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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE FAMILY PLANNING ASSOCIATION OF MAINE D/B/A MAINE FAMILY PLANNING, on behalf of itself, its staff, and its patients, *et al.*,	)	Case No. 1:19-cv-00100-LEW
Plaintiffs,	)	**AMICUS BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**
v.	)	
UNITED STATES DEPART OF HEALTH AND HUMAN SERVICES, *et al.*,	)	
Defendants.	)	

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CORPORATE DISCLOSURE STATEMENT

Amici curiae are non-profit organizations. They have no parent corporations and do not issue stock.

INTEREST OF *AMICI CURIAE*

The American College of Obstetricians and Gynecologists ("ACOG"), the American Academy of Pediatrics ("AAP"), the American College of Physicians ("ACP"), the Society for Adolescent Health and Medicine ("SAHM"), and the Society for Maternal-Fetal Medicine ("SMFM") (collectively, "*Amici*") submit this *amici curiae* brief in support of Plaintiffs. *Amici* share the common goal of ensuring access to high-quality reproductive health care that is comprehensive, ethical, and evidence-based.

ACOG is the nation's leading group of physicians providing health care for women. With more than 58,000 members—representing more than 90% of all ob-gyns in the United States—ACOG advocates for quality health care for women, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care. ACOG is committed to ensuring access to the full spectrum of evidence-based quality reproductive health care for all women. ACOG believes that the full array of clinical services should be available to women without costly delays or the imposition of cultural, geographic, financial, or legal barriers.

ACOG members care for women of all socioeconomic backgrounds, including low-income women and adolescents who rely on Title X funded projects for their care. ACOG has previously appeared as *amicus curiae* in various courts throughout the country, including the United States Supreme Court. In addition, ACOG's work has been cited by numerous courts seeking authoritative medical data regarding childbirth and abortion.

AAP is a non-profit professional organization founded in 1930 and dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults. Its membership is comprised of 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. The AAP has become a powerful voice for child and adolescent health through education, research, advocacy, and the provision of expert advice. The AAP has worked with the federal and state governments, health care providers, and parents on behalf of America's families to ensure the availability of safe and effective reproductive health services.

ACP is the largest medical specialty organization in the United States with members in more than 145 countries worldwide. ACP membership includes 154,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

SAHM, founded in 1968, is a non-profit multidisciplinary professional society committed to the promotion of health, well-being, and equity for all adolescents and young adults by supporting adolescent health and medicine professionals through the advancement of clinical practice, care delivery, research, advocacy, and professional development. It strives to empower its 1,200 members who are professionals and trainees in medicine, nursing, research, psychology, public health, social work, nutrition, education and law from a variety of settings. Through education, research, clinical services and advocacy activities, SAHM enhances public and professional awareness of adolescent health issues among families, educators, policy makers, youth-serving organizations, students in the field as well as other health professionals around the world. SAHM continues to advocate on behalf of all adolescents and young adults both on federal and state government levels for the availability of safe and effective reproductive health services.

Founded in 1977, SMFM is the medical professional society for obstetricians who have additional training in the area of high-risk, complicated pregnancies. Representing over 4,000 members who care for high-risk pregnant women, SMFM supports the clinical practice of maternal-fetal medicine by providing education, promoting research, and engaging in advocacy to reduce disparities and optimize the health of high-risk pregnant women and their babies. SMFM and its members are dedicated to optimizing maternal and child outcomes, and assuring that medically appropriate treatment options are available is critically important. SMFM has advocated at the state and federal level to ensure that high-risk women have access to high-quality, preventive health care and family planning services prior to pregnancy to improve maternal and infant health outcomes.

INTRODUCTION AND SUMMARY OF ARGUMENT

Amici are leading medical societies in the United States whose members collectively provide medical care to people in all stages of their lives. *Amici* are dedicated to the provision of evidence-based, quality health care and work to promote health policies based on science and evidence. *Amici* recognize that the provision of evidence-based, quality reproductive health care is essential to the overall health of individuals and, accordingly, oppose government interference through the imposition of restrictions that will create cultural, geographic, financial or legal barriers to care. Although the plaintiffs in this action have carefully briefed this Court on the need for an immediate injunction, *Amici*—whose ethical codes, policies, and guidance represent the considered judgment of the medical community in the United States—submit this brief to directly highlight for the Court the extreme, immediate, and irreparable harm that will result to millions of Americans and to the integrity of the patient-provider relationship if this Court fails to enjoin the rule at issue.

The rate of unintended pregnancy is higher in the United States than in most other developed countries.[1] Low-income women have disproportionately high rates of unplanned pregnancies, as well as disproportionally high rates of adverse reproductive health outcomes.[2] For decades, Title X of the Public Health Services Act ("Title X") has provided funds that enable low-income women and men to obtain essential preventive and reproductive health care at low or no cost. Services historically available through Title X health care providers include FDA-approved contraceptive methods and counseling services, well-woman exams, breast and cervical cancer screenings, screening and treatment for sexually transmitted infections ("STIs"), testing for HIV, pregnancy testing and counseling, and other patient education and/or health referrals. The regulation promulgated by the Department of Health and Human Services ("HHS") entitled "Compliance with Statutory Program Integrity Requirements" (the "Final Rule") threatens to restrict the quality and availability of this reproductive health care for low-income individuals. It also puts providers in ethically compromised positions, requiring that providers refer patients for care that is not medically indicated or consistent with the patient's desires. These radical changes will have disproportionate effects on vulnerable populations, such as people of color and individuals living in rural or underserved areas, who face structural barriers in access to care.

For more than 2,500 years, the practice of medicine has been guided by principles of medical ethics. The patient-physician relationship is the central focus of all ethical concerns, and

[1] ACOG, Comm. on Health Care for Underserved Women, *Opinion No. 615: Access to Contraception*, 125 OBSTETRICS & GYNECOLOGY 250, 251 (2015), *available at* https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co615.pdf?dmc=1&ts=20190407T1339146283 (reaffirmed 2017).

