No. 19-35386(L)

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

STATE OF OREGON, et al.,

Plaintiffs-Appellees,

v.

ALEX M. AZAR II, in his Official Capacity as Secretary of the U.S. Department of Health & Human Services, et al.,

Defendants-Appellants.

AMERICAN MEDICAL ASSOCIATION et al.,

Plaintiffs-Appellees,

v.

ALEX M. AZAR II, in his Official Capacity as Secretary of the U.S. Department of Health & Human Services, et al.,

Defendants-Appellants.

On Appeal from the United States District Court for the District of Oregon

BRIEF OF *AMICI CURIAE* AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN ACADEMY OF PEDIATRICS, AMERICAN ACADEMY OF FAMILY PHYSICIANS, AMERICAN COLLEGE OF PHYSICIANS, CALIFORNIA MEDICAL ASSOCIATION, SOCIETY FOR ADOLESCENT HEALTH AND MEDICINE, AND SOCIETY FOR MATERNAL-FETAL MEDICINE IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

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Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, *amici curiae* state that they are non-profit organizations, with no parent corporations or publicly traded stock, and no publicly held company has 10% or greater ownership in *amici*.

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Fairfield Cty. Med. Ass'n v. United Healthcare of New England,
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State of N.Y. v. Schweiker,
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Statutes & Regulations

84 Fed. Reg. 7714 (Mar. 4, 2019)..14, 15

Department of Defense and Labor, Health and Human Services, and
Education Appropriations Act, Pub. L. No. 115-245, 132 Stat.
2981 (2018)..7

Omnibus Consolidated Rescissions and Appropriations Act of 1996,
Pub. L. No. 104-134, 110 Stat. 1321 (1996) 7

Other Authorities

AAFP, *America Needs More Family Doctors: 25x2030*,
https://www.aafp.org/about/initiatives/family-doctor-expansion.html (last visited June 29, 2019) 19

AAP, Comm. on Bioethics, *Policy Statement—Physician Refusal to Provide Information or Treatment on the Basis of Claims of Conscience*, 124 PEDIATRICS 1689 (2009)..12

ACOG, CODE OF PROFESSIONAL ETHICS (2018) 10, 13, 17

ACOG, Comm. On Adolescent Health Care, *Opinion No. 699: Adolescent Pregnancy, Contraception, and Sexual Activity*, 129 OBSTETRICS & GYNECOLOGY 142 (2017) 19

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ACOG, Comm. on Ethics, *Opinion No. 297: Nonmedical Use of Obstetric Ultrasonography*, 104 OBSTETRICS & GYNECOLOGY 423 (2004) 17

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ACOG, Comm. on Ethics, *Opinion No. 439: Informed Consent*, 114 OBSTETRICS & GYNECOLOGY 401 (2009; reaffirmed 2015)....................11, 14

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ACOG, Comm. on Ethics and Comm. on Genetics, *Opinion No. 410: Ethical Issues in Genetic Testing,* 111 OBSTETRICS & GYNECOLOGY 1495 (2008; reaffirmed 2014) 8

ACOG, Comm. on Health Care for Underserved Women, *Opinion No. 615: Access to Contraception*, 125 OBSTETRICS & GYNECOLOGY 250 (2015; reaffirmed 2017)....................19

ACOG, *FAQ 168: Pregnancy Choices: Raising the Baby, Adoption, and Abortion* (2013)....................15

ACOG, GUIDELINES FOR WOMEN'S HEALTH CARE: A RESOURCE MANUAL (4th ed. 2014) 13, 15, 16

ACOG, *Position Statement: Counseling Patients with Zika Infection* (2013)....................9

AMA, CODE OF MEDICAL ETHICS: PRINCIPLES OF MEDICAL ETHICS (2016)....................10, 11

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Laurie L. Hornberger & AAP Comm. on Adolescence, *Options Counseling for the Pregnant Adolescent Patient*, 140 PEDIATRICS 1 (2017) 9

Stephen M. Petterson et al., *Projecting US Primary Care Physician Workforce Needs: 2010-2025,* 10 ANNALS FAM. MED. 503 (2012) 19

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INTERESTS OF *AMICI CURIAE*[1]

The American College of Obstetricians and Gynecologists ("ACOG"), the American Academy of Pediatrics ("AAP"), the American College of Physicians ("ACP"), the California Medical Association ("CMA"), the American Academy of Family Physicians ("AAFP"), 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-Appellees. *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

[1] All parties consented to the filing of this *amicus* brief. No party's counsel in this case authored this brief in whole or in part. No party or party's counsel contributed any money intended to fund preparing or submitting this brief. No person, other than *amici*, their members, or their counsel contributed money that was intended to fund preparing or submitting this brief.

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.

