UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

MAYOR AND CITY COUNCIL OF BALTIMORE,

Plaintiff,

v.

ALEX M. AZAR II et al.,

Defendants.

Case No. 1:19-cv-01103-RDB

AMICUS BRIEF OF AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS ET AL. IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF PLAINTIFF'S OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT; OR ALTERNATIVELY IN SUPPORT OF PLAINTIFF'S OPPOSITION TO DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT

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INTERESTS OF AMICI CURIAE

The American College of Obstetricians and Gynecologists ("ACOG"), the American Academy of Pediatrics ("AAP"), the American College of Physicians ("ACP"), and the Society for Maternal-Fetal Medicine ("SMFM") (collectively, "Amici") submit this amici curiae brief in support of Plaintiff. 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 obstetrician–gynecologists 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 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. AAP has become a powerful voice for child and adolescent health through education, research, advocacy, and the provision of expert advice. 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.

SMFM, founded in 1977, 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 ensuring that medically appropriate treatment options are available. 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 whose ethical codes, policies, and guidance represent the collective judgment of the physicians and other medical professionals in the United States. Amici respectfully submit this brief in support of Plaintiff's November 1, 2019 Motion for

Summary Judgment[1] and Plaintiff's December 2, 2019 Memorandum in Opposition to Defendants' Cross-Motion for Summary Judgment and Reply in Support of Plaintiff's Motion for Summary Judgment.[2] Plaintiff has comprehensively briefed this Court on the history of the Title X program and its critical importance to low-income and uninsured patients. Amici submit this brief to directly highlight for the Court the ways in which the regulation promulgated by the Department of Health and Human Services ("HHS"), entitled "Compliance with Statutory Program Integrity Requirements" (the "Final Rule") conflicts with the ethical duties that medical professionals owe their patients.

Amici write to express the medical community's grave concerns regarding the Final Rule. HHS asserts a fundamentally misguided view of patient counseling that is contrary to well-established principles of medical practice and ethics for at least two key reasons. *First*, HHS incorrectly assumes that referral is not part of counseling.[3] As commonly understood by medical practitioners and in daily medical practice, counseling patients may include and, in some cases, must include, providing referrals. Well-established medical ethical principles not only recognize referrals as part of counseling, but impose obligations on practitioners to provide patients with appropriate and necessary health care, including information about their treatment options and referrals. *Second*, HHS incorrectly claims that restrictions on referral for abortion and mandated referral to prenatal counseling for a patient expressing a desire to terminate her pregnancy are not "directive."[4] This argument is flawed. It twists the meaning of non-directive counseling and ignores clear principles of medical ethics.

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[1] Pl.'s Mot. Summ. J., ECF No. 81.
[2] Pl.'s Mem. Opp'n to Defs.' Cross-Mot. Summ. J. and Reply Supp. Pl.'s Mot. Summ. J., ECF No. 84.
[3] Defs.' Mem. Opp'n to Pl.'s Mot. Summ. J. and Supp. of Defs.' Cross-Mot. Summ. J. 15-17, ECF No. 83.
[4] *Id.* at 14-15.

The Final Rule places medical professionals in a precarious and ethically compromised position by forcing them to subvert the needs of their patients to the directives of the Final Rule. Amici urge the Court to grant Plaintiff's Motion for Summary Judgment and deny Defendants' Motion for Summary Judgment in order to prevent harm to people who depend on Title X clinics for critical reproductive health care. If Defendants' Motion is granted, patient care available to individuals who rely on Title X will be severely compromised and some Title X projects will stop providing care altogether, given the Rule's ethically infirm directives. The result will be devastating to the particularly vulnerable patient populations who rely on Title X for health care.

ARGUMENT

I. HHS Asserts a Flawed Understanding of Patient Counseling That Is Contrary to Well-Established Principles of Medical Practice and Ethics

A. HHS Incorrectly Assumes That Referral Is Not Part of Counseling

Amici disagree with HHS's arguments regarding the statutory provision that requires "all pregnancy counseling shall be nondirective," which has been legislated by Congress in each HHS appropriations act since 1996.[5] HHS argues that the "nondirective provision is limited to 'pregnancy counseling,' a term that does not apply to referrals."[6] This assumption underlying HHS's position—that counseling and referral are distinct—is fundamentally at odds with medical guidance for clinical practice and longstanding principles of medical ethics.