[2] *Id.*

the welfare of the patient must form the basis of all medical judgments.[3] A fundamental principle of medical ethics, which applies equally to the health care services offered in family planning clinics as in any other context, is that providers must respect the autonomy of their patients.[4] Providers should serve as their "patient's advocate and exercise all reasonable means to ensure that the most appropriate care is provided to the patient."[5]

The Final Rule ignores these longstanding ethical principles. It dictates mandatory referrals for patients to prenatal care, limits providers' ability to answer their patients' questions, and undermines protections for low-income people who seek evidence-based reproductive health care. If a patient presents to a Title X clinic with an unintended pregnancy, the Final Rule limits the provider's ability to discuss abortion care with his or her patient. If a patient expressly states that she wishes to terminate her pregnancy, the Final Rule prohibits the provider from referring for abortion care, and requires the provider to refer the patient to a health care provider for prenatal care.[6] The Final Rule does allow providers to supply a list of referrals to primary health care providers, but the majority of providers on this list *cannot* provide abortion care, and neither the list nor the provider can delineate which of the providers on that list actually provide the needed care.[7] This intentionally inefficient system erodes trust between patients and physicians, inhibits

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[3] ACOG, CODE OF PROFESSIONAL ETHICS 1 (2018), *available at* https://www.acog.org/About-ACOG/ACOG-Departments/Committees-and-Councils/Volunteer-Agreement/Code-of-Professional-Ethics-of-the-American-College-of-Obstetricians-and-Gynecologists.

[4] *Id.*

[5] *Id.* at 2.

[6] Compliance with Statutory Program Integrity Requirements, 84 Fed. Reg. 7714, 7787–90 (Mar. 4, 2019) (to be codified at 42 C.F.R. §§ 59.5(a)(5), 59.14, 59.16).

[7] *Id*. at 7789 (to be codified at 42 C.F.R. §§ 59.14(c)(2), 59.14(e)(3)).

open and frank communication, and creates needless delay for patients who have highly time-sensitive medical needs.

The Final Rule impedes the provider's ability to serve as the "patient's advocate" and to "exercise all reasonable means to ensure the most appropriate care is provided to the patient."[8] It further restricts the provider's ability to offer care consistent with his or her best medical judgment, substantially eroding the patient-provider relationship.

The impact of these limitations imposed by the Final Rule on the practice of medicine are serious. When attempting to comply with the Final Rule, many providers will conclude that they cannot do so consistent with their ethical principles, which may lead to vulnerable populations being deprived of the care they need. Even providers who may attempt to comply with the Final Rule will not be able to effectively provide many patients with prompt access to needed care as a result of both the Final Rule's requirement that women seeking to terminate a pregnancy be referred for medically unnecessary care, and its restrictions on referrals to, and identification of, providers of abortion care. This interference with the patient-provider relationship impairs a patient's ability to access timely medical care and also threatens to irreparably damage the trust between Title X medical providers and the vulnerable population of patients they serve.

Other aspects of the Final Rule will also restrict the availability of evidence-based reproductive health care for millions of low-income Americans. For example, the Final Rule states that only physicians and advanced practice providers may provide counseling under the Rule to patients—a limit that is both medically unnecessary and contrary to common practice, and also could severely limit patients' ability to obtain such counseling. The Final Rule also imposes onerous "separation" requirements on Title X projects that are not consistent with medical based

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[8] ACOG, CODE OF PROFESSIONAL ETHICS, *supra* note 3, at 2.

practices aimed at facilitating continuity of quality care . These requirements mandate separation between Title X project activities and abortion-related activities, including requiring separate health records, separate facilities, and separate personnel. Requiring complete physical separation is a clear effort to force out from the Title X program reproductive health-focused providers that would limit the number of patients they see or, worse, close their doors. Additionally, the "close proximity" requirement could lead to rural health clinics losing Title X status. The Final Rule also removes the requirement that Title X projects provide "medically approved" contraception, threatening to undermine the provision of effective contraception to low-income women in favor of non-scientific alternatives.

In sum, the Final Rule is inconsistent with medical ethics and medical science. The Final Rule threatens the health of millions of individuals across the United States by imposing burdens on the provision of reproductive health care that are likely to lead to such care being restricted or compromised. Because of the irreparable harm that will be caused by the Final Rule and the substantial medical ethics concerns posed by its terms, *Amici* urge this Court to issue an immediate injunction.

ARGUMENT

I. TITLE X ENABLES HEALTH CARE PRACTITIONERS TO PROVIDE LOW-INCOME AND VULNERABLE PATIENTS ACCESS TO CRITICAL HEALTH CARE SERVICES

All people—regardless of their economic circumstances—should receive medically accurate, evidence-based, and quality reproductive health care. For low-income women, publicly funded reproductive health clinics are an important source of family planning services.[9] Signed

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[9] Laurie Sobel et al., HENRY J. KAISER FAMILY FOUNDATION, *New Title X Regulations: Implications for Women and Family Planning Providers* 2 (Mar. 8, 2019), *available at* https://www.kff.org/womens-health-policy/issue-brief/new-title-x-regulations-implications-for-women-and-family-planning-providers/.

into law by President Richard M. Nixon and enacted with broad bipartisan support,[10] Title X is the only federal grant program dedicated exclusively to providing low-income patients with essential family planning and preventive health services and information.[11] These include, for example, cancer and sexually transmitted infection ("STI") screenings, well-woman exams, contraceptive and pregnancy counseling, and other health referrals, with priority given to persons from low-income families. By statute, Title X funding is not used for abortions.[12]

To date, the benefits of medical care provided through Title X projects have been significant. Title X funds are integral in ensuring that safe, timely, and evidence-based care is available to all patients, regardless of financial circumstances. According to the HHS Office of Population Affairs, access to quality family planning and reproductive health services is "integral to overall good health for both men and women."[13] In 2017 (the most recent year for which statistics are available), more than four million individuals obtained Title X services.[14] 67% of those individuals had family incomes at or below the poverty level, and 42% of those individuals

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[10] Richard Nixon, *Statement on Signing the Family Planning Services and Population Research Act of 1970*, Am. Presidency Project (Dec. 26, 1970), *available at* https://www.presidency.ucsb.edu/node/240809.

