAL AND REPRODUCTIVE HEALTH 201-05 (Sept. 2012), https://www.guttmacher.org/journals/psrh/2012/09/public-health-risks-crisis-pregnancy-centers ("Clinics that offer pregnancy tests are well positioned to provide information about contraception and STD prevention to a sexually active clientele. However, most crisis pregnancy centers do not

because the centers are under no obligation to disclose that they do not provide abortion, do not refer for abortion, or that any referral list they provide does not include an abortion provider—even if the patient specifically requests a referral for an abortion.

Women have suffered significant harm as a result of the practices of fake women's health centers. Besides the additional time and money required to obtain care that the fake women's health center has refused to provide, some women have, as a result, been prevented from obtaining abortion care entirely by the center's delay tactics or outright lies about the availability of abortion care.[81] Fake women's health centers have also given misleading or wrong information about patients' pregnancies that led to miscarriages or other adverse health consequences.[82]

In addition, the proposed changes to the range of family planning methods and services, combined with the new definition of "family planning" (which emphasizes provision of a "broad range of acceptable and effective *choices*"[83]) betray the proposed rule's intent to shift the Title X program's focus from high-quality medical services to behavioral changes. The revised requirements could allow fake women's health centers to band together with other underqualified entities and qualify as a "broad range" of family planning services under the proposed rule by providing a limited suite of abstinence-only education, natural family planning, and adoption services—despite not providing any of the drugs and devices most patients would expect in a family planning visit. This contravenes the intent of the Title X program to ensure that low-income women have access to the same quality and range of services, including contraceptive care, as women who receive care through private practice.

Finally, the proposed rule does not guarantee that grantees must be licensed medical providers, allowing fake women's health centers that deny access to care to enter the program and effectively prevent women from accessing care through licensed providers.

IV. The Proposed Rule Violates the Administrative Procedure Act

The proposed rule violates the Administrative Procedure Act ("APA") on multiple grounds. Under the APA, "agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" shall be set aside.[84] An agency must provide "adequate reasons" for its rulemaking, in part by "examin[ing] the relevant data

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provide such information."); David A. Grimes, *Crisis Pregnancy Centers Lie About Contraception, Too,* HUFFINGTON POST (Jan. 15, 2016), https://www.huffingtonpost.com/david-a-grimes/crisis-pregnancy-centers-_b_8979258.html (Citing the Statement of Principle for a North Carolina fake women's health center: "Does not recommend, provide, or refer single women for contraceptives. (Married women seeking contraceptive information should be urged to seek counsel, along with their husbands, from their pastor and/or physician)").

[81] *See, e.g.*, Brief for 51 Reproductive Rights, Civil Rights, and Social Justice Organizations as Amici Curiae in Supporting Respondents at 27-28, NIFLA v. Becerra, 138 S. Ct. 2361(2018).

[82] *See id.* at 23-24.

[83] 83 Fed. Reg. 25529 (June 1, 2018) (emphasis added).

[84] 5 U.S.C.A. § 706(2)(A).

and articulat[ing] a satisfactory explanation for its action including a rational connection between the facts found and the choice made."[85]

As detailed below, the proposed rule is arbitrary and capricious, an abuse of discretion, and not in accordance with law. Among other things, the Department fails to articulate an ample justification for a revision of Title X compliance requirements, as demonstrated by the dearth of supporting facts and data in the NPRM, and fails to engage in an appropriate cost-benefit analysis. Instead, it advances the unsubstantiated claim that current regulations, which for decades have successfully governed the program, are now somehow causing confusion and suddenly violate federal health care refusal laws. The regulations have gone virtually unchanged for 18 years, thoroughly and effectively spell out how the Title X program is to operate (in full satisfaction of its statutory mandates), and are not confusing to Title X-funded health centers. The NPRM also fails to identify any inadequacies in Title X family planning care, any material failures of compliance, or any other evidence that might justify its proposed regulatory overhaul. HHS's current regulations and oversight powers already give it the capability to manage Title X grants and work effectively with the Title X network to best serve patients. Title X's primary issue today is lack of sufficient funding—a problem made worse by this NPRM, not any purported problems with the rules governing this decades-old, well-functioning program.[86] Because the rule violates the APA, HHS should withdraw the proposed rule in its entirety.

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[85] Encino Motorcars, LLC v. Navarro, 136 S. Ct. 2117, 2125 (June 20, 2016) (citing Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co., 463 U.S. 29, 103 (1983)). Typically, a court will find an agency action to be arbitrary and capricious if the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (internal citations omitted); Envtl. Def. Fund, Inc. v. Costle, 657 F.2d 275, 283 (D.C. Cir. 1981) ("While we are admonished from rubber stamping agency decisions as correct, our task is complete when we find that the agency has engaged in reasoned decisionmaking within the scope of its Congressional mandate.") (internal citations and quotations omitted). The Department claims that for revised rulemaking, it "suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates." (83 Fed. Reg. 25506 (June 1, 2018) (citing U.S. Aid Funds, Inc. v. King, 200 F. Supp. 3d 163, 169–70 (D.D.C. 2016))). However, the Department fails to even meet its own standard.

[86] Institute of Medicine, *A Review of the HHS Family Planning Program: Mission, Management, and Measurement of Results* (May 2009), http://nationalacademies.org/hmd/~/media/Files/Report%20Files/2009/A-Review-of-the-HHS-Family-Planning-Program-Mission-Management-and-Measurement-of-Results/Review-of-HHS-report-brief.pdf ("The Title X program has demonstrated its value to society over time and its success in providing critical services to those who have the most difficulty obtaining them."); Office of Management and Budget, *Title X Program Assessment* (2005), https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/omb/expectmore/summary/10003513.2005.html ("Women who utilize Title X (Family Planning program) services as their primary source of health care have significantly greater odds of receiving contraceptive services and/or care for sexually transmitted diseases (STDs) than women who utilize private physicians or HMOs.").

a. The proposed rule's changes to existing counseling requirements are arbitrary and capricious, and not in accordance with law

For more than two decades, Congress has required all pregnancy counseling in the Title X program to be "nondirective."[87] The proposed rule's ban on "presenting" abortion as a family planning method conflicts with the text and intent of this law.

Congress has repeatedly and consistently expressed its clear intent that nondirective pregnancy counseling is a key component of the Title X program. In 1988, the Department of Health and Human Services issued a rule substantially similar to today's proposed rule that banned abortion counseling and referrals and mandated strict physical and financial separation. After the 1988 gag rule was upheld by the Supreme Court in *Rust v. Sullivan*,[88] the outcry from the medical community against the ban on abortion counseling remained so great that Congress took action, passing the Family Planning Amendments Act of 1992. The amendments, later codified in the regulations currently in force, required counseling and referral on all pregnancy options, including prenatal care and delivery, infant care, foster care, and adoption; and pregnancy termination.[89]

In passing the requirement, members of Congress from both parties did not mince words. Representative Henry Waxman called the Reagan-era gag rule "bad medicine, bad law, and bad precedent."[90] Representative Bill Richardson asserted that "[e]very woman in America, regardless of income, is entitled to receive all the information about her pregnancy options."[91] Others cautioned that "without [eliminating the gag rule] we will take another step toward two-tier health care in America. Already the gap in health care is widening between the haves and have nots. [If the gag rule remains in place] the gap will get wider."[92] Many recognized that

[87] A statutory provision passed annually in the Title X appropriation since 1996 requires that "all pregnancy counseling shall be nondirective." *See, e.g.*, Consolidated Appropriations Act, 2018, Public Law 115-141, Div. H, Title II, 132 Stat. 348, 716-17 (2018).

[88] Rust v. Sullivan, 500 U.S. 173 (1991).

[89] 102 CONG. REC. 9862 (1992).

[90] *Id.* at 9859.

[91] *Id.* (statement of Rep. Richardson).

[92] *Id.* at 9860 (1992) (statement of Rep. Wyden); *see also id.* at 9864 (statement of Rep. Lowey) ("Most importantly, the gag rule discriminates against low-income women by creating a two-tiered health care system. Under the rule, low-income women receive censored medical information while women who can afford private insurance have access to counseling on all of their legal, medical options."); *Id.* at 9877 (statement of Rep. DeLauro) ("This regulation will create a two-tier system for medical advice. Americans who can afford private health care will get it. Those who can't won't. We must overturn this rule [. . .]."); *Id.* at 9861 (statement of Rep. Lloyd) ("Prohibiting health care professionals from all available options with title X clients would establish one set of criteria for low-income women and a different set for women who are financially secure-in effect establishing a two-tier system for health care."); *Id.* at 9867 (statement of Rep. Snow) ("the repeal of the gag rule is our last opportunity to put an end to the appalling and humiliating· second class treatment women will receive beginning in May under the administration's regulations."); *Id.* at 9870 (statement of Rep. Collins) ("the lack of appropriate counseling will once again relegate women to the status of second-class citizens."); *Id.* at 9871 (statement of Rep. Williams) ("When the administration issued regulations limiting health care professionals from expressing their professional guidance and advice and the Supreme Court upheld those regulations I believe it sent two clear messages, the first being that

overriding the gag rule was necessary to "retain the credibility of medical professionals,"[93] emphasizing that "quality patient care will be severely impaired"[94] if the gag rule remained in place. According to Representative Margaret Roukema, "constraints on what a physician can say to a patient can only result in serious medical implications for the patient."[95] Representative Les AuCoin called the gag rule "institutionalized medical malpractice."[96] Lest the intent of Congress be unclear, Representative Gerry Studds unequivocally stated: "When we created the title X program 20 years ago, we did not intend to muzzle health care providers. But we didn't say that loudly and clearly enough. But this time, let there be no mistake. Title X providers must be able to inform individuals of all pregnancy management options and we must write this explicitly into law."[97] More bluntly, Representative Chester Atkins simply stated: "Madam Chairman, the gag rule is monumentally stupid."[98]