[5] Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, Pub. L. No. 115-245, 132 Stat. 2981, 3070-71 (2018); *see also, e.g.*, Omnibus Consolidated Rescissions and Appropriations Act of 1996, Pub. L. No. 104-134, 110 Stat. 1321, 1321-22 (1996).
[6] Defs.' Mem. Opp'n 15, ECF No. 83.

1. The Final Rule Is at Odds with Well-Established Guidance for Clinical Practice

Guidance for counseling patients, published by leading authorities on the provision of health care and routinely referenced by clinicians in a range of medical specialties, recognizes that referrals are an integral part of patient counseling.

Counseling throughout the medical field is understood to encompass necessary referrals. For example, consistent with medical ethics, a patient diagnosed with a genetic susceptibility to cancer should be offered counseling, including referral to a specialist.[7] Proper counseling of a patient diagnosed with diabetes should include a referral to a registered dietician nutritionist.[8] In all areas of medicine, appropriate referrals are an inextricable part of the counseling relationship between a patient and his or her care provider. Both patients and the courts have accepted this; indeed, delay or failure to refer a patient for appropriate treatment is a common ground for medical liability claims.[9] The need for a referral and an understanding of what may be appropriate treatment for a particular patient are part and parcel of patient counseling, and HHS's divergent claim is inconsistent with basic principles of medical practice and guidance.

In the reproductive health context, counseling patients in any number of situations may require referral. In the context of contraception counseling, for example, a clinician counseling a patient may find it necessary to refer the patient to another medical professional for care. This is

[7] ACOG, Comm. on Ethics and Comm. on Genetics, *Opinion No. 410: Ethical Issues in Genetic Testing,* 111 Obstetrics & Gynecology 1495, 1495 (2008; reaffirmed 2014) (the patient "should be offered counseling and follow-up, with referral as appropriate, to ensure delivery of care consistent with current standards").
[8] Eileen Stellefson Myers, *Nutrition Counseling for Patients with Prediabetes or Diabetes*, Pharmacy Times (Oct. 27, 2016).
[9] Xiao Xu et al., *The Effect of Medical Malpractice Liability on Rate of Referrals Received by Specialist Physicians*, 8 Health Econ. Pol'y Law 453, 454 (2013) ("failure or delay in referral are among the reasons most cited for medical negligence claims in the United States").

also the case in the context of counseling regarding fertility, pregnancy, and health conditions one may experience during pregnancy, among others.

Indeed, clinical guidance on counseling instructs clinicians to refer patients when necessary, illustrating that referral is an integral part of patient counseling. As AAP plainly states, "*Counseling includes . . . referring* the adolescent to appropriate resources and services."[10] Other prominent sources contain similar guidance; for example, Simmonds & Likis write that "comprehensive, respectful pregnancy options counseling . . . . may require *that the nurse refer patients* to a colleague or to a different setting entirely,"[11] ACOG's Opinion No. 710 observes that obstetrician-gynecologists "have the *duty to refer* patients in a timely manner to other health care providers if they do not feel that they can provide the standard reproductive services that their patients request,"[12] and a recent ACOG position statement explains that, when counseling a pregnant patient diagnosed with the Zika virus, which causes an increased likelihood of life-threatening birth defects, a physician must be prepared to refer patients to abortion care.[13] Put plainly, in the reproductive counseling context, clinicians understand, and good clinical practice dictates, that counseling includes referrals. HHS's view of the two as separate is inconsistent with reality and clinical guidance.