AAFP, headquartered in Leawood, Kansas, is the national medical specialty society representing family physicians. Founded in 1947 as a not-for-profit corporation, its 134,600 members are physicians and medical students from all 50 states, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, and the Uniformed Services of the United States. AAFP seeks to improve the health of patients, families, and communities by advocating for the health of the public and serving the needs of its members with professionalism and creativity.

CMA is a non-profit, incorporated professional association for physicians with more than 44,000 members throughout the State of California. For more than 150 years, CMA has promoted the science and art of medicine, the care and well-being of patients, the protection of public health, and the betterment of the medical profession. CMA's physician members practice in all specialties and settings, including providing comprehensive family planning and reproductive health services.

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.

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 providers in the United States. *Amici* respectfully submit this brief in support of Plaintiffs-Appellees and affirmance of the District Court's April 29, 2019 Opinion and Order in *Oregon v. Azar* ("Order").[2] Plaintiffs-Appellees have 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 providers 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

[2] No. 19-cv-317 (D. Or. Apr. 29, 2019).

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.

The Final Rule places medical providers 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 affirm the district court's preliminary injunction order to prevent harm to people who depend on Title X clinics for critical reproductive health care. In the absence of an injunction, patient care available to individuals who rely on Title X will be severely compromised and some providers will stop providing care altogether, given the Rule's ethically

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[3] HHS's Opening Br. (Dkt. 27), at 25–28.

[4] HHS's Opening Br. (Dkt. 27), at 24, 29.

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.

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.

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[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] HHS's Opening Br. (Dkt. 27), at 25.

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. Indeed, delay or failure to refer a patient for appropriate treatment is a common ground for medical malpractice 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

[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").

example, a clinician counseling a patient may find it necessary to refer the patient to another provider for care. This is 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] *See also, e.g.*, Katherine E. Simmonds & Frances E. Likis, *Providing Options Counseling for Women with Unintended Pregnancies*, 34 J. OBSTETRIC, GYNECOLOGIC, & NEONATAL NURSING 373, 375 (2005) ("comprehensive, respectful pregnancy options counseling . . . . may require *that the nurse refer patients* to a colleague or to a different setting entirely");[11] ACOG, Comm. on Adolescent Health Care, *Opinion No. 710: Counseling Adolescents About Contraception*, 123 OBSTETRICS & GYNECOLOGY 389, 392 (2017) ("[o]bstetrician–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"); ACOG, *Position Statement: Counseling Patients with Zika Infection* (2016) (when

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[10] Laurie L. Hornberger & AAP Comm. on Adolescence, *Options Counseling for the Pregnant Adolescent Patient* 140 PEDIATRICS 1, 1 (2017) (emphasis added).

[11] Unless otherwise indicated, all emphasis is added.

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). 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 Ethics, codify medical providers' ethical duties and unequivocally state that providers have a duty to refer when appropriate.[12] ACOG's Code of Professional Ethics states that providers 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."[13]

[12] 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).

[13] ACOG, CODE OF PROFESSIONAL ETHICS, *supra* note 12, at 2–3.

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."[14] ACOG's Committee Opinions also routinely require physicians to make appropriate referrals.[15] 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 providers' broader ethical duties to ensure a patient's welfare, respect patient autonomy, 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

[14] AMA, CODE OF MEDICAL ETHICS, *supra* note 12, at 1.

[15] *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.").

patients' best interests and wellbeing.[16] 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 provider to obtain complete information about all relevant options.[17] For these reasons, a provider'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. Nondirective counseling thus requires that the patient be fully informed

[16] AMA, CODE OF MEDICAL ETHICS OPINION 1.2.3 (2016).

[17] 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.").

about the appropriate courses of care relevant to the patient's particular situation and expressed needs.[18]

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.[19] This may require that a provider inform a patient "about all options, including raising the child herself, placing the child for adoption, and abortion."[20] Such nondirective pregnancy counseling accords with a provider's ethical duties to maintain a trusting patient-physician relationship and obtain informed consent.[21] 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 desires to terminate her pregnancy, she should be provided

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[18] *See, e.g.*, Hasstedt, *supra* note 15, at 1; ACOG, GUIDELINES FOR WOMEN'S HEALTH CARE: A RESOURCE MANUAL 345, 719 (4th ed. 2014); Katherine E. Simmonds & Frances E. Likis, *Providing Options Counseling for Women with Unintended Pregnancies*, 34 J. OBSTETRIC, GYNECOLOGIC, & NEONATAL NURSING 373, 375 (2005) ("Although the woman may make a decision that is different from what the nurse wishes or believes best, upholding patient autonomy is paramount.").

[19] Hasstedt, *supra* note 15, at 1 (physician should provide "complete, medically accurate, and unbiased information and resources for all [of a patient's] pregnancy options.").