[11] OFFICE OF POPULATION AFFAIRS, PROGRAM REQUIREMENTS FOR TITLE X FUNDED FAMILY PLANNING PROJECTS 5 (2014), *available at* https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf.

[12] 42 U.S.C. § 300a-6 (2012).

[13] *Family Planning Guidelines*, OFFICE OF POPULATION AFFAIRS, https://www.hhs.gov/opa/guidelines/program-guidelines/index.html (last updated Nov. 22, 2016) ("Few health services are used as universally. In fact, more than 99% of women aged 15–44 who have ever had sexual intercourse have used at least one contraceptive method.").

[14] CHRISTINA FOWLER ET AL., OFFICE OF POPULATION AFFAIRS, TITLE X FAMILY PLANNING ANNUAL REPORT: 2017 NATIONAL SUMMARY 8 (Aug. 2018), *available at* https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2017-national-summary.pdf [hereinafter TITLE X ANNUAL REPORT].

were uninsured.[15] As a result of services made available through programs such as Title X, the United States has had a dramatic drop in the unintended pregnancy rate, which reached a 30-year low in 2011.[16] Indeed, Title X funding helps prevent nearly one million unintended pregnancies each year.[17]

Title X also provides other important preventive reproductive health care services for patients. In 2017, Title X projects provided over five million STI tests, approximately 700,000 Pap tests (used to detect cervical cancer), and 900,000 clinical breast exams.[18] It is estimated that in 2010 alone, services provided by Title X projects helped avert 53,450 chlamydia infections, 8,810 gonorrhea infections, 250 HIV infections, and 6,920 cases of pelvic inflammatory disease.[19]

The impact of prior state laws that restricted service providers like Planned Parenthood, which is the largest Title X service provider, further underscores the vital role of Title X providers. In 2013, when Texas excluded Planned Parenthood from a state program serving low-income patients, the number of women using the most effective methods of birth control decreased by

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[15] *Id.* at 21, 23–24.

[16] Lawrence B. Finer & Mia R. Zolna, *Declines in Unintended Pregnancy in the United States, 2008–2011*, 374 NEW ENG. J. MED. 843, 850 (2016), *available at* https://www.nejm.org/doi/full/10.1056/NEJMsa1506575. These services include offering contraceptives to patients. Of the 3.1 million female clients considered at risk of unintended pregnancy, 70% left Title X providers with effective contraceptives. TITLE X ANNUAL REPORT, *supra* note 14, at ES-2, B-11.

[17] *Fact Sheet: Publicly Funded Family Planning Services in the United States,* GUTTMACHER INST. at 3 (Sept. 2016), *available at* https://www.guttmacher.org/sites/default/files/factsheet/fb_contraceptive_serv_0.pdf.

[18] TITLE X ANNUAL REPORT, *supra* note 14, at 41–48.

[19] Adam Sonfield, *Beyond Preventing Unplanned Pregnancy: The Broader Benefits of Publicly Funded Family Planning Services*, 17 GUTTMACHER POL'Y REV. 2, 3 (2014), *available at* https://www.guttmacher.org/sites/default/files/article_files/gpr170402.pdf.

35%, and the number of births covered by Medicaid increased by 27%.[20] Similarly, when public health funding cuts in Indiana forced many clinics providing STI testing, including Planned Parenthood health centers, to close, rural areas of the state experienced a dramatic HIV outbreak.[21] The services offered by Title X service providers are critical in reducing unintended births and protecting the population of the United States against dangerous and avoidable STIs.

Despite the instrumental role of Title X service providers in this country, the United States is facing a shortage of practitioners who can provide reproductive health care services, and this trend, which especially impacts rural and underserved communities, is expected to worsen.[22] If Title X facilities are no longer able to serve as many patients or, worse, are forced to close as a result of the Final Rule, this problem will be exacerbated, causing irreparable harm to the ability of providers to care for their patients, and will result in a critical gap in needed care for patients in underserved communities.

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[20] Amanda J. Stevenson et al., *Effect of Removal of Planned Parenthood from the Texas Women's Health Program*, 374 NEW ENG. J. MED. 853, 853 (2016), *available at* https://www.nejm.org/doi/full/10.1056/nejmsa1511902.

[21] Hal C. Lawrence & Debra L. Ness, *Planned Parenthood Provides Essential Services That Improve Women's Health*, 166 ANNALS INTERNAL MED. 443, 444 (2017).

[22] For example, about half of the counties in the United States currently lack an ob-gyn, and ACOG projects that by 2030 there will be an 18% nationwide shortage of ob-gyns. WILLIAM F. RAYBURN, ACOG, THE OBSTETRICIAN-GYNECOLOGIST WORKFORCE IN THE UNITED STATES 4, 121 (2017), *available at* https://m.acog.org/~/media/BB3A7629943642ADA47058D0BDCD 1521.pdf. Similarly, the Association of American Medical Colleges has projected a shortfall of as many as 49,300 primary care physicians and as many as 72,700 non-primary care physicians by 2030. TIM DALL ET AL., COMPLEXITIES OF PHYSICIAN SUPPLY AND DEMAND: PROJECTIONS FROM 2016 TO 2030 at v (2018). The United States is expected to need nearly 52,000 additional primary care physicians by 2025. *See, e.g.*, Stephen M. Petterson et al., *Projecting US Primary Care Physician Workforce Needs: 2010-2025* 10 ANNALS FAM. MED. 503, 507 (2012), *available at* http://www.annfammed.org/content/10/6/503.full.pdf.