2. The Final Rule Is at Odds with Well-Established Principles of Medical Ethics

Leading authorities on medical ethics and rules of ethical conduct for medical professionals, such as the AMA's Code of Medical Ethics and ACOG's Code of Professional

[10] Laurie L. Hornberger & AAP Comm. on Adolescence, *Options Counseling for the Pregnant Adolescent Patient*, 140 Pediatrics 1, 1 (2017) (emphasis added). Unless otherwise indicated, all emphasis is added.
[11] Katherine E. Simmonds & Frances E. Likis, *Providing Options Counseling for Women with Unintended Pregnancies*, 34 J. Obstetric, Gynecologic, & Neonatal Nursing 373, 375 (2005).
[12] ACOG, Comm. on Adolescent Health Care, *Opinion No. 710: Counseling Adolescents About Contraception*, 123 Obstetrics & Gynecology 389, 392 (2017).
[13] ACOG, *Position Statement: Counseling Patients with Zika Infection* (2016).

Ethics, codify medical professionals' ethical duties and unequivocally state that these professionals have a duty to refer when appropriate.[14] ACOG's Code of Professional Ethics states that medical professionals have an ethical duty, to both the patient and to the medical community, to "exercise all reasonable means to ensure that the most appropriate care is provided to the patient," including by "refer[ring]" a patient to "other physicians, health care professionals, and institutions to the extent necessary to serve the best interests of their patients."[15] Similarly, the AMA Code of Medical Ethics states that "[a] physician shall . . . make relevant information available to patients . . . obtain consultation, and use the talents of other health professionals when indicated."[16] ACOG's Committee Opinions also routinely require physicians to make appropriate referrals.[17] These medical authorities confirm the ethical duty to refer patients is an integral component of patient counseling.

This ethical duty to make appropriate and timely referrals is part of medical professionals' broader ethical duties to ensure a patient's welfare, respect patient autonomy,

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[14] AMA's Code states its principles are "standards of conduct that define the essentials of honorable behavior for the physician." AMA, *Code of Medical Ethics: Principles of Medical Ethics* 1 (2016). Noncompliance with ACOG's Code of Professional Ethics "may affect an individual's initial or continuing Fellowship in [ACOG]." ACOG, *Code of Professional Ethics* 1 (2018).

[15] ACOG, *Code of Professional Ethics* at 2-3.

[16] AMA, *Code of Medical Ethics: Principles of Medical Ethics* at 1.

[17] *See* ACOG, Comm. on Ethics, *Opinion No. 439: Informed Consent*, 114 Obstetrics & Gynecology 401, 407 (2009; reaffirmed 2015) ("[P]hysicians must provide the patient with accurate and unbiased information about her medical options and make appropriate referrals."); ACOG, Comm. on Ethics, *Opinion No. 528: Adoption*, 119 Obstetrics & Gynecology 1320, 1322 (2012; reaffirmed 2018) ("Physicians often may best fulfill their obligations to patients through referral to other professionals who have the appropriate skills and expertise."); ACOG, Comm. on Ethics, *Opinion No. 385: The Limits of Conscientious Refusal in Reproductive Medicine*, 110 Obstetrics & Gynecology 1203, 1203 (2007; reaffirmed 2016) (describing "duty to refer patients in a timely manner to other providers if [providers] do not feel that they can in conscience provide the standard reproductive services that their patients requests"). *See also* 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) ("The guidelines of a number of leading professional medical organizations specifically address the need for comprehensive, unbiased information on and referral for all of a woman's pregnancy options—parenting, adoption or abortion—as a fundamental component of a patient's right to self-determination.").

provide a patient with truthful information sufficient for informed consent, and do no harm. As the AMA has affirmed, "referring patients to other professionals to provide care" is part of a physician's obligation to promote patients' best interests and wellbeing.[18] In other words, when a referral would serve a patient's best interests, that referral is a required component of the patient-physician relationship. The duty to refer also stems from the duty to provide patients with information sufficient for informed consent, as patients may need to be referred to another medical professional to obtain complete information about all relevant options.[19] For these reasons, a medical professional's duty to refer is part of bedrock medical ethical principles. Because clinicians cannot separate their duty to refer from their provision of counseling, the Court should reject HHS's faulty argument that referral is separate from counseling and affirm the lower court on this issue.