The Family Planning Amendments Act, passed by bipartisan majorities in both houses of Congress, was vetoed by then-President George H.W. Bush.[99] Undeterred, Congress continued to press for counseling to be nondirective, with the goal of protecting the patient-provider relationship from political interference even after the gag rule was formally suspended in 1993.[100] In every year since 1996, Congress has passed a requirement that "all pregnancy counseling shall be nondirective" as part of Title X appropriations.[101] The proposed rule's ban on presenting abortion as an option would require providers to violate this law by forcing them to provide prenatal care information but omit information about abortion, thus by default directing a patient away from abortion. Only if a Title X project entirely refrained from providing any pregnancy counseling could it avoid violating the law—a result that Congress surely did not intend, or it would have simply chosen to prohibit pregnancy counseling altogether.

The proposed rule would also rescind the existing rule that requires providers to offer counseling on prenatal care, adoption, and abortion. This rescission is arbitrary and capricious.

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physicians did not have the right to express their medical opinions to patients. The second message is that low-income women are second-class citizens and, therefore, deserve incomplete medical information from their doctors.").

[93] 102 CONG. REC. 9863 (1992) (statement of Rep. McDermott).

[94] *Id.* at 9864.

[95] *Id.* (statement of Rep. Roukema).

[96] *Id.* at 9867 (statement of Rep. AuCoin).

[97] *Id.* at 9872 (statement of Re. Studds).

[98] *Id.* at 9873 (statement of Rep. Atkins).

[99] S.B. 323, Family Planning Amendments Act of 1992, 102nd Congress, https://www.congress.gov/bill/102nd-congress/senate-bill/323/actions.

[100] The gag rule was formally suspended by President Clinton in 1993. *See* 58 Fed. Reg. 7185, 7455 (Feb. 5, 1993).

[101] *See, e.g.*, Consolidated Appropriations Act, 2018, Public Law 115-141, Div. H, Title II, 132 Stat. 348, 716-17 (2018).

The Department claims that federal health care refusal laws necessitate the rescission of these counseling requirements.[102] This is incorrect. The Church, Coats-Snowe, and Weldon amendments—the federal refusal laws cited by the Department—do not exempt entire entities from counseling requirements. In fact, of the cited laws, only the Church amendments address religious or moral objections to counseling at all. Under the Church amendments, an entity receiving federal funding may not discriminate against applicants for training or study that object to counseling—but the grantee entity must still make other arrangements to ensure that a patient is able to obtain counseling. This is intended to ensure patients can still access the information they need to obtain timely and appropriate care.

Congressional action indicates an intent for nondirective counseling and federal refusal laws to coexist. The statutory requirement that pregnancy counseling be nondirective[103] is reaffirmed by Congress annually with the full knowledge of the existence of federal health care refusal laws. Indeed, the same Congress passed both the initial requirement that counseling be nondirective and the Coats-Snowe amendment; the Weldon amendment was passed nearly ten years later, even as Congress continued to require that counseling be nondirective.[104] Moreover, the Department presents no data indicating that religious objections to compliance with both the counseling requirement and federal refusal laws have been a problem since the nondirective counseling requirement first went into effect. The Department cites to no court case that would indicate that these requirements have been unable to coexist. Laws are meant to be read in harmony wherever possible, and their peaceful coexistence for decades gives no indication that they cannot.[105] If anything, the proposed rule's ban on referrals violates the religious rights of those providers who feel a moral or religious obligation to provide patients with the standard of care. The Department's argument that federal refusal laws necessitate the rescission of the nondirective counseling requirement accordingly cannot stand.

The Department reaches far beyond its authority by attempting to overrule Congress. The proposed changes to the counseling requirements are arbitrary and capricious, and not in accordance with law.

b. The proposed physical separation requirements and reduced flexibility of funds are arbitrary and capricious and not in accordance with law

The NPRM advances a radical departure from the time-tested approach of prorating any costs shared between Title X and non-Title X services while requiring strict financial separation of the costs of abortion services. Under the proposed rule, the Department proposes to extend separation requirements to the physical facilities of health care entities to demonstrate "objective integrity and independence" of the Title X project from abortion services. The proposed rule

[102] 83 Fed. Reg. 25506 (June 1, 2018).

[103] *See, e.g.*, Consolidated Appropriations Act, 2018, Public Law 115-141, Div. H, Title II, 132 Stat. 348, 716-17 (2018).

[104] Public Law 104-134 (Apr. 26, 1996); 42 USC § 238n; Public Law 108–447 (Dec. 8, 2004).

[105] *See, e.g.*, Watt v. Alaska, 451 U.S. 259, 267 (1981) (A court "must read [two allegedly conflicting] statutes to give effect to each if [it] can do so while preserving their sense and purpose.").

would grant the Secretary unchecked discretion to determine whether sufficient separation between programs exists, based on a non-exclusive list of factors: (1) the existence of separate, accurate accounting records; (2) the "degree of separation from facilities" (including waiting rooms, entrances and exits, and shared phone numbers) in which prohibited activities, including abortion and abortion referrals, occur and the "extent of such prohibited activities;" (3) separate personnel, workstations, and health care records; and (4) the degree to which signs identifying the Title X program are present and signs referencing abortion are absent.[106] The Department fails to adequately justify why such a radical change is necessary, and the proposed changes are likely unworkable.

The Reagan-era separation requirements, which are nearly identical to the proposed rule, were never fully implemented, and there is no evidence that the rules can or will work operationally. To the contrary, all evidence points towards the unworkability of these rules—as the Department itself acknowledged when it rescinded the 1988 rule: "[T]he practical difficulty of drawing lines in this area, both as experienced prior to 1988 and as evident in the history of the gag rule itself, suggests that this legal interpretation is not likely ever to result in an enforceable compliance policy that is consistent with the efficient and cost-effective delivery of family planning services."[107] The proposed rule advances a number of factors the Secretary may, in their discretion, consider in determining whether an organization sufficiently separates Title X and abortion services. But as the Department has recognized regarding the near-identical factors advanced in 1988 "the fundamental measure of compliance under that section remained ambiguous."[108] The requirement is in no way objective, because it is dependent upon the Secretary's interpretation at any given time, nor does it establish any kind of discernible standard for grantees to follow. Coupled with this administration's apparent hostility towards health care providers who perform abortions, this requirement ensures that virtually every affected entity would feel compelled to undergo a complete and total physical separation in order not to run afoul of the Secretary's totality of the circumstances analysis.

Such a complete transformation would result in excessive costs to providers that could force them to significantly raise the cost of care, to turn away Title X patients, or even to shutter their doors completely. In response to the Reagan-era proposed rule, small and rural clinics commented that they "cannot afford to operate separate facilities or to employ separate staff for these services without substantially increasing the prices of [. . .] services."[109] As a result, clinics would be unable to provide as many individuals with free or low-cost family planning services.

Compounding the financial burden on service providers, the proposed rule imposes additional strict limitations on the use of Title X funding. The NPRM proposes that at least 50% of Title X funds be spent on direct services; the other 50% is restricted to costs that are not shared with programs that provide abortion services. This means that many critical infrastructure costs can no longer be covered by Title X services unless there is complete physical separation. Because other

[106] 83 Fed. Reg. 25532 (June 1, 2018).

[107] 65 Fed. Reg. 41276 (July 3, 2000).

[108] *Id.* at 41276.

[109] *Id.* at 41275.

federal funding sources do not allow the use of funds for infrastructure costs, Title X funds provide a critical part of a clinic's funding portfolio that may cover infrastructure costs that make the difference between whether or not a clinic can keep its doors open. Many grantees would be faced with the impossible choice of forgoing Title X funds and potentially closing completely or accepting Title X funds and discontinuing certain non-Title X services. This outcome is contrary to legislative intent given Congress' explicit assertion at the time of Title X passage that it does not intend the legislation "to interfere with or limit programs conducted in accordance with State or local laws and regulations which are supported by funds other than those authorized under this legislation."[110] It is arbitrary and capricious to enact regulations that would force service providers vital to the Title X program to close their doors to Title X patients.

The proposed rule would arbitrarily reverse course on a system that has been in place for nearly twenty years, with no evidence supporting the necessity for change. The Department merely speculates that there may be the potential for a misuse of funds, but fails to show that it is actually a systemic problem. In fact, the Department can point to only a handful of individual cases that identified a misuse of Title X funds, and those cases were properly identified and adjudicated under the current system. The current structure of pro-rating costs between Title X and non-Title X activities ensures that Title X funding does not go towards programs that provide abortion care, as required by the statute.