II. THE FINAL RULE IS INCONSISTENT WITH CORE PRINCIPLES OF MEDICAL ETHICS AND RESTRICTS PRACTITIONERS' ABILITY TO PROVIDE CARE CONSISTENT WITH THEIR BEST MEDICAL JUDGMENT

The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. Medical professionals must recognize responsibility to patients first and foremost.[23] Several fundamental principles underlie a physician's ethical obligations, including respect for patient autonomy, beneficence, informed consent, trust, honesty, and confidentiality.[24] Medical decisions should be based on the patient's wishes and the medical provider's best judgment. Political interference in the provision of care between a patient and medical provider undermines the strength of the relationship and the provision of quality health care.

The Final Rule adds new requirements on patient counseling that restrict the ability of Title X providers to supply information to their patients regarding abortion care even where a patient specifically desires that course of treatment.[25] The Final Rule also requires that providers refer patients seeking to terminate a pregnancy for care that they may not desire and that is not medically indicated.[26] These requirements place providers in ethically compromised situations and severely damage the foundation of the patient-provider relationship.

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[23] AMA, AMA CODE OF MEDICAL ETHICS (2016), *available at* https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/principles-of-medical-ethics.pdf.

[24] *Id.*; ACOG, CODE OF PROFESSIONAL ETHICS, *supra* note 3, at 1.

[25] 84 Fed. Reg. at 7787–90 (to be codified at 42 C.F.R. §§ 59.5, 59.14, 59.16).

[26] *Id.* at 7789 (to be codified at 42 C.F.R. § 59.14(b)).

A. The Final Rule Undermines Patient Autonomy By Restricting Medical Information and Referrals Available to Patients

Respect for patient autonomy is a fundamental principle of medical ethics. It entitles patients to obtain care that is free from "controlling interferences by others and from personal limitations that prevent meaningful choice, such as inadequate understanding."[27] It also "acknowledges an individual's right to hold views, to make choices, and to take actions based on her own personal values and beliefs" and provides a "strong moral foundation for informed consent, in which a patient, adequately informed about her medical condition and the available therapies, freely chooses specific treatments or nontreatment."[28]

ACOG's Code of Professional Ethics and the AMA's Code of Medical Ethics unequivocally prioritize the patient's welfare.[29] Medical providers are ethically required to provide a patient with "pertinent medical facts and recommendations consistent with good medical practice."[30] In the context of pregnancy, medical practices should provide "complete, medically accurate and unbiased information and resources for all of their pregnancy options," including prenatal care, abortion, and other options for which the patient may want information.[31] According

[27] ACOG, Committee on Ethics, *Opinion No. 390: Ethical Decision Making in Obstetrics and Gynecology,* 110 OBSTETRICS & GYNECOLOGY 1479, 1481 (2007), *available at* https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Ethics/Ethical-Decision-Making-in-Obstetrics-and-Gynecology (reaffirmed in 2016).

[28] *Id.*

[29] ACOG, CODE OF PROFESSIONAL ETHICS, *supra* note 3, at 1–2; AMA, AMA CODE OF MEDICAL ETHICS*, supra* note 23.

[30] ACOG, CODE OF PROFESSIONAL ETHICS, *supra* note 3, at 2.

[31] Kinsey Hasstedt, *Unbiased Information on and Referral for All Pregnancy Options Are Essential to Informed Consent in Reproductive Health Care,* 21 GUTTMACHER POL'Y REV. 1, 1 (2018), *available at* https://www.guttmacher.org/sites/default/files/article_files/gpr2100118.pdf; ACOG, CODE OF PROFESSIONAL ETHICS*, supra* note 3, at 2; ACOG, Comm. on Ethics, *Ethical Decision Making in Obstetrics and Gynecology*, *supra* note 27; ACOG, Comm. on Ethics, *Opinion No. 439, Informed Consent*, 114 OBSTETRICS & GYNECOLOGY 401, 407 (2009), *available at*

to standards of care and medical guidance, patients who desire to continue a pregnancy to term should be referred for prenatal care. Pregnant patients who are ambivalent about their pregnancy or unsure about the next steps they would like to take should be offered full information about their options in a neutral and balanced way. Such options include continuing the pregnancy to term (and either raising the child or placing the child for adoption) or terminating the pregnancy.[32] After learning of her options, if the patient desires to continue the pregnancy to term, the proper course of care would be to refer her for prenatal care and, if she is contemplating adoption, provide information on services related to adoption.[33] If the patient wishes to obtain an abortion or states that she is considering doing so, then a provider should refer the patient to another provider who can discuss with the patient her options for terminating her pregnancy, and provide her with the appropriate abortion care. Prenatal care is not medically indicated for patients who wish to terminate their pregnancies.

Consistent with recognized principles of medical ethics, the prior Title X regulations promulgated in 2000 required practitioners to offer patients the opportunity to receive neutral, factual information and nondirective counseling on each of the patient's options—including prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination—and

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https://www.acog.org/-/media/Committee-Opinions/Committee-on-Ethics/co439.pdf (reaffirmed in 2015).

[32] ACOG Executive Board, *Abortion Policy* 2014 STATEMENT OF POLICY 1, *available at* https://www.acog.org/-/media/Statements-of-Policy/Public/sop069.pdf; *see also* ACOG, Comm. on Ethics, *Opinion No. 528, Adoption,* 119 OBSTETRICS & GYNECOLOGY 1320, 1320 (2012), *available at* https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Ethics/Adoption (reaffirmed in 2018).