B. HHS Incorrectly Claims That a Prohibition on Referral for Abortion and a Mandated Referral to Prenatal Health Care for Patients Seeking to Terminate a Pregnancy Are "Nondirective"

The Final Rule improperly promotes directive pregnancy counseling by prohibiting referrals for abortion and mandating referrals for prenatal health care regardless of a patient's expressed need. The essential feature of *non*directive pregnancy counseling, as required by Congress, is that it is necessarily *patient*-directed—not directed by the counseling physician. Nondirective counseling thus requires that the patient be fully informed about the appropriate

[18] AMA, *Code of Medical Ethics Opinion 1.2.3* (2016).
[19] AAP, Comm. on Bioethics, *Policy Statement—Physician Refusal to Provide Information or Treatment on the Basis of Claims of Conscience*, 124 Pediatrics 1689, 1689 (2009) ("As part of informed consent, physicians also have a duty to inform their patients of all relevant and legally available treatment options, including options to which they object. They have a moral obligation to refer patients to other health care professionals who are willing to provide those services when failing to do so would cause harm to the patient.").

courses of care relevant to the patient's particular situation and expressed needs.[20]

Nondirective counseling is tailored to the patient's expressed needs. In cases where a pregnant patient is ambivalent about her pregnancy, nondirective counseling requires that she be informed in a balanced manner about all pregnancy options that are relevant to her expressed needs.[21] This may require that a medical professional inform a patient "about all options, including raising the child herself, placing the child for adoption, and abortion."[22] Such nondirective pregnancy counseling accords with a physician's ethical duties to maintain a trusting patient-physician relationship and obtain informed consent.[23] In situations where a pregnant patient intends to carry her pregnancy to term, she should be provided information about how to promote a healthy pregnancy and referred for prenatal care. In situations where a patient intends to terminate her pregnancy, she should be provided information about abortion and referred for care consistent with her expressed wishes. Contrary to the statutory mandate of nondirective counseling, the Final Rule's requirement that a clinician refer a patient who is *not* seeking to carry a pregnancy to term for prenatal care requires that the clinician *direct* the patient

[20] *See, e.g.*, Hasstedt, 21 Guttmacher Pol'y Rev. at 1; ACOG, *Guidelines for Women's Health Care: A Resource Manual* 345, 719 (4th ed. 2014); Simmonds & Likis, 34 J. Obstetric, Gynecologic, & Neonatal Nursing at 375 ("Although the woman may make a decision that is different from what the nurse wishes or believes best, upholding patient autonomy is paramount.").
[21] Hasstedt, 21 Guttmacher Pol'y Rev. at 1 (physician should provide "complete, medically accurate, and unbiased information and resources for all [of a patient's] pregnancy options.").
[22] ACOG, *Guidelines for Women's Health Care* at 719; ACOG, *Code of Professional Ethics* at 2.
[23] ACOG, *Code of Professional Ethics* at 2 (a medical professional should serve as the "patient's advocate" and "exercise all reasonable means to ensure the most appropriate care is provided to the patient.").

to a course of treatment.[24] Additionally, the Final Rule's restrictions on providing abortion counseling or clear referrals to abortion providers are directive.[25]

As understood by the medical community, nondirective pregnancy counseling enables patient choice through the provision of information tailored to the patient's expressed needs and conditions. It is unethical for medical professionals to provide therapies that are medically unnecessary and of no benefit to the patient; a patient should be referred to only a health care professional who will be able to provide the services the patient seeks or requires.[26] Prenatal care is not medically indicated when a patient plans to terminate her pregnancy—it is recommended only when a patient plans to continue her pregnancy.[27]

The Final Rule's requirement that a pregnant patient in all cases "*shall be*" referred to prenatal care, and may be provided with only limited abortion counseling, regardless of the patient's wishes, is not "nondirective."[28] If a pregnant patient walks into a medical clinic and informs her provider that she is considering obtaining an abortion, she trusts that her provider will give her objective, balanced information, just as she would expect in any other medical

[24] Op. Prelim. Inj. 20, ECF No. 43; Compliance with Statutory Program Integrity Requirements, 84 Fed. Reg. 7,714, 7,789 (Mar. 4, 2019) (to be codified at 42 C.F.R. § 59.14(b)(1)) ("once a client served by a Title X project is medically verified as pregnant, she *shall be* referred to a health care provider for medically necessary prenatal health care").