The proposed rule would create a system that would undermine the purpose of the very program it purports to implement. Title X's purpose is to provide free or low-cost reproductive health care to those who cannot afford it[111]—but the proposed requirements could undermine many providers' ability to provide Title X services.

c. The proposed rule's regulation of referrals is arbitrary and capricious, and not in accordance with law

The proposed rule's extensive, unjustified restrictions on a provider's ability to refer a patient for care outside the Title X program are arbitrary and capricious, and dangerous for women's health.

The proposed rule would rescind the current requirement that Title X recipients must provide abortion referrals upon request, making abortion referrals optional even when a patient requests the information. The proposed rule would also ban all direct abortion referrals except in medical

[110] 116 CONG. REC. 39873 (1970) (At the time of passage, Title X's legislative history explains in great detail the need for expanded family planning services for low-income individuals, citing to the "extreme shortage" of services for that population across the country. "This legislation is designed to make comprehensive, voluntary family planning services, and information relating thereto, readily available to all persons in the United States desiring such services. [. . .] The bill [. . .] will enable us to make services more readily available to the more than 5 million poor and near-poor women who, for the most part, have not been given the opportunity to avail themselves of family planning services in order to exercise their right to determine the size and spacing of their families. [. . .] These new authorizations, when added to funds currently committed under title V, would make it possible to reach President Nixon's goal of serving all 5.4 million women in need within the next 5 years.").

[111] S. Rep. No. 91-1004 (1970).

emergency, and imposes a complicated set of requirements surrounding referrals for pregnant people:

If a patient who "clearly states that she has already decided to have an abortion" requests a referral for an abortion, a medical doctor may provide only a mixed list of "comprehensive health service providers" who provide prenatal care, some, but not all of which also offer abortion.[112] The list may not identify which providers on the referral list offer abortion care.[113] To patients that do not explicitly request an abortion referral or have not made up their mind to have an abortion, providers may give only a list of prenatal care providers. At the same time, providers are *required* to refer all pregnant patients for "appropriate prenatal and/or social services," and to "provide[] . . . information necessary to protect her health and the health of the unborn child until . . . the referral appointment is kept," regardless of the patient's wishes for information or referral.[114] These requirements are arbitrary and capricious, and not in accordance with law.

Congress has repeatedly made clear that any counseling under Title X must be nondirective. "Nondirective counseling," as the proposed rule itself points out, is the provision of "information on all available options without promoting, advocating, or encouraging one option over another."[115] Yet, the proposed rule imposes a *mandatory* referral for prenatal care for all pregnant patients. Mandatory referrals for prenatal care are a direct violation of that principle—especially when they must be made despite a patient's wishes to the contrary. It is also a violation of the essential legal and ethical principle of voluntary, non-coercive care in all Title X services.

The proposed rule also fails to explain how the prohibition on identifying the providers who also perform abortion advances the principle of nondirective counseling. If anything, requiring providers to withhold such information from patients is mis-directive and would cause patient confusion. A patient is likely to assume that her provider gives her accurate information. Even if the patient knew that the list is mixed, she would be forced to spend additional time and research to identify the relevant referral information, which is information that she should be able to obtain from her provider as a matter of right. Moreover, the NPRM proposes that a mixed list of referrals that includes providers offering abortion services may only be provided to a patient who "clearly states that she has already decided to have an abortion." This is a highly subjective standard, and as such would be nearly impossible to implement consistently and fairly.

The proposed rule's requirement that providers give patients who are undecided only a list of prenatal care providers who do not perform abortions presents another clear violation of the requirement that counseling be nondirective. Allowing providers to give a mixed list that identifies both prenatal and abortion care providers to a patient who is still undecided would give

[112] 83 Fed. Reg. 25531 (June 1, 2018).

[113] *Id.*

[114] *Id.*

[115] *Id.* at 25512, fn.41.

the patient "information on all available options without promoting, advocating, or encouraging one option over another,"[116] the very definition of nondirective counseling. Instead, the list intentionally steers undecided patients away from abortion, undercutting their agency and decision-making abilities. And the proposed rule does not even attempt to justify this violation of patients' rights, as it provides no explanation as to how the new requirements would somehow enhance, rather than harm, the health of women. These requirements are arbitrary and capricious, and in violation of federal law requiring that counseling be nondirective.

Additional aspects of the restrictions on abortion referrals are arbitrary and capricious. The NPRM proposes that only "a medical doctor" may provide a list of referrals that includes providers who also perform abortion. The proposed rule provides no data or justification for excluding non-physician medical staff who would be qualified to provide referral information, such as registered nurses or physician assistants. There is a nationwide shortage of physicians, especially OB/GYNs.[117] Moreover, research shows that medical services paid for by public funding sources are disproportionately more likely to be provided by physician assistants and nurse practitioners than physicians, who are more likely to care for privately insured patients.[118] One reason for this disparity is likely that there is a proportionally higher distribution of physician assistants and nurse practitioners, with a lower distribution of physicians, in rural versus in urban areas.[119] Rural areas, as they are typically underserved areas, are in turn a key target for Title X services. This provision could therefore effectively eliminate or substantially delay abortion referrals, and thus access, for a large portion of the Title X population.

The proposed rule also claims that the existing requirement to refer for abortion care violates federal refusal laws and must be rescinded. But the Department cites to no court case or other evidence that would indicate that these requirements have been unable to coexist. That certain individuals or entities may be exempted from the requirement to provide care does not

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[116] *Id.*

[117] The United States faces a dangerous shortage of physicians, especially in rural areas. *See, e.g.*, Sarah Mann, *Research Shows Shortage of More than 100,000 Doctors by 2030*, AMERICAN ASSOCIATION OF MEDICAL COLLEGES NEWS (Mar. 14, 2017), https://news.aamc.org/medical-education/article/new-aamc-research-reaffirms-looming-physician-shor/; Kirk Siegler, *Doctor Shortage In Rural Arizona Sparks Another Crisis In 'Forgotten America*', NPR (July 14, 2017), https://www.npr.org/sections/health-shots/2017/07/14/535792864/doctor-shortage-in-rural-arizona-sparks-another-crisis-in-forgotten-america ("the shortage, especially of primary care providers, has grown steadily worse in recent years. According to the National Rural Health Association, rural areas could be short 45,000 doctors by 2020."); Annalisa Merelli, *America is running out of OB/GYNs*, QUARTZ (June 29, 2018), https://qz.com/1315458/the-link-between-medicaid-and-americas-shortage-of-ob-gyns/ ("Half the counties in the US don't have any practicing OB-GYNs. The American College of Obstetricians and Gynecologists (ACOG) puts the current shortage at 6,000 to 9,000 OB-GYNs countrywide, a number it's expecting to balloon to 22,000 by 2050.").

[118] Joseph Benitez et al., *Payment source and provider type in the US healthcare system*, 28 JOURNAL OF THE AMERICAN ACADEMY OF PAS (2015), https://journals.lww.com/jaapa/fulltext/2015/03000/Payment_source_and_provider_type_in_the_US.8.aspx.

[119] *See, e.g.*, *2016 Family Planning Annual Report* (finding that in 2016, 3,550 full- time equivalent (FTE) clinical services providers (CSPs) delivered Title X-funded care. Nurse practitioners, certified nurse midwives, and physician assistants accounted for 71% of total CSP FTEs, followed by physicians (22%) and registered nurses with an expanded scope of practice (7%)); *see also* Joseph Benitez et al., *Payment source and provider type in the US healthcare system*, 28(3) JOURNAL OF THE AMERICAN ACADEMY OF PAS (March 2015), https://journals.lww.com/jaapa/fulltext/2015/03000/Payment_source_and_provider_type_in_the_US.8.aspx;

necessitate eliminating the requirement for others as well. Such a scheme would run contrary to the framework envisioned by federal refusal laws. These laws are premised on creating an exemption or opt-out for individuals, which presumes a system in which abortions are referred for or provided in the first place. The requirement to refer for abortion upon request was intended to ensure timely access to health care services. Eliminating the abortion referral requirement is arbitrary and capricious, and would be harmful for women.

For the reasons described above, the changes to abortion referral requirements are arbitrary and capricious, and contrary to law, and therefore must be withdrawn.

d. The proposed changes to the selection criteria are arbitrary and capricious, and would allow HHS to reshape the Title X network with unchecked discretion

Under current grant applicant criteria, which have remained unchanged since they were first promulgated in 1971, reviewers must consider the following criteria for a proposed Title X project:

> (1) The number of patients, and, in particular, the number of low-income patients to be served;
>
> (2) The extent to which family planning services are needed locally;
>
> (3) The relative need of the applicant;
>
> (4) The capacity of the applicant to make rapid and effective use of the federal assistance;
>
> (5) The adequacy of the applicant's facilities and staff;
>
> (6) The relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project; and
>
> (7) The degree to which the project plan adequately provides for the requirements set forth in these [Title X] regulations.[120]

By utilizing these criteria, the network of grantees and subrecipients has reliably delivered high-quality services. Decades of experience in the program has given Title X participants a deep expertise in delivering family planning services to their communities, with proven results. The quality of the Title X program is undisputed.[121] The revised criteria proposed by this rule would

[120] 42 C.F.R. § 59.7(a)(1-7).