[33] ACOG, *FAQ 168: Pregnancy Choices: Raising the Baby, Adoption, and Abortion* (2013), *available at* https://www.acog.org/Patients/FAQs/Pregnancy-Choices-Raising-the-Baby-Adoption-and-Abortion.

then, if requested, to provide the patient with additional counseling regarding the care she seeks.[34] The Final Rule eliminates these protections in favor of new provisions that, while purporting to be "nondirective,"[35] are anything but nondirective.

Under the Final Rule, when a patient expressly states that she is seeking abortion care, the provider is required to provide the patient with a referral to prenatal care—even if the patient has explicitly stated that she does not want the referral.[36] The provider cannot provide the patient with a referral for abortion services.[37] As explained above, prenatal care is not a medically indicated course of care for a patient seeking to terminate a pregnancy.

The Final Rule also restricts a provider's ability to discuss abortion care with a patient who seeks information about pregnancy termination.[38] For example, the practitioner may provide a list that "may include licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), some, but not the majority, of which also provide abortion as part of their comprehensive health care services."[39] However, not only must the list include a "majority" of providers that do not provide abortion services, "neither the list nor project staff may identify which providers on the list perform abortion."[40] The fact that the list of referrals is required to contain information about care that a patient does not need is confusing and misleading—

[34] Standards of Compliance for Abortion-Related Services in Family Planning Services Projects, 65 Fed. Reg. 41,270, 41,279 (Jul. 3, 2000) (codified at 42 C.F.R. § 59.5(a)(5)).

[35] *See*, *e.g.*, 84 Fed. Reg. at 7789 (to be codified at 42 C.F.R. § 59.14(b)(1)(i)); *id.* at 7716.

[36] *Id.* at 7789 (to be codified at 42 C.F.R. § 59.14(b)(1)).

[37] *Id.* at 7787–90 (to be codified at 42 C.F.R. §§ 59.5(a)(5), 59.14, 59.16).

[38] *See id.* at 7724, 7744, 7787–90 (to be codified at 42 C.F.R. §§ 59.5(a)(5), 59.14, 59.16).

[39] *Id.* at 7789 (to be codified at 42 C.F.R. § 59.14(c)(2)).

[40] *Id.*

especially for those vulnerable patients who may not have the resources to research the providers on the list.

Thus, the Final Rule restricts providers from offering care in accordance with the needs and desires of patients, and instead requires that providers direct patients toward a course of care (*i.e.,* prenatal care) even in cases where the care is neither desired nor necessary.

B. The Final Rule Interferes with the Ability of Providers to Render Care Consistent With Their Best Medical Judgment and Undermines the Patient-Provider Relationship

The patient-provider relationship is essential to the provision of safe and quality medical care. It is the bedrock of medical practice. Patients expect medically accurate, comprehensive information from their medical providers. Indeed, the ability of providers to effectively and compassionately communicate information to patients is critical to a successful and safe patient-provider relationship.[41] Both the United States Supreme Court and federal appellate jurisprudence echo these ethical concerns. The Supreme Court has recently recognized that in medicine, the "free flow" of information "can save lives" and is therefore extremely important to safeguard.[42] Circuit courts have likewise emphasized that medical professionals "must be able to speak frankly and openly to patients"[43] because "it only furthers the public interest to ensure that [medical

[41] ACOG, Comm. on Patient Safety and Quality Improvement and Committee on Health Care for Underserved Women, *Committee Opinion No. 587, Effective Patient-Physician Communication*, 123 OBSTETRICS & GYNECOLOGY 389, 389 (2014), *available at* https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Effective-Patient-Physician-Communication.

[42] *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 566 (2011).

[43] *Wollschlaeger v. Governor, Fla.*, 848 F.3d 1293, 1313 (11th Cir. 2017) (*en banc*) (citing *Trammel v. United States*, 445 U.S. 40, 51 (1980); *Conant v. Walters*, 309 F.3d 629, 636 (9th Cir. 2002)).

decisions] are intelligent and well-informed."[44] "[B]arriers to full disclosure" undermine the values served by the relationship between medical professionals and their patients.[45]

In dictating the way medical professionals treat and communicate with their patients, the Final Rule undermines full, frank, and open communications that are the foundation of the patient-provider relationship. For example, medical professionals should never have to "prescribe, provide, or seek compensation for therapies that are of no benefit to the patient."[46] Yet, the Final Rule requires a referral to prenatal care that is of no benefit to a patient seeking abortion care, and bars referrals to the abortion care sought by the patient. As noted above, prenatal care is not medically indicated or beneficial for a patient seeking to terminate a pregnancy. Moreover, a provider may, in his or her medical judgment, believe it would be best to refer a patient wishing to terminate a pregnancy to a gynecological practice that offers abortion care but that does not offer "comprehensive primary health care." However, under the counseling restrictions in the Final Rule, a provider would not be able to make any such referral for abortion care, let alone a referral to a specialized reproductive health care provider—even if it is what he or she believes is in the best interest of the patient.[47]

The Final Rule's intrusion on the patient-provider relationship will substantially and detrimentally impact the low-income and adolescent women who turn to Title X providers for their care. Indeed, rates of adverse reproductive health outcomes are higher among low-income and

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[44] *United States v. Caronia*, 703 F.3d 149, 167 (2d Cir. 2012) (internal citations omitted) (upholding doctor's right to speak freely to patients about off-label usage of prescription drugs).

[45] *Wollschlaeger*, 848 F.3d at 1313; *see also Varner v. Stovall*, 500 F.3d 491, 496 (6th Cir. 2007) (internal citations omitted).

[46] ACOG, Comm. on Ethics, *Informed Consent*, *supra* note 31, at 7.