[25] Under the Final Rule, "a Title X project may not . . . refer for . . . abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion." 84 Fed. Reg. at 7,788-89 (to be codified at 42 C.F.R. § 59.14(a)). HHS itself characterizes the Final Rule as amounting to a "prohibition on abortion referrals." Defs.' Mem. Opp'n 14, ECF No. 83. The Final Rule also limits abortion counseling by requiring that the provider may not "encourage," "promote," "support" or "advocate" "abortion as a method of family planning." 84 Fed. Reg. 7,788-89 (to be codified at 42 C.F.R. §§ 59.5(a)(5), 59.14(a), 59.16).

[26] ACOG, *Informed Consent* at 7; AMA, *Code of Medical Ethics Opinion 1.2.3*.

[27] *See, e.g.*, Pl.'s Mem. Supp. Mot. Summ. J. Ex. 10 at PEP403, ECF No. 81 ("Prenatal care is not a medically indicated or appropriate course of care for a patient who intends to terminate her pregnancy."); ACOG, *FAQ 168: Pregnancy Choices: Raising the Baby, Adoption, and Abortion* (2013) ("If you choose to raise the baby or give the baby up for adoption, it is best to begin prenatal care as soon as vou can.").

[28] 84 Fed. Reg. at 7,788-89 (to be codified at 42 C.F.R. §§ 59.14(a), 59.14(b)(1)); Hasstedt, 21 Guttmacher Pol'y Rev. at 1; ACOG, *Guidelines for Women's Health Care* at 719.

situation. Under the Final Rule, however, the patient will instead be referred to prenatal care.[29] When the patient expressly asks for a referral for an abortion, the Final Rule allows the medical professional to give a list of referrals, but the majority of providers on this list cannot provide abortions, and neither the list nor the referring medical professional can delineate which of the providers on that list, if any, actually offer the needed care.[30] The referring professional is thus prevented from giving the patient full information about appropriate courses of treatment.[31] This is directive care based on the *government's directive*: regardless of the patient's interests, she will not be given the information she seeks, and instead will be referred to prenatal care.[32] This is precisely what Congress prohibited.

II. There Is No Genuine Dispute That, as the Court Previously Found, the Final Rule Will Cause Irreparable Harm

In May, this Court found that the Final Rule was likely to violate the law and that the harm was sufficiently grave to warrant a preliminary injunction. There is no genuine dispute of material fact that the Court's finding is correct. Amici, as medical practitioners, write to explain that HHS's unsupported speculation about the effects of the Final Rule is inconsistent with the existing medical landscape. The Court should grant Plaintiff's Motion and deny Defendants' Motion, given that there exists no genuinely disputed material facts, and Plaintiff is entitled to judgment as a matter of law.

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[29] *See, e.g.*, 84 Fed. Reg. at 7,730, 7,748.
[30] *Id*. at 7,789 (to be codified at 42 C.F.R. §§ 59.14(c)(2), 59.14(e)(3)).
[31] HHS's argument that the Final Rule's prohibition on abortion referrals is not directive pregnancy counseling because the provider does not "direct" the patient to do anything (*see* Defs.' Mem. Opp'n 14, ECF No. 83) is belied by the medical community's understanding of directive counseling. "Directive pregnancy counseling" does not necessarily involve literally directing a patient to perform one particular action. *See* ACOG, *Guidelines for Women's Health Care* at 345, 719. The purposeful omission of medically appropriate and patient-requested information is directive. Preventing a provider from offering a patient who seeks to terminate her pregnancy with requested referrals for abortion care constitutes *directive* pregnancy counseling.
[32] AMA, *Code of Medical Ethics Opinion 2.1.1* (2016) (clinicians should "present relevant information accurately and sensitively, in keeping with the patient's preferences").