[121] *See, e.g.*, Kinsey Hasstedt, *Title X: An Essential Investment, Now More than Ever*, 16 GUTTMACHER POLICY REVIEW (2013), https://www.guttmacher.org/gpr/2013/09/title-x-essential-investment-now-more-ever; C.I. Fowler et al., *Family Planning Annual Report: 2015 National Summary*, RTI INTERNATIONAL (2015), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2015.pdf; Kiersten Gillette-Pierce & Jamila Taylor, *The Threat to Title X Family Planning: Why it Matters and What's at Stake for Women*, CENTER FOR AMERICAN PROGRESS (Feb. 9, 2017), https://www.americanprogress.org/issues/women/reports/2017/02/09/414773/the-threat-to-title-x-family-planning/.

dilute the quality of providers within the network and make reproductive health specialists less competitive—all without any explanation of why new criteria are necessary or would improve the provision of care when the current criteria are already very successful in selecting quality providers.

The proposed rule would radically change this time-tested assessment by reducing the number of criteria from seven to four criteria and adjusting the criteria to prioritize new and non-traditional efforts over proven techniques and experienced providers. The proposed rule eliminates the requirement that independent reviewers consider the adequacy of an applicant's facilities and staff. By dropping this requirement, the proposed rule would allow lower-quality applicants, such as fake women's health centers that do not employ licensed medical providers, to apply for funding, while reducing the competitiveness of applications from proven, high-quality providers. The Department gives no justification or rationale for eliminating a requirement that helps ensure quality care. Gone also is the requirement to consider the relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project.

The remaining criteria are modified to be internally inconsistent and more vague. For example, the proposed §59.7(c)(3) requires applicants to consider the "number of patients to be served," while simultaneously requiring them to target areas that are more sparsely populated. The directive is unclear on how applicants should both maximize the number of patients they can reach and serve areas with fewer potential patients. Proposed section 59.7(c)(4) would link consideration of the extent to which family planning services are needed locally to the entirely unrelated criteria of how the applicant "proposes innovative ways to provide services to unserved or underserved patients." Objective panel reviewers are given zero guidance on how to weigh each of the criterion's requirements against each other to produce a score for the overall category.

The criteria in proposed §59.7(2) would link consideration of the applicant's capacity to "make rapid and effective use" of grant funds to their use "including and especially among a broad range of partners and diverse subrecipients . . . and among non-traditional Title X partnering organizations." The Department provides no justification or rationale for why the Title X program, as a highly successful, effective and high-quality program, requires the introduction of new and inexperienced partners. The wording of the proposed provision also appears to require that projects must each year attempt to partner with new organizations that have not yet participated in the Title X program—an unworkable proposition that not only would greatly reduce the capacity and quality of the Title X network by shunning tried and true, high-capacity networks, but would also quickly become unimplementable because there are presumably not an unlimited number of providers new to Title X to partner with each year. The criterion provides no guidance to panel reviewers on how to weigh "rapid and effective use" of funds against the extent to which these funds are used among non-traditional Title X partnering organizations. The Department provides no basis to show that the promotion of nontraditional Title X partners would serve the purpose and text of the statute. By merging criteria and failing to articulate how a review board should apply them, the proposed rule exhibits a lack of transparency that could undermine the program's integrity.

The proposed rule would also grant the Department unchecked discretion to dismiss applications before they even reach the objective review panel stage—before an application may even be evaluated based on the criteria for selection of grant recipients. Proposed Section 59.7(b) requires applicants to "clearly" address how their proposal would fulfill the regulation's requirements in order to advance to the competitive review process. It also requires each applicant to describe how they will achieve "affirmative compliance with each provision." These provisions allow for an inappropriately subjective compliance check prior to advancing applications to the objective review stage, and establishes a scheme that could be subject to abuse.

In other words, only if HHS, using undisclosed criteria, deems an application to have sufficiently described their future compliance with the regulation would HHS permit the application to be assessed by objective reviewers. This renders an objective review board toothless, because HHS can preemptively withhold applications from their review. At the same time, HHS has also designated itself as the ultimate decisionmaker even after the review board makes its recommendations.[122] The resulting scheme allows the Department to arbitrarily dismiss any applicant for any reason, both before and after the competitive review process. Such a system is arbitrary and capricious, and the proposed rule advances no justification for a scheme that allows the Department unchecked discretion.

e. The proposed shift away from medically-approved family planning methods is arbitrary and capricious, and will reduce the quality of care provided

The NPRM proposes arbitrary and capricious changes to the required range of family planning methods that would radically limit the options and quality of care available to low-income women under the Title X program.

Currently, Title X projects are required to "[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)."[123] The proposed rule would make two significant changes: (1) rescind the term "medically approved" from the requirement for "a broad range of acceptable and effective medically approved family planning methods;" and (2) add adoption as a family planning service.

For over four decades, Title X regulations have required recipients to provide "medically approved" family planning methods.[124] Providing no evidence to support their claim, the Department speculates that the phrase "may cause confusion about the type of family planning methods or services that a project may or should provide, and the type of approvals (if any) necessary before a Title X project can provide such method or service."[125] The Department fails to demonstrate that any project in the program's several decades of including this requirement

[122] *See* Office of the Assistant Secretary for Health, Office of Population Affairs, *Announcement of Anticipated Availability of Funds for Family Planning Services Grants* 44 (Feb. 2018).

[123] 42 CFR § 59.5(a)(1).

[124] This requirement has been a part of Title X regulations since 1971. 36 Fed. Reg. 18466 (Sept. 15, 1971).

[125] 83 Fed. Reg. 25515 (June 1, 2018).

has ever experienced confusion over the term. Instead, the Department appears to use "confusion" as a pretext to shift the program away from evidence-based medical services towards a program focused on disproven behavioral changes promoted by nonmedical, anti-choice organizations.

The proposed definition of "family planning" is a powerful indicator of this shift:

> *Family planning* means 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. These means 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) [. . .].[126]

The shift towards abstinence-focused methods is especially troubling given recent research reaffirming that abstinence-only policies are ineffective and can even be harmful, especially for young people. According to an expert review, "considerable scientific evidence accumulated over the past 20 years has found that [abstinence-only] programs 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."[127]

The addition of adoption as a Title X service offers yet another indication of the program's shift away from evidence-based health services.[128] The Department offers no justification for this addition, or how it would enhance the health of medically underserved low-income individuals in the Title X program. Combined with the rescission of the requirement for "medically approved" family planning methods, this opens the door for an entirely different and concerning "broad" range of services that could qualify as a Title X project: under the revised requirements, it is conceivable that a "broad range" of family planning methods could consist entirely of entities that provide abstinence-only education, natural family planning, and adoption, but none of the family planning drugs or devices most patients expect as options in a family planning visit. Not only does the proposed rule fail to provide a reason for this substantial shift in program requirements, but it is also contrary to the intent of the law, which sought to address the "extreme shortage" of health care services for low-income individuals and was "designed to make *comprehensive*, voluntary family planning services [and information] readily available" (emphasis added).[129]

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[126] 83 Fed. Reg. 25529 (June 1, 2018).

[127] Guttmacher Institute, *News Release: Abstinence-Only-Until-Marriage Programs Are Ineffective and Harmful to Young People, Expert Review Confirms* (Aug. 22, 2017), https://www.guttmacher.org/news-release/2017/abstinence-only-until-marriage-programs-are-ineffective-and-harmful-young-people.

[128] *See* 83 Fed. Reg. 25529 (June 1, 2018).

[129] S. Rep. No. 91-1004 (1970).

Finally, the Department clarifies that "conscience concerns may be taken into account when grantees or subrecipients determine which methods they will offer in the scope of their services."[130] This explicitly invites grantees to limit access to care based on religious or moral beliefs, contravening the intent and purpose of the underlying authorizing statute itself.

The new requirements are arbitrary and capricious, and contravene the intent of the underlying statute.

f. The proposed definition of "low-income family" is arbitrary and capricious, not in accordance with law, and contravenes the intent of both the Affordable Care Act and Title X

Under interim final rules issued by HHS in October 2017 (currently under a nationwide injunction), employers with religious or moral objections to birth control may refuse to provide contraceptive coverage for their employees who would otherwise be eligible to receive this coverage copay-free under the Affordable Care Act ("ACA").[131] If these interim final rules go into effect, countless women could be unable to obtain copay-free coverage for their contraception. The Department makes a misguided attempt to fill the coverage gap it has created by including these women in the definition of "low-income family." However, this attempt would not solve the problem created by the Department, and it is both arbitrary and capricious and contrary to law.

Title X was designed to serve the low-income population of the United States, and requires by law that grantees certify that "priority will be given. . . to the furnishing of [family planning] services to persons from low-income families."[132] The Secretary is authorized to define "'low-income family' in accordance with such criteria as he may prescribe so as to insure that *economic status shall not be a deterrent to participation* in the programs assisted in this title."[133] (emphasis added). In giving this directive, Congress clearly outlined the bounds of the Secretary's discretion in defining "low-income." The proposed rule, however, would allow women who are denied birth control coverage, regardless of their economic status, to be considered low-income. This is plainly contrary to law.

Moreover, the proposed definition of "low-income family" does not mandate that Title X grantees consider these women as eligible for Title X services, and thus would not guarantee that women can access contraceptive care through the program. The proposed rule states that

[130] 83 Fed. Reg. 25516 (June 1, 2018).