[47] 84 Fed. Reg. at 7789 (to be codified at 42 C.F.R. § 59.14(c)).

minority women.[48] The counseling restrictions in the Final Rule will exacerbate these inequities and lead to delays in care. Accordingly, the Court should enjoin these harmful and unnecessary restrictions that prevent medical professionals from caring for patients in accordance with their best medical judgment.

C. The Final Rule Undermines the Patient-Provider Relationship for Adolescents Who Seek Reproductive Health Care

The detrimental effect the Final Rule has on the patient-provider relationship between adolescents and their health care providers merits special emphasis. Adolescents have the highest rate of unintended pregnancy of any age group in the United States.[49] Increased access to contraceptive and sexual health care for adolescents has been directly attributed to the reduction in rates of unplanned pregnancy and STIs.[50] While *Amici* recognize and embrace the value in involving family as much as possible in the care of adolescents, considerable evidence shows that many young people would forgo contraceptive and STI services if they could not obtain such care confidentially, while remaining sexually active, and therefore would be at greater risk for negative sexual and reproductive health outcomes.[51] The guarantee of confidentiality for many young

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[48] ACOG, Comm. on Health Care for Underserved Women, *Access to Contraception*, *supra* note 1, at 254.

[49] *Fact Sheet: Unintended Pregnancy in the United States*, GUTTMACHER INST. at 1 (Jan. 2019), *available at* https://www.guttmacher.org/sites/default/files/factsheet/fb-unintended-pregnancy-us.pdf.

[50] ACOG, Comm. on Adolescent Health Care, *Committee Opinion No. 699, Adolescent Pregnancy, Contraception, and Sexual Activity*, 129 OBSTETRICS & GYNECOLOGY 142, 143, 146 (2017), *available at* https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Adolescent-Health-Care/Adolescent-Pregnancy-Contraception-and-Sexual-Activity.

[51] Kinsey Hasstedt, *Ensuring Adolescents' Ability to Obtain Confidential Family Planning Services in Title X,* 21 GUTTMACHER POL'Y REV. 48, 50 (2018), *available at* https://www.guttmacher.org/gpr/2018/11/ensuring-adolescents-ability-obtain-confidential-family-planning-services-title-x.

women in particular is critical in order for them to obtain the methods of contraception that work best for them.[52]

The Final Rule undermines confidentiality protections for adolescents seeking family planning care, including care relating to pregnancy, contraception, and the prevention of STIs. Title X regulations have long required that medical providers encourage family participation in the provision of reproductive health care.[53] However, the Final Rule heightens a provider's obligations for encouraging family participation by requiring, for the first time, that providers take "specific action" (and document such action) to encourage a minor to involve her or his family, except in circumstances of abuse.[54] This additional requirement is not supported by medical science. When taking a health history, clinicians sometimes learn of circumstances (short of abuse) in a minor's family that make it not practical, unrealistic, or perhaps even harmful, to encourage the minor to involve her parents or guardian.[55] In these situations, providers should not be required to take "specific actions" to encourage the minor to do so (and then document those

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[52] Megan L. Kavanaugh et al., *Use of Health Insurance Among Clients Seeking Contraceptive Services at Title X-Funded Facilities in 2016*, 50 PERSP. ON SEXUAL & REPROD. HEALTH 101, 108 (2018) ("Over half of younger clients with insurance indicated that they would not use it to cover the services because of confidentiality concerns.").

[53] *See* 42 U.S.C. § 300 (2012).

[54] 84 Fed. Reg. at 7787 (to be codified at 42 C.F.R. § 59.2 (definition of "low income family")).

[55] *See* AMA, AMA Council on Ethical and Judicial Affairs, *The American Medical Association Code of Medical Ethics' Opinions on Confidential Care for Sexually Active Minors and Physicians' Exercise of Conscience in Refusal of Services: Opinion 5.055 – Confidential Care for Minors*, 14 AMA J. ETHICS 118, 118 (2012), *available at* https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2018-05/coet1-1202.pdf ("When an immature minor requests contraceptive services . . . physicians must recognize that requiring parental involvement may be counterproductive to the health of the patient."); *Policy: Confidentiality, Patient/Physician*, AMERICAN ACADEMY OF FAMILY PHYSICIANS (2018), *available at* https://www.aafp.org/about/policies/all/patient-confidentiality.html ("Only in a setting of trust can a patient share the private feelings and personal history that enable the physician to comprehend fully, to diagnose logically, and to treat properly.").

specific actions) as the Final Rule requires.[56] Requiring providers to document "specific actions" in such circumstances may drive some adolescents away from returning for critical health care services, including contraception and testing and treatment for STIs.[57]

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In short, the Final Rule's requirement that a patient seeking pregnancy termination be referred for prenatal care—care that is medically unnecessary and that the patient may not desire—is inconsistent with bedrock ethics principles that have guided the medical profession for centuries. The Final Rule's requirements also stand to compromise the quality of care that patients will receive. The Court should enjoin these extreme regulations on the practice of medicine and permit providers to render neutral care consistent with their best medical judgment and their patients' desires.

III. THE FINAL RULE IMPOSES ADDITIONAL MEDICALLY UNNECESSARY RESTRICTIONS ON ACCESS TO EVIDENCE-BASED REPRODUCTIVE HEALTH CARE

Amici oppose medically unnecessary regulations that restrict access to reproductive health care through adding administrative burdens and obstacles that are so costly that providers may have to stop rendering care. The Final Rule contains a number of such administrative requirements for which there is no medical basis. As a result of the costs associated with these requirements,

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[56] 84 Fed. Reg. at 7787-8 (to be codified at 42 C.F.R. §§ 59.2, 59.5(a)(14)).