First, as described *supra*, the Final Rule's restrictions contravene medical ethics and best practices. A regulation that imposes significant constraints on a medical professional's ability to provide continued quality care for his or her patients causes irreparable harm.[33] Here, as the Court already recognized, the Final Rule restricts medical professionals' ability to provide care consistent with best practices and ethical norms. This Court correctly held that the Final Rule "requires physicians to withhold relevant medical information from patients."[34] HHS has not disputed this finding. Instead, HHS asserts that withholding such information is not "directive,"[35] but as explained *supra*, failing to fully inform a patient about her options is directive counseling, as non-directive counseling requires a patient to be fully informed about the appropriate courses of care relevant to the patient's particular situation and expressed needs; otherwise the patient is directed away from at least those courses of care about which she was not informed.

Second, the Final Rule undermines the patient-provider relationship, which is the cornerstone of ethical medical practice. As this Court determined, "[r]equiring physicians to disregard a patient's wishes and provide information that the patient does not want or need eliminates patients' ability to make fully informed 'voluntary' choices about their medical care," and the Final Rule requires Title X providers to act coercively toward patients.[36] HHS's argument that a patient can obtain "voluntary" care under the Final Rule because the care is not

[33] *See Fairfield Cty. Med. Ass'n v. United Healthcare of New England*, 985 F. Supp. 2d 262, 271-72 (D. Conn. 2013), *aff'd as modified sub nom. Fairfield Cty. Med. Ass'n v. United Healthcare of New England, Inc.*, 557 F. App'x 53 (2d Cir. 2014) (finding irreparable injury to physicians where they would suffer "disruption of their relationships with their . . . patients" and noting "several district and circuit courts have found that disruption of the physician-patient relationship can cause irreparable harm… particularly when the patient belongs to a vulnerable class"); *State of New York. v. Schweiker*, 557 F. Supp. 354, 360 (S.D.N.Y. 1983) (HHS regulation requiring physicians to disclose adolescent health information to patients' parents was an irreparable harm because it would deter patients from seeking care and cause physicians to breach their ethical duty to maintain patient confidentiality.").
[34] Op. Prelim. Inj. 17, ECF No. 43.
[35] Defs.' Reply Supp. Mot. Dismiss 3, ECF No. 72.
[36] Op. Prelim. Inj. 19-20, ECF No. 43.

conditioned upon the receipt of a further service or benefit fails to address these coercive effects of withholding information on a patient's care.[37] Moreover, interfering with patients' ability to make informed and voluntary choices about their own health will likely undermine patients' trust, making patients less likely to turn to medical professionals for other critical care, such as timely cancer screenings or obtaining effective contraceptive care.[38]

Third, the implementation of the Final Rule will exacerbate the ongoing shortage of providers of necessary medical care. Currently, there is a nationwide shortage of obstetrician-gynecologists.[39] This trend is expected to worsen: leading groups predict that by 2030 there will be an 18% nationwide shortage of obstetrician-gynecologists,[40] and a shortfall of as many as 55,200 primary care physicians ("PCPs") and 65,800 non-primary care physicians by 2032.[41] The current and projected shortage of family care physicians, a subgroup of PCPs, is particularly dire, as these physicians tend to host more office visits, and are more likely to be located in rural areas, than the other PCP subgroups.[42] The Final Rule has generated extreme uncertainty regarding the continued provision of this critical care. HHS required Title X grantees to comply

[37] Defs.' Mem. Opp'n 19-20, ECF No. 83.
[38] ACOG, Comm. on Health Care for Underserved Women, *Opinion No. 615: Access to Contraception*, 125 Obstetrics & Gynecology 250, 251 (2015; reaffirmed 2017); ACOG, Comm. on Adolescent Health Care, *Opinion No. 699: Adolescent Pregnancy, Contraception, and Sexual Activity*, 129 Obstetrics & Gynecology 142, 143, 146 (2017).
[39] *See* William F. Rayburn, ACOG, *The Obstetrician-Gynecologist Workforce in the United States* 4, 121 (2017) (half of the counties in the United States already do not have any obstetrician-gynecologists).
[40] *Id*.
[41] Tim Dall et al., *Complexities of Physician Supply and Demand: Projections from 2017 to 2032* at viii (2019) ("*Complexities of Physician Supply*"). The United States is expected to need nearly 52,000 additional primary care physicians by 2025. Stephen M. Petterson et al., *Projecting US Primary Care Physician Workforce Needs: 2010-2025*, 10 Annals Fam. Med. 503, 507 (2012).
[42] Stephen Petterson et al., Robert Graham Center, *The State of Primary Care in the United States: A Chartbook of Facts and Statistics* 8, 13 (2018); AAFP, *America Needs More Family Doctors: 25x2030*, https://www.aafp.org/about/ initiatives/family-doctor-expansion.html (last visited Dec. 9, 2019); *Complexities of Physician Supply* at 6. *See generally* Stephen Petterson et al., Robert Graham Center, *The State of Primary Care Physician Workforce* (2019).