[131] Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47792 et seq. (Oct. 13, 2017); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47656 et seq. (Oct. 13, 2017); enjoined by Pennsylvania v. Trump, 281 F. Supp. 3d 553 (2017) and California v. HHS, 281 F. Supp. 3d 806 (2017).

[132] 42 U.S.C § 300a-4(c)(1).

[133] 42 U.S.C § 300a-4(c).

> [w]ith respect to contraceptive services, a woman *can* be considered from a 'low-income family' if she has health insurance coverage through an employer which does not provide the contraceptive services sought by the woman because it has a sincerely held religious or moral objection to providing such coverage.[134] (emphasis added).

Thus, Title X grantees have discretion to deny free or low-cost services to a woman who would not otherwise qualify for Title X services.

Under current Title X guidelines, an individual qualifies for free services if they earn less than 100% of the most recent Federal Poverty Guidelines, or are otherwise unable to pay for services.[135] Individuals with an income above 100% of the Poverty Guidelines are charged discounted fees based on their incomes, up to 250% of the Poverty Guidelines.[136] The proposed definition does not guarantee that women whose employers refuse to provide coverage, but would not otherwise qualify for Title X services would be eligible for free—or even low-cost—contraceptive services. Because the addition of these women is optional, many clinics may default to only serving those of these women who are already within their sliding scale or qualify for free services—those who, private insurance or not, would already qualify for Title X services. Accordingly, this proposal fails to put these women on equal footing with those who have copay-free coverage under the ACA. In passing the Affordable Care Act, Congress understood and intended for cost-free contraception and family planning services to be included as an integral and essential part of women's preventive care, [137] intending to improve women's health care by providing "affordable family planning services" to "enable women and families to make informed decisions about when and how they become parents."[138] The Department's half-hearted attempt at accomplishing this here does not absolve it of its culpability for the

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[134] 83 Fed. Reg. 25530 (June 1, 2018).

[135] *Id.* at 25529.

[136] *See* OPA Program Policy Notice: 2016-11, *Title X Program Policy Notice* 2 (Nov. 22, 2016), https://www.hhs.gov/opa/sites/default/files/Title-X-Program-Policy-Notice-Integrating-with-Primary-Care-Providers.pdf.

[137] *See* 155 CONG. REC. S12026 (daily ed. Dec. 1, 2009) (statement of Sen. Boxer) (noting the importance of reforming the health care system to "[i]ncrease[] health insurance coverage for women," and "require[] coverage of comprehensive reproductive health services."); *see also* 77 CONG. REC. E1199-1200 (daily ed. May 19, 2009) (statement of former Rep. Moran) (noting an increase in women who no longer have money to pay for medical care and that "[t]hese women are literally choosing between a month of birth control and bus fare."); Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39,887. Congress required that "all health plans cover comprehensive women's preventive care and screenings . . . at little or no cost to women." 155 CONG. REC. S12025 (daily ed. Dec. 1, 2009) (statement of Sen. Boxer); *see also* 155 CONG. REC. S12114 (daily ed. Dec. 2, 2009) (statement of Sen. Feinstein) ("[Preventive care] may include mammograms, Pap smears, family planning, screenings to detect postpartum depression, and other annual women's health screenings.").

[138] 155 CONG. REC. S12052 (daily ed. Dec. 1, 2009) (statement of Sen. Franken); *see, e.g.*, 155 CONG. REC. S12671 (daily ed. Dec. 8, 2009) (statement of Sen. Durbin) ("Today, there are 17 million women of reproductive age in America who are uninsured. This bill will expand health insurance coverage to the vast majority of them, which . . . will reduce unintended pregnancies and reduce abortions."); 156 CONG. REC. H1893 (daily ed. Mar. 21, 2010) (statement of Rep. Kaptur) ("This legislation will help millions of women obtain health coverage and thus reduce abortion by enhancing broad coverage options for women's and children's health.").

exemptions it carved out in the interim final rules. To the contrary, this attempt fails yet again to guarantee women's access to the ACA's contraceptive coverage benefit.

Furthermore, the Title X program is not designed to absorb the needs of insured individuals who are at a higher income level. At its present funding levels, the Title X program is already starkly underfunded. To adequately serve the low-income uninsured and underinsured population, Title X requires an estimated funding level of $737 million.[139] Title X is currently funded at only $286.5 million, less than 40% of what is needed.[140] The proposed rule accurately notes that the number of Americans at or below the poverty level, and thus in need of Title X services, has increased.[141] The impact of providing free or low-cost care to even a small percentage of women at higher income levels would put a significant strain on Title X, a program that is chronically underfunded even without this additional influx of patients. The shortage of reproductive health care providers, especially in rural areas, adds additional stress to the Title X system and means that many women may be unable to obtain services. As a result of this proposed rule, an additional number of health care providers may cease providing Title X services, creating a greater shortage and a bottleneck for patients to obtain services at all. The introduction of additional eligible patients would only exacerbate this shortage. This expanded definition would impose a burden on an already severely underfunded program and would divert resources and services intended for those most in need.

The Center supports and advocates for copay-free contraceptive access for all, but the proposed definition does not advance this mission. Instead, it would divert services from those who need it most, and reduce the quality of care for newly eligible women who should, by right, have contraceptive coverage through the ACA. The Department makes no attempt to justify how the proposed definition is necessary or furthers the goals of the Title X statute. As a result, the proposed definition is not only bad policy, but also arbitrary and capricious, and not in accordance with law. The Department must withdraw the proposed rule and rescind the currently-enjoined Interim Final Rules on contraceptive coverage.

g. *The proposed rule violates the APA because it is not justified by underlying facts and data, and it fails to engage in an appropriate cost-benefit analysis*

The NPRM is arbitrary and capricious because it fails to adequately assess the costs imposed by this proposed rule by underestimating or omitting certain quantifiable costs and completely ignoring the significant additional costs that would result from delayed or denied care. The proposed rule also fails to demonstrate quantifiable benefits. Executive Order 13563 requires that before promulgating a rule each agency make a "reasoned determination that its benefits justify its costs."[142] The Order also requires each agency "to use the best available techniques to

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[139] Euna M. August et al., *Projecting the Unmet Need and Costs for Contraception Services After the Affordable Care Act*, 106 AM. J. PUBLIC HEALTH 334 (Feb. 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4985850/.

[140] National Family Planning & Reproductive Health Association, *Title X Budget & Appropriations*, https://www.nationalfamilyplanning.org/title-x_budget-appropriations.

[141] 83 Fed. Reg. 25508 (June 1, 2018).

[142] Exec. Order No. 13563, 76 Fed. Reg. 3821 at Sec. 1(b) (Jan. 18, 2011).

quantify anticipated present and future benefits and costs as accurately as possible."[143] Despite these well-established requirements, HHS has failed to conduct a reasoned cost-benefit analysis for this proposed rule, omitting substantial and obvious costs from its analysis.

First, the NPRM provides no basis for its extremely low estimate of the cost of compliance with physical separation requirements. The proposed rule estimates that the first-year compliance cost per service site would average $20,000, at a program-wide cost of $24.38 million.[144] The rule's proposed physical separation requirements grant the Secretary discretion to determine whether a grantee is in compliance, based on a series of factors that include whether the grantee has separate waiting rooms, entrances and exits, personnel, work stations, health record systems, websites, accounting records, and signage. Presumably, a grantee would be required to fulfill several of these options in order to be considered in compliance. However, the Department provides no guidance as to which factors it considered to make this estimate. Many of these factors—particularly those that most obviously indicate physical separation, such as separate staff, separate entrances and exits, and separate health record systems—are extremely costly. Indeed, even hiring one additional full-time staff member would easily outstrip the Department's estimated cost of $20,000, yet presumably be insufficient on its own to demonstrate compliance. The cost of implementing an additional electronic health record system would cost tens of thousands, if not hundreds of thousands of dollars for large practices—in addition to the monthly maintenance costs each system incurs.[145] Physical alterations to the building layout—such as creating additional waiting rooms or additional entrances and exits—can also run thousands of dollars. The proposed rule appears to ignore these and other significant costs entirely.

Because the proposed rule gives the Secretary complete discretion on how to weigh the proposed factors to determine compliance, and because critical funding is at stake, grantees likely would feel compelled to undergo a complete physical separation. Nonetheless, the Department fails to consider the full cost of a complete physical separation—information it had readily available from the comments to the 1988 rulemaking. Commenters noted that there would be a substantial cost in duplicating facilities, personnel, etc., which would result in an increase in operating costs for both facilities, that would "render Title X funds uneconomic to accept" with the practical effect of barring them from the program.[146] Commenters noted that the impact would fall "particularly severely on rural areas, where existing resources are scarce and where distance is a

[143] Exec. Order No. 13563, 76 Fed. Reg. 3821 at Sec. 1(c) (Jan. 18, 2011).

[144] The real-life cost of implementing electronic health records (EHRs) in an average five-physician primary care practice, operating within a large physician network committed to network-wide implementation of electronic health records, is about $162,000 with an additional $85,500 in maintenance expenses during the first year. [. . .] The cost of implementing the EHR system was $32,409 per physician through the first 60 days after system launch[. . .]. One-time hardware costs were $25,000 per practice for Internet switches, cables, and wireless Internet connections—plus approximately $7,000 per physician for personal computers, printers, and scanners. Software and maintenance costs (which began at implementation) came to approximately $17,100 per physician annually. 83 Fed. Reg. 25525 (June 1, 2018).