[57] Liza Fuentes et al., *Adolescents' and Young Adults' Reports of Barriers to Confidential Health Care and Receipt of Contraceptive Services*, 62 J. ADOLESCENT HEALTH 36, 38 (2018), *available at* https://www.ncbi.nlm.nih.gov/pubmed/29157859; 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 JAMA 340, 347 (2005), *available at* http://www.jblei.com/documents/notes/notes/5_PH_Jones%20et%20al.%202005.pdf; Diane M. Reddy et al., *Effect of Mandatory Parental Notification on Adolescent Girls' Use of Sexual Health Care Services*, 288 JAMA 710, 713 (2002), *available at* https://www.ncbi.nlm.nih.gov/pubmed/12169074.

the reproductive health care provided to millions of Americans who rely on Title X will be severely compromised or eliminated altogether. Accordingly, the Court should issue an injunction to prevent this irreparable harm.

A. The Restriction on Who Can Provide "Nondirective" Counseling Limits Access to Such Counseling

The Final Rule restricts which medical professionals are permitted to provide purportedly "nondirective" pregnancy counseling by permitting only physicians or advanced practice providers ("APPs") to do so.[58] As a result, registered nurses and health care assistants, who do not qualify as APPs under the Final Rule, are no longer permitted to provide nondirective pregnancy counseling. By contrast, any member of the staff at a Title X project can provide lists of prenatal care providers, referrals to social services or adoption agencies, or information about maintaining the health of the "mother and unborn child during pregnancy."[59]

This restriction is not supported by medical reasoning. Medical professional staff are competent to counsel patients regarding pregnancy options. In 2017, HHS reported that professional medical staff, such as registered nurses and health care assistants, provided 22% of Title X family planning counseling.[60] These trained practitioners are qualified to provide counseling and referrals to patients.

This restriction will undermine patient access to nondirective counseling by creating administrative burdens on Title X providers, which operate on extremely limited budgets and

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[58] 84 Fed. Reg. at 7728 ("The Department defines APPs to include those medical professionals who receive at least a graduate level degree in the relevant medical field and maintain a federal or State-level certification and licensure to diagnose, treat, and counsel patients.").

[59] *Id.* at 7789 (to be codified at 42 C.F.R. § 59.14(b)(1)(iv)). Separately, the term "unborn child" is not a medical term but rather an ideological term that does not align with evidence-based medicine, and should not be used to govern a federal public health program.

[60] TITLE X ANNUAL REPORT, *supra* note 14, at 50–51.

employ non-physicians to provide much-needed pregnancy counseling.[61] Many Title X providers rely on these staff to provide critical reproductive health services, particularly due to the nationwide shortage in physicians.[62] If only APPs and physicians are allowed to provide nondirective counseling, patients will be unable to obtain such counseling in those counties if there is no Title X physician or APP available.[63]

B. The Final Rule's Separation Requirements Threaten Patients' Access to Health Care

The Final Rule also imposes a costly new administrative burden requiring physical separation from abortion-related activities. Such separation is not medically required and will be devastating to millions of Americans who rely on Title X facilities for their care.

The separation requirements will impact a significant number of Title X projects. For example, Planned Parenthood health centers serve over 40% of all Title X patients, and provide both Title X services and non-Title X services while ensuring that Title X funds are used exclusively for Title X services.[64] Many other current grantees offer abortions outside their Title X projects without using Title X funds. Even more grantees that do not offer abortion care engage in activities that are prohibited by the Final Rule, including abortion referral.[65] Title X grantees therefore must either discontinue the care they provided that would be prohibited by the Rule or

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[61] *Id.* at 49.

[62] RAYBURN, *supra* note 22, at 4, 12; DALL, *supra* note 22, at v; Petterson, *supra* note 22, at 507.

[63] RAYBURN, *supra* note 22, at 9 ("Medical needs of the U.S. adult female population during the next decade cannot be met by ob-gyns, family physicians, and general internists alone.").

[64] Jennifer J. Frost et al., Guttmacher Inst., *Publicly Funded Contraceptive Services at U.S. Clinics, 2015,* at 1 (Apr. 2017), *available at* https://www.guttmacher.org/sites/default/files/report_pdf/publicly_funded_contraceptive_services_2015_3.pdf.

[65] *See* 84 Fed. Reg. at 7781–82 (HHS estimates between 10% and 30% of service sites may be affected by the physical separation requirement).

leave the Title X program altogether. Such additional imitations on access to the reproductive health services provided by Title X projects could irreparably harm the health of patients across the United States, particularly in areas where the only reproductive health care available is through Title X providers.

C. There Is No Medical Basis for the "Close Physical Proximity" Requirement and Such a Requirement Threatens Access to Health Care in Rural Areas

The Final Rule requires Title X funding recipients to either offer "comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity."[66] The Final Rule does not define "close physical proximity," and there is no medical or scientific basis for the requirement. If the Final Rule is not enjoined, any Title X project that offers only specialty care (such as family planning or gynecology) and not primary care may not qualify for funding if it is not located near a primary health provider.

Some stand-alone family planning clinics are the only health care providers in rural areas, and their closure will force many patients to go without care. Indeed, residents in rural areas are more likely to be poor, lack health insurance, or rely substantially on Medicaid and Medicare; they also travel longer distances to receive care or to access a range of medical, dental, and mental health specialty services.[67] Less than one-half of women living in rural areas live within a 30-minute drive to the nearest hospital offering perinatal services.[68] A recent study, noting Title X clinics are the "backbone" of family planning care for low-income women, found that there are

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[66] 84 Fed. Reg. at 7788 (to be codified at 42 C.F.R. § 59.5(a)(12)).

[67] ACOG, Comm. on Health Care for Underserved Women, *Opinion No. 586: Health Disparities in Rural Women*, 123 Obstetrics & Gynecology 384, 385 (2014), *available at* https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Disparities-in-Rural-Women (reaffirmed 2018).

[68] *Id.*

already significant disparities in the accessibility of family planning services in rural versus urban areas.[69] Closures of stand-alone family planning clinics risks further diminishing access to care in rural areas.