with substantial portions of the Final Rule beginning on July 15, 2019.[43] This resulted in an immediate and steep decline in the existing number of Title X projects. As of October 9, more than one in four of approximately 4,000 Title X projects have announced that they are no longer using Title X funds or are withdrawing from the program.[44] Recent analysis shows that the exit of Planned Parenthood clinics alone (not taking into account the additional exiting projects) would require remaining Title X projects to increase their contraceptive client caseloads by an average of 70%.[45] Remaining Title X projects will struggle to fill this service gap. Between March and September 2019, approximately 1,345 Title X projects have exited the program while only approximately 200 new projects have been added.[46] The continued existence of family planning clinics that have left Title X is tenuous, as these clinics seek to gather temporary sources of funding from states, individual reserves, or other sources.[47] Any budget shortfalls may force these clinics to reduce hours, cut education and outreach programming, and reduce their supply of contraceptives available to patients.[48]

These shortages will only worsen as practitioners continue to be forced to forego necessary Title X funds in order to comply with medical best practices and ethical duties. Such

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[43] HHS, *Fact Sheet: Final Title X Rule Detailing Family Planning Grant Program*, https://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/statutes-and-regulations/compliance-with-statutory-program-integrity-requirements/fact-sheet/index.html (last visited Dec. 9, 2019).
[44] *The Status of Participation in the Title X Federal Family Planning Program*, Kaiser Family Foundation (2019), https://www.kff.org/interactive/the-status-of-participation-in-the-title-x-federal-family-planning-program/ (last visited Dec. 9, 2019).
[45] Kinsey Hasstedt, *Beyond the Rhetoric: The Real-World Impact of Attacks on Planned Parenthood and Title X*, 20 Guttmacher Pol'y Rev. 86, 89 (2017).
[46] *Compare* Title X Family Planning Directory, HHS (September 2019), https://www.hhs.gov/opa/sites/default/files/Title-X-Family-Planning-Directory-September2019.pdf (last visited Dec. 9, 2019), *with* Title X Family Planning Directory, HHS (March 2019), https://www.hhs.gov/opa/sites/default/files/Title-X-Family-Planning-Directory-March2019.pdf (last visited Dec. 9, 2019) (This analysis takes into account all Title X grantees, sub-recipients, and service sites.).
[47] Brittni Frederiksen et al., *Data Note: Impact of New Title X Regulations on Network Participation*, Kaiser Family Foundation (2019).
[48] *Id.*

shortages cause a clear harm to patients who rely on Title X. 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.[49] Title X provides necessary services, including well-woman exams, breast and cervical cancer screenings, FDA-approved contraceptive methods and counseling services, screening and treatment for sexually transmitted infections, testing for HIV, pregnancy testing and counseling, and other patient education and/or health referrals.[50]

Contrary to HHS's unsupported speculation, the harmful impacts of the Final Rule are already impacting millions of lives.

CONCLUSION

For the foregoing reasons, Amici respectfully request that this Court grant Plaintiff's Motion for Summary Judgment and deny Defendants' Motion for Summary Judgment.

(Signature page follows)

[49] Christina Fowler et al., Office of Population Affairs, *Title X Family Planning Annual Report: 2017 National Summary* at ES-1 (Aug. 2018).
[50] *Id.*

Date: December 9, 2019

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