[145] *See* Neil S. Fleming et al., *The Financial and Nonfinancial Costs of Implementing Electronic Health Records in Primary Care Practices*, 30 HEALTH AFFAIRS (Mar. 2011), https://doi.org/10.1377/hlthaff.2010.0768.

[146] 53 Fed. Reg. 2938-39 (Feb. 2, 1988).

major barrier to service."[147] At the time, commenters submitted estimates of the cost of complying with the physical separation at up to $150 million for the program in total. Due to inflation and the rise in prices since complete separation was last proposed, the cost today would likely be substantially higher—and a far cry from the proposed rule's estimate of $24.38 million. These costs will be more than many Title X projects can bear, on top of the NPRM's new restrictions on spending for infrastructure, and will undoubtedly lead to some providers leaving Title X for economic reasons alone and, as a result, lay off staff, reduce hours, or close their doors altogether.

Second, the proposed rule fails to quantify the full range of administrative compliance costs it would impose on Title X grantees. For example, with regard to the required documentation of compliance requirements, the proposed rule considers time spent in recording the required information. However, the proposed rule fails to acknowledge that compliance would require changes to electronic medical systems and additional time in training and management that far exceed the limited costs estimated in the NPRM. Further, the inclusion of women into the Title X program who are privately insured, but whose employers or insurers deny them contraceptive coverage, adds an additional administrative burden. Title X is set up to provide free contraceptive coverage to individuals who earn less than 100% of the Federal Poverty Guidelines, and sliding scale costs to those who are between 100%-250% of the Federal Poverty Guidelines. To offer free or low-cost contraceptive services to women who would not qualify for the program based on their income, grantees would need to create a modified pay scale for contraceptive services for these women. Finally, there is also an administrative cost associated with the proposed rule's mandatory referrals for prenatal care for all pregnant people. The rule requires providers to give referrals even against a woman's wishes, wasting valuable staff time and resources.

Third, the proposed rule entirely disregards the enormous costs it would impose on women's health care and their economic security. For example, the nonpartisan Congressional Budget Office has estimated that if Planned Parenthood exits the program, fifteen percent of low-income people in rural or underserved areas would lose access to care, and has projected several thousand additional births in the Medicaid program in the following year.[148] The proposed rule would also force women to bear the cost of mandatory prenatal referrals they do not want or need, possibly requiring them to pay fees for canceling or skipping unwanted appointments. Women would likely also experience a greater number of service denials by newly eligible religious entities that refuse to provide referral information for contraception or abortion at all, or refuse to counsel on contraception or abortion. For patients who obtain care with sliding scale fees, health care costs would increase substantially, including for cancer screenings, birth control and STI testing as clinics increase their fees to compensate for the immense compliance costs the proposed rule would impose.

Even where providers would like to provide the prevailing standard of care, the rule would prohibit them from providing comprehensive options and referral information, resulting in

[147] *Id.* at 2939.

[148] Paul J. Weber, *Get by without Planned Parenthood? One Texas effort stumbles*, ASSOCIATED PRESS (Mar. 14, 2017), https://apnews.com/f7645d59944d47228f2eb195a35a19a4.

additional costs because of service delays and, for some women, unavailability of needed care. As discussed in detail above, the proposed rule's ban on referrals could force women seeking an abortion to spend additional time researching whether providers on the list perform abortions. In the worst-case scenario, a woman may trust her provider's referral list as an accurate list of abortion providers, and end up paying co-pays to see a provider who turns out not to perform abortions.

Well-documented research shows the significant health care costs women experience when care is delayed or denied.[149] Service denials result in delays for patients, who must then spend additional time and resources searching for a willing provider. Delays also have the effect of increasing the overall cost of an abortion. The average first-trimester abortion costs $470; the cost increases with each additional week in the second trimester, for example, the average cost for an abortion at 20 weeks is $1500.[150] Delays raise not just the cost of the procedure, but also incidental costs such as additional and farther travel to access a clinic, including related expenses such as lost wages and childcare. As a result, health care denials that result in a delay in care can significantly drive up the cost of care for a woman seeking an abortion.

Cutting off access to abortion care can also have severe economic consequences. Recent research found that women who were denied a wanted abortion had higher odds of being in poverty six months after denial than did women who received abortions, and that women denied abortions were also more likely to be in poverty for four years following denial of abortion.[151] A clear consequence of this proposed rule is that many women seeking an abortion may be unable to obtain care or may experience significant, costly delays in obtaining care.

The Department makes no attempt to quantify—and in fact does not even acknowledge—these broader medical, social, and economic costs imposed by the proposed rule. HHS's priorities are clear: to defund grantees who separately also provide abortion care, no matter the consequence. The NPRM's failure to properly consider the very real and severe costs to women that could result from this regulatory proposal, while completely failing to articulate any quantifiable benefit, constitutes arbitrary and capricious rulemaking, and therefore the proposed rule should be withdrawn in its entirety.

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[149] *See, e.g.,* National Women's Law Center, *When health care providers refuse: The impact on patients of providers' religious and moral objections to give medical care, information or referrals* (Apr. 2009), https://www.nwlc.org/wp-content/uploads/2015/08/April2009RefusalFactsheet.pdf.

[150] Guttmacher Institute, *News Release: Second-Trimester Abortions Concentrated Among Certain Groups of Women* (Dec. 16, 2011), https://www.guttmacher.org/news-release/2011/second-trimester-abortions-concentrated-among-certain-groups-women.

[151] Diana Greene Foster et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 108 AM. J. PUB. HEALTH 407 (2018), https://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2017.304247.

V. Gag rules that prevent providers from giving pertinent health information are never in the best interest of the patient, and are uniformly opposed by medical professionals

Medical professionals and patient advocates know that preventing providers from giving patients honest and comprehensive health information is never in the best interest of the patient. Even the Supreme Court has acknowledged the importance of a health care provider's ability to counsel to their best medical judgment: "'Doctors help patients make deeply personal decisions, and their candor is crucial.' Throughout history, governments have 'manipulat[ed] the content of doctor-patient discourse' to increase state power and suppress minorities."[152] Pertinently, the Court has observed that as with other kinds of speech, regulating the content of professionals' speech "pose[s] the inherent risk that the Government seeks not to advance a legitimate regulatory goal, but to suppress unpopular ideas or information"[153] History has shown that when providers are subject to gag rules, patients are harmed.[154]

Nowhere is this more evident, nor more relevant to the present issue, than in the case of the "global gag rule." Recently reinstated and expanded by the Trump administration, the rule prohibits nongovernmental organizations that receive U.S. global health assistance funds from using this money or any of their own funds from any other sources to perform or actively promote abortion as a "method of family planning."[155] Similar to this proposed rule, the global gag rule prohibits providing referrals and counselling for abortion as "a method of family planning" and advocacy to make abortion safe and legal as "a method of family planning."[156] A 2011 study of the previous iteration of the global gag rule found that abortion rates *increased* across twenty African countries during the duration of the policy, even when controlled for a variety of potential confounding factors.[157] The former Ghanaian minister of health noted that the policy "results in more unwanted pregnancies, more unsafe abortions, and more deaths of women and girls. We who have seen those effects first-hand can no longer tolerate silence about

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[152] NIFLA v. Becerra, 138 S. Ct. 2361, 2374 (2018) (*citing* Wollschlaeger v. Governor of Florida, 848 F.3d 1293, 1328 (2017) (en banc) (W. Pryor, J. concurring)).

[153] NIFLA v. Becerra, 138 S. Ct. 2361 (2018) (*citing* Turner Broadcasting Systems, Inc. v. FCC, 512 U.S. 622, 641 (1994)).

[154] *See, e.g.*, National Partnership for Women & Families, National Physicians Alliance, Natural Resources Defense Council & Law Center to Prevent Gun Violence, *Politics in the Exam Room: A Growing Threat* (Oct. 2015), http://www.nationalpartnership.org/research-library/repro/politics-in-the-exam-room-a-growing-threat.pdf.

[155] Center for Reproductive Rights, *Factsheet: The Global Gag Rule and Human Rights* (Jan. 2018), https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/GLP-GGR-FS-0118-Web.pdf.

[156] *Id.*

[157] Eran Bendavid et al., *United States Aid Policy and Induced Abortions in Sub-Saharan Africa*, 89 BULLETIN OF THE WORLD HEALTH ORGANIZATION 873-80 (2011), http://www.who.int/bulletin/volumes/89/12/11-091660/en/ (The study controlled for variables such as fixed effects related to the country and the year of reporting, the women's place of residence and educational level, the use of modern contraceptives, and the receipt of funding for family planning activities from sources outside the United States.).

[its] tragic effects."[158] The global gag rule is a clear example of how restrictions on abortion counseling and referrals harm women.