As the examples of Title X provider closures in Texas and Indiana illustrate, provider closures negatively impact patient health outcomes.[70] Title X providers offer a range of important and even life-saving care, including HIV screening, cancer screenings, and contraception. As merely one example, closures of Title X-funded facilities in Indiana were followed by a dramatic HIV outbreak.[71] Closure of these clinics could deprive patients of access to this critical care.

There is no basis to impose "proximity" requirements that could lead to the defunding of many rural health clinics. Doing so runs counter to the statutory purpose of Title X, namely to ensure the availability of family planning services.[72]

D. The Final Rule Risks Limiting Access to FDA-Approved Contraceptives by Funding Providers of Ineffective and Unapproved Contraceptive Methods

The Final Rule also contains terms that could restrict access to effective contraception methods for low-income women. Title X projects are currently required to provide a "broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services."[73] Access to the "full range of FDA-approved contraceptive

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[69] Summer L. Martins et al., *Differences in Family Planning Services by Rural-Urban Geography: Survey of Title X–Supported Clinics in Great Plains and Midwestern States*, 48 PERSP. ON SEXUAL & REPROD. HEALTH 9, 15 (2016).

[70] *See supra* Section I (discussing negative ramifications of Title X provider closures in Texas and Indiana).

[71] Hal C. Lawrence & Debra L. Ness, Planned Parenthood Provides Essential Services That Improve Women's Health, 166 Ann. Intern Med. 443, 444 (2017).

[72] Family Planning Services and Population Research Act of 1970, Pub. L. No. 91-572, § 2(1), 84 Stat. 1504 (1970).

[73] 65 Fed. Reg. 41,278–79 (codified at 42 C.F.R. §59.5(a)(1)).

methods" has likewise been deemed an essential feature of quality family planning by the United States Office of Population Affairs, as well as the Center for Disease Control and Prevention.[74]

The Final Rule eliminates the former requirement that a provider must provide "medically approved" family planning services in order to be offered in a Title X program.[75] Consequently, providers that offer *only* methods of contraception that are not FDA-approved, such as natural family planning ("NFP") and "other fertility-awareness based methods"—but do not also provide FDA-approved methods of contraception—will be able to obtain Title X funding.[76] Fertility-awareness based methods, which are based on the timing of sex during a woman's menstrual cycle, are far less effective than other methods of contraception.[77] Allocating Title X funds to providers of only these unapproved and less effective methods of contraception jeopardizes the health of patients by reducing the number of providers who provide effective, evidence-based contraception.

This lowered standard for Title X eligibility is particularly dangerous for vulnerable populations. Adolescents and young adults, for whom long-acting reversible contraceptives ("LARCs")—considered the "first-line contraceptive choices for adolescents" by the AAP[78]—and other hormonal contraceptive methods have been associated with decreased rates of teen and

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[74] OFFICE OF POPULATION AFFAIRS, PROGRAM REQUIREMENTS FOR TITLE X, *supra* note 11, at 5; Loretta Gavin et al., PROVIDING QUALITY FAMILY PLANNING SERVICES: *Recommendations of CDC and the U.S. Office of Population Affairs*, CTR. FOR DISEASE CONTROL & PREVENTION MORBIDITY & MORTALITY WKLY. REP., Apr. 25, 2014, at 2, *available at* https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf.

[75] *Compare* 42 C.F.R. § 59.5, *with* 84 Fed. Reg. at 7787 (to be codified at 42 C.F.R. § 59.5).

[76] 84 Fed. Reg. at 7787 (to be codified at 42 C.F.R. § 59.5(a)(1)) ("A participating entity may offer only a single method or a limited number of methods of family planning as long as the entire project offers a broad range of such family planning methods and services.").

[77] ACOG, *FAQ 024: Fertility Awareness-Based Methods of Family Planning* (Jan. 2019), *available at* https://www.acog.org/-/media/For-Patients/faq024.pdf.

[78] AAP Committee on Adolescents, *Contraception for Adolescents*, 134 PEDIATRICS e1244, e1251 (2014), *available at* https://pediatrics.aappublications.org/content/pediatrics/134/4/e1244.full.pdf.

unintended pregnancy, may become unable to access these more effective methods of contraception.[79] Other medically underserved women, including those who are low-income, already experience the highest rates of unintended pregnancy and abortion,[80] and could be disproportionately left without alternate sources of contraception. Indeed, when qualified providers of services who offered effective contraception were previously prevented from serving low-income patients, the number of women using the most effective methods of birth control decreased by 35% and the number of births covered by Medicaid increased by 27%.[81] Because this shift in Title X's focus will have irreparable detrimental effects on many patients, including the most vulnerable, and is not medically justified, *Amici* also oppose this provision of the Final Rule.

CONCLUSION

For the foregoing reasons, the Final Rule will cause irreparable harm to the ability of health care professionals to provide evidence-based quality reproductive health care to their patients. *Amici* urge the Court to enjoin implementation of the Final Rule.

(Signature page follows)

[79] Sue Ricketts et al., *Game Change in Colorado: Widespread Use of Long-acting Reversible Contraceptives and Rapid Decline in Births Among Young, Low-income Women*, 46 PERSP. ON SEXUAL & REPROD. HEALTH 125, 129–30 (2014), *available at* https://pdfs.semanticscholar.org/4031/85ea5104c36dfab5ba3653cd8a7737b8bdd1.pdf; Gina M. Secura et al., *Provision of No-cost, Long-acting Contraception and Teenage Pregnancy*, 371 NEW ENG. J. MED. 1316, 1320–22 (2014), *available at* https://core.ac.uk/download/pdf/70384838.pdf.

[80] Finer & Zolna, *supra* note 16, at 849.

[81] Stevenson et al., *supra* note 20, at 853.

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