State-level gag rules relating to gun safety, oil fracking and pharmacists have been consistently condemned by leading medical entities and organizations. For example, across the country, states have adopted gag rules that prohibit health care providers from providing comprehensive counseling on gun safety—even though such counseling is a standard practice for pediatricians and family physicians and despite overwhelming evidence demonstrating the effectiveness of gun safety counseling.[159] Such counseling is recommended by major medical societies such as the American Medical Association, American Academy of Pediatrics, American Academy of Family Physicians and American College of Physicians.[160] Moreover, the Department itself has come out in opposition to gag rules. In the context of pharmacist gag rules, the Department vowed that they would end gag clauses and "are committed to empowering patients with the information they need to make informed decisions about their care."[161] We agree that HHS should end gag clauses and allow informed decision-making for all patients, including pregnant people.

There is a consensus among the medical community that the proposed rule would violate medical ethics and be harmful for patients. Over 110 organizations—among them the American Psychological Association, the American Sexual Health Association, the HIV Medical Association, the National Hispanic Medical Association, and Physicians for Reproductive Health—recently co-signed a letter urging HHS to "reject calls for any iteration of the domestic gag rule," stating that "professional medical organizations…underscore informed consent as a cornerstone of medical care."[162] This stance is reflected in various associations' Code of Ethics,

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[158] *See* Ipas, *African health leaders, lawyers, women's advocates call for action to save women's lives from unsafe abortion* (Mar. 17, 2003), https://www.pambazuka.org/gender-minorities/africa-call-save-womens-lives-unsafe-abortion.

[159] *See, e.g.*, Teresa L. Albright & Sandra K. Burge, *Improving Firearm Storage Habits: Impact of Brief Office Counseling by Family Physicians*, 16 JOURNAL OF THE AMERICAN BOARD OF FAMILY PRACTICE 40 (2003) (finding that 64 percent of individuals who received verbal firearm storage safety counseling from their doctors improved their gun storage practices.).

[160] Law Center to Prevent Gun Violence, *Eleventh Circuit Upholds Florida Law Preventing Doctors from Asking About Gun Ownership* (July 21, 2014), http://smartgunlaws.org/eleventh-circuit-upholds-florida-law-preventing-doctors-from-asking-about-ownership-2.

[161] *See, e.g.*, Department of Health & Human Services, Centers for Medicare & Medicaid Services, *Unacceptable Pharmacy Gag Clauses* (May 17, 2018), https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/Other-Content-Types/2018-05-17.pdf (discussing eliminating gag clauses to ensure that patients receive full information from their healthcare providers to make informed decisions); *see also* Department of Health and Human Services, *Remarks on Drug Pricing Blueprint* (May 14, 2018), https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html; 83 Fed. Reg. 22695, 22699 (May 16, 2018).

[162] American Humanist Association, *AHA Joins Over 110 Orgs Urging HHS Not to Reinstate "Domestic Gag Rule"* (May 21, 2018), https://americanhumanist.org/featured/aha-joins-110-orgs-urging-hhs-not-reinstate-domestic-gag-rule; *see also* Molly Walker, *Groups believe Trump administration will soon impose new Title X restrictions*, MEDPAGE TODAY (May 4, 2018), https://www.medpagetoday.com/obgyn/generalobgyn/72714. The American College of Obstetricians and Gynecologists and the American College of Physicians, which together represent more

which set the standard for medical professionals across the country. For example, the American Medical Association's Code of Ethics unambiguously states that "withholding information without the patient's knowledge or consent is ethically unacceptable."[163] The American Nurses Association's code of ethics similarly asserts that "patients have the moral and legal right to [. . .] be given *accurate, complete* and understandable information in a manner that facilitates an informed decision,"[164] (emphasis added). The American College of Physicians declares that even when a certain medical option may conflict with a provider's religious or ethical beliefs, "the physician has a duty to inform the patient about care options and alternatives, or refer the patient for such information, so that the patient's rights are not constrained."[165] The verdict is unanimous: Patients have the right to full and honest medical information, and providers have an obligation to present it.

Gag rules also undermine fundamental human rights. For example, the right to health encompasses the right to sexual and reproductive health.[166] States have an obligation to guarantee available, accessible, and good quality reproductive health information, services, goods, and facilities for all women and girls, free from discrimination, violence and coercion.[167] The proposed gag on providers with regards to abortion counseling and referral inhibits the realization of the right to health by creating a chilling effect on access to all sexual and reproductive health services, in addition to the direct health impacts of denying access to safe and legal abortion. The policy also undermines the right to information by censoring health care providers from informing patients of all their options related to abortion.[168] Human rights treaty monitoring bodies have consistently recognized that the denial of abortion information and services profoundly affects women's lives and health and hinders the fulfillment of a range of civil, political, economic, and social rights.[169] Governments have an obligation to ensure that information on sexual and reproductive health provided to women and girls both in and out of

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than 200,000 physicians across the U.S., have jointly expressed concern that imposing a gag rule "move[s] away from science-based principles and erode[s] standard of care by interfering in the patient/provider relationship." *Id.*

[163] American Medical Association, *Withholding Information From Patients*, https://www.ama-assn.org/delivering-care/withholding-information-patients.

[164] American Nurses Association, *Code of Ethics for Nurses with Interpretive Statements, Section 1.4* (2015), https://www.nursingworld.org/practice-policy/nursing-excellence/ethics/code-of-ethics-for-nurses/coe-view-only/.

[165] American College of Physicians, *Ethics Manual* (6th Ed. 2012), https://www.acponline.org/clinical-information/ethics-and-professionalism/acp-ethics-manual-sixth-edition/acp-ethics-manual-sixth-edition#informed.

[166] *See* ESCR Committee, *General Comment No. 14: The Right to the Highest Attainable Standard of Health (art. 12)*, para. 8, U.N. Doc. E/C.12/2000/4 (2000) [hereinafter ESCR Committee, *Gen. Comment No. 14*]; ESCR Committee, *Gen. Comment No. 22, on the right to sexual and reproductive health (article 12 of the International Covenant on Economic, Social and Cultural Rights)*, para. 28, U.N. Doc. E/C.12/GC/22 (2016) [hereinafter ESCR Committee, *Gen. Comment No. 22*].

[167] *See* ESCR Committee, *Gen. Comment No. 14*, para. 12; ESCR Committee, *Gen. Comment No. 22*, paras. 62-63; CEDAW Committee, *Gen. Recommendation No. 24, Article 12 of the Convention (Women and Health)*, para. 2, U.N. Doc. A/54/38/Rev.1, chap. I (1999).

[168] *See* ESCR Committee, *Gen. Comment No. 22*, para. 41. Safe abortion services are primary health care procedures that can be provided early on by a range of providers.

[169] ESCR Committee, *Gen. Comment No. 22*, paras. 13, 18, 28 & 49.

health care settings—in public and to individuals—is complete and accurate and that information is not censored or withheld.[170]

VI. The proposed rule contravenes the mission of HHS

By its own statement, HHS' mission is to "enhance and protect the health and well-being of all Americans [. . .] providing for effective health and human services."[171] But the proposed rule does not make even a feeble attempt at addressing how the rule would preserve, much less enhance, the health of patients. HHS appears far more concerned with ensuring that those who call themselves health care providers but refuse to provide care or referrals are permitted to participate in the program, than ensuring that Title X's target population is able to access care. HHS's failure to ensure that above all, patients receive the care they require indicates that the proposed rule is driven by ideology, instead of HHS' stated mission to enhance the health of all Americans.

VII. The proposed regulation is unconstitutional

a. The proposed rule violates the First Amendment

The proposed rule imposes unconstitutional conditions on the freedom of speech of Title X grantees. The government is prohibited from using a funding condition to burden a fundamental right, *e.g.* from "doing indirectly what it cannot do directly."[172] The proposed rule goes beyond limiting speech within the Title X program. In fact, the practical effect of the proposed rule's counseling and referral requirements would actually be to prevent doctors and clinics who receive Title X funds from engaging in the prohibited speech at all. Because Title X clinics are the only place where providers can counsel the large number of Title X patients for whom Title X services are their usual or only source of care,[173] the proposed rule's counseling and referral requirements effectively "force the Title X grantee to give up abortion-related speech"[174] and as such are impermissible under the First Amendment.

Alternatively, even assuming *arguendo* that the government, under some circumstances, can place limits on private speakers to control information pertaining to the government's own

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[170] *Id.*, para. 41.

[171] U.S. Department of Health and Human Services, *About HHS*, https://www.hhs.gov/about/index.html.

[172] Peter A. Clodfelter & Edward J. Sullivan, *Substantive Due Process Through the Just Compensation Clause: Understanding Koontz's "Special Application" of the Doctrine of Unconstitutional Conditions by Tracing the Doctrine's History*, 46 URB. LAW 569, 570 (2014); *see also* Koontz v. St. Johns River Water Mgmt. Dist., 133 S. Ct. 2586, 2594 (2013) (the doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up.").

[173] In a nationally representative 2016 survey, six in ten Title X patients reported that a Title X-supported health care center was their only source of care in that year. *See* Megan L. Kavanaugh et. al, *Use of Health Insurance Among Clients Seeking Contraceptive Services at Title X–Funded Facilities in 2016*, 50 PERSPECTIVES ON SEXUAL AND REPRODUCTIVE HEALTH (2018), https://onlinelibrary.wiley.com/doi/epdf/10.1363/psrh.12061.

[174] Rust v. Sullivan, 500 U.S. at 196.

programs, the proposed rule nonetheless violates the First Amendment because it intrudes on the free expression that is key to the patient-provider relationship. The Supreme Court recently clarified that the patient-provider relationship is unique because "[d]octors help patients make deeply personal decisions, and their candor is crucial"[175] and "in the fields of medicine and public health, [. . .] information can save lives." [176] Indeed, in the medical community it is universally acknowledged that "withholding information without the patient's knowledge or consent is ethically unacceptable," and accordingly medical ethics require medical professionals to provide comprehensive counseling on their health care options.[177] Based on this current understanding, it is clear that the patient-provider relationship is among the "traditional sphere[s] of free expression [that are] so fundamental to the functioning of our society that the Government's ability to control speech within that sphere by means of conditions attached to the expenditure of Government funds is restricted by the [limits] of the First Amendment."[178] And this reasoning clearly applies to Title X providers, just like any other doctors from whom patients expect comprehensive medical advice in situations where "candor is crucial," including complete, transparent information about their health care options. Indeed, this is especially true with respect to Title X providers, since a large number of women use Title X clinics as their primary or only health care providers. The proposed rule would infringe upon this traditional sphere of free expression inherent in the patient-provider relationship, exceeding the government's power to place limits on the free speech of private actors.

b. The proposed rule is unconstitutionally vague

Laws that regulate persons or entities must give fair notice of conduct that is forbidden or required.[179] The proposed rule fails to give such notice, and as such is unconstitutionally vague.

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[175] NIFLA v. Becerra, 138 S. Ct. 2361, 2374 (2018) (quoting Wollschlaeger v. Governor of Florida, 848 F.3d 1293, 1328 (11th Cir. 2017) (en banc)).

[176] NIFLA v. Becerra, 138 S. Ct. 2361, 2366 (2018) (quoting Sorrell v. IMS Health Inc., 564 U.S. 552, 566, 131 S. Ct. 2653, 180 L. Ed. 2d 544).

[177] The American Medical Association code of ethics states that "withholding information without the patient's knowledge or consent is ethically unacceptable." *See* American Medical Association, *Withholding Information From Patients*, https://www.ama-assn.org/delivering-care/withholding-information-patients; The American College of Obstetricians and Gynecologists recommends that all patients "should be counseled about [their] options: continuing the pregnancy to term and raising the infant, continuing the pregnancy to term and placing the infant for legal adoption, or terminating the pregnancy." *See* Kinsey Hasstedt, *Unbiased Information on and Referral for All Pregnancy Options Are Essential to Informed Consent in Reproductive Health Care*, 21 GUTTMACHER POLICY REVIEW (2018), https://www.guttmacher.org/gpr/2018/01/unbiased-information-and-referral-all-pregnancy-options-are-essential-informed-consent.

[178] Rust v. Sullivan, 500 U.S. at 199.

[179] *See, e.g.*, Connally v. General Constr. Co., 269 U.S. 385, 391, 46 S.Ct. 126, 70 L.Ed. 322 (1926) ("[A] statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first essential of due process of law"); Papachristou v. Jacksonville, 405 U.S. 156, 162(1972) ("Living under a rule of law entails various suppositions, one of which is that '[all persons] are entitled to be informed as to what the State commands or forbids'" (quoting Lanzetta v. New Jersey, 306 U.S. 451, 453 (1939) (alteration in original)). This requirement of clarity in regulation is essential to the protections provided by the Due Process Clause of the Fifth Amendment. *See* United States v. Williams, 553 U.S. 285, 304 (2008).

The proposed rule's nondirective counseling and referral requirements are vague and inconsistent. A number of conflicting statements in the proposed rule create confusion. For example, the preamble to the NPRM states that "a doctor, though not required to do so, would be permitted to provide nondirective counseling on abortion,"[180] but the regulatory text prohibits providers from "present[ing]" abortion as a family planning method. The proposed rule fails to define "present" to clarify how to distinguish it from "counseling." As a result, the counseling requirements are too vague to provide guidance as to what counseling activities are permitted. The proposed rule also states that "[r]eferrals for abortion are, by definition, directive," but simultaneously requires prenatal care referrals for all patients. Thus, there appears to be no consistent understanding by the agency as to what "nondirective" means, and how it would be applied to abortion counseling and referral under the proposed rule.

The proposed maintenance of physical and financial separation is also unduly vague. All evidence points toward the unworkability of these rules—as the Department acknowledged when it rescinded virtually identical rules in the past: "[T]he practical difficulty of drawing lines in this area, both as experienced prior to 1988 and as evident in the history of the gag rule itself, suggests that this legal interpretation is not likely ever to result in an enforceable compliance policy that is consistent with the efficient and cost-effective delivery of family planning services."[181] The proposed rule advances a number of factors the Secretary may consider in determining whether an organization has sufficiently separated Title X from abortion activities. But as the Department has recognized, regarding the near-identical factors advanced in 1988, "the fundamental measure of compliance under that section remained ambiguous."[182] Because the rule grants unchecked discretion to the Secretary as to how to weigh the factors presented, it fails to provide sufficient guidance as to what reasonably would be considered sufficient physical and financial separation. As such, the rule is unconstitutionally vague.

c. *The proposed rule is an undue burden on women's access to abortion*

The proposed rule burdens access to abortion by requiring physicians to obstruct their patients' ability to identify an abortion provider among the list of health care providers the physician may distribute when a patient requests an abortion referral. The proposed rule makes clear that the list may not identify which providers perform abortions, ensuring patients would expend time and scarce resources—and likely encounter delays—as a result of receiving the list. The real-world effects are predictable: low-income patients and those living in rural areas would expend their already limited time and resources contacting health care providers that do not provide abortion care. Combined with the ban on "presenting" abortion as an option, this would require physicians to obstruct their patient's access to information about abortion, and then intentionally delay that care regardless of the patient's wishes, simply because the patient is low-income and sought care at a Title X facility. Such a restriction, especially when operated in conjunction with the physical separation requirements, would present an undue burden for a woman's right to access abortion care.

[180] 83 Fed. Reg. 25518 (June 1, 2018).

[181] 65 Fed. Reg. 41276 (July 3, 2000).

[182] *Id.*

If providers who also perform abortion are forced to separate their shared facilities, the burden on patients would be substantial. The physical separation requirements likely will cause a number of providers to stop providing abortion altogether. Unlike thirty years ago, when *Rust v. Sullivan* upheld similar separation requirements, providers today have built their medical practices in reliance on the longstanding policy allowing shared facilities. Since it will be extremely difficult, and in some cases impossible, to separate facilities without going bankrupt, some providers will stop performing abortion care rather than go out of business altogether. A significant reduction in providers who also offer abortion would place a substantial burden on patients seeking abortion care, particularly because the overall number of abortion clinics already has significantly declined since *Rust* was decided. As of 2014, eighty-nine percent of counties in the United States did not have a single abortion clinic.[183] In several states, only one clinic offers abortion care.[184]

d. The proposed rule violates the Equal Protection Guarantee of the Fifth Amendment by discriminating between pregnant women seeking abortion services and those seeking prenatal care

The proposed rule defines "family planning" to exclude *all* "post-conception care (including obstetric or prenatal care) or abortion as a method of family planning."[185] And the NPRM repeatedly acknowledges that "Title X projects do not themselves provide post-conception care."[186] Yet, the proposed rule requires that pregnant women be referred outside of the Title X project for prenatal care, but prohibits (or in a narrow set of circumstances severely restricts) referral for abortion services. In other words, *both* prenatal care *and* abortion services fall outside the ambit of the Title X program. Yet, only women seeking abortion services are singled out, stigmatized, and denied the assistance they need as a result of the proposed rule.

Under an equal protection analysis, the question is not whether the government has a duty to provide abortion access. Rather, the issue is that, once the government enters the family-planning business (defined as only pre-conception care), and once it allows that business to provide counseling and referrals for post-conception treatment related to pregnancy *outside* the program, the government cannot then discriminate between two classes of women in need of post-conception services, neither of whose condition is subsidized or covered by the program (for example, patients seeking to carry to term versus patients seeking abortion).

Among other things, the ban on referrals disrupts the continuum of care and puts an undue burden on women, who must expend additional time and money in order to obtain the care they need—if they are able to obtain care at all. Whereas, under longstanding regulations, Title X clinics could streamline the process for their patients by providing direct referral information

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[183] Rachel K. Jones & Jenna Jerman, *Abortion incidence and service availability in the United States, 2014*, 49(1) PERSPECTIVES ON SEXUAL AND REPRODUCTIVE HEALTH 17–27 (Mar. 2017).

[184] Allison McCann, *The Last Clinics*, VICE NEWS (May 23, 2017), https://news.vice.com/story/last-clinics-seven-states-one-abortion-clinic-left.

[185] 83 Fed. Reg. 25513 (June 1, 2018).

[186] *Id*. at 25518.

about abortion providers outside the Title X program, a woman now would have to research where to access an abortion on her own. As described in detail above, the additional burden of locating a willing provider, the delays inherent in the research and appointment-making process and the potentially added cost of a delay can have harmful health consequences for a pregnant woman that are the result of unequal treatment. The proposed rule violates the constitutional guarantee of equal protection and must be withdrawn.

I. Conclusion

In conclusion, we strongly oppose this proposed rule. For all the reasons stated above, we urge HHS to withdraw this regulation in its entirety. Thank you for the opportunity to comment.

Sincerely,

The Center for Reproductive Rights