[20] ACOG, GUIDELINES FOR WOMEN'S HEALTH CARE, *supra* note 18, at 719; ACOG, CODE OF PROFESSIONAL ETHICS, *supra* note 12, at 2.

[21] ACOG, CODE OF PROFESSIONAL ETHICS, *supra* note 12, at 2 (a provider should serve as the "patient's advocate" and "exercise all reasonable means to ensure the most appropriate care is provided to the patient.").

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 to a course of treatment. [22] Additionally, the Final Rule's restrictions on providing abortion counseling or clear referrals to abortion providers are directive.[23]

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 only be referred to a health care professional who will be able to provide the services the patient seeks or requires.[24] Prenatal care is

[22] Order at 19; Compliance with Statutory Program Integrity Requirements, 84 Fed. Reg. 7714, 7789 (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").

[23] 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 7788–89 (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." HHS's Opening Br. (Dkt. 27), at 24. 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. 7788–89 (to be codified at 42 C.F.R. §§ 59.5(a)(5), 59.14(a), 59.16).

[24] ACOG, *Informed Consent*, *supra* note 15, at 7; AMA, CODE OF MEDICAL ETHICS OPINION 1.2.3, *supra* note 16.

not medically indicated when a patient plans to terminate her pregnancy—it is recommended only when a patient plans to continue her pregnancy.[25]

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."[26] 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. Under the Final Rule, however, the patient will instead be referred to prenatal care.[27] When the patient expressly asks for a referral for an abortion, the Final Rule allows the provider to give a list of referrals, but the majority of providers on this list cannot provide abortions, and neither the list nor the provider can delineate which of the providers on that list, if any, actually offer the needed care.[28] The provider is thus prevented from giving the patient full

[25] *See, e.g.*, Ewing Decl., ER55 ¶ 43 ("Prenatal care is not medically necessary for a woman who has decided to terminate her pregnancy; for such a woman, an abortion is the 'medically necessary' treatment."); 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 you can.").

[26] 84 Fed. Reg. at 7788–89 (to be codified at 42 C.F.R. §§ 59.14(a), 59.14(b)(1)); Hasstedt, *supra* note 15, at 1; ACOG, GUIDELINES FOR WOMEN'S HEALTH CARE, *supra* note 18, at 719.

[27] *See, e.g.,* 84 Fed. Reg. at 7730, 7748.

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

information about appropriate courses of treatment.[29] 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.[30] This is precisely what Congress prohibited.

Even HHS appears to acknowledge that the Final Rule's blanket prenatal referral requirement and the ban on abortion referral may violate medical best practices and ethics. HHS offers as a solution that "[p]roviders could even expressly include a disclaimer that the prenatal-care referral is a general requirement and should not be taken as directing the patient's ultimate decision about her pregnancy."[31] But asking providers to "disclaim" the care they provide their patients is yet another grave misunderstanding of the ethical requirements providers must abide by when communicating with patients. Providers should never give medically unnecessary referrals to their patients; referrals should always

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[29] HHS's argument that the Final Rule's prohibition on abortion referrals is not directive pregnancy counseling because the provider is not "directing" the patient to do anything (*see* HHS's Opening Br. (Dkt. 27), at 24) 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, *supra* note 18, 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.

[30] 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").

[31] HHS's Response to Appellees' Emergency Motions for Reconsideration *En Banc* (Dkt. 72) at 9.

be based upon a patient's medical needs.[32] By suggesting that providers "disclaim" their patient recommendations, HHS acknowledges that the Final Rule would require providers to give inappropriate care to some patients. Further, the act of providing a referral that is inconsistent with a patient's expressed need and then immediately disclaiming its validity would send mixed signals, confuse the patient, and sow mistrust within the provider-patient relationship. Indeed, *Amici* have raised concerns about disclaimers in other contexts, fearing that they would lead to patient confusion and be ineffective.[33] HHS's proffered solution that a provider may disclaim the mandated prenatal referral is inconsistent with medical ethical requirements and the functional practice of medicine.[34]

II. Absent an Injunction, the Final Rule Will Cause Irreparable Harm

Three district court judges in this Circuit who considered the Final Rule found that it was likely to violate the law and that the harm was sufficiently grave to warrant a preliminary injunction. *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. Contrary to HHS's speculation,

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[32] ACOG, CODE OF PROFESSIONAL ETHICS, *supra* note 12, at 2; AMA Code of Ethics Opinion 1.2.3, *supra* note 16.

[33] *See* ACOG, Comm. on Ethics, *Opinion No. 297: Nonmedical Use of Obstetric Ultrasonography*, 104 OBSTETRICS & GYNECOLOGY 423, 423 (2004).

[34] AMA Code of Ethics Opinion 1.2.3, *supra* note 16 (instructing that referring physicians should "[e]xplain the rationale for the consultation, opinion, or findings and recommendations clearly to the patient").

real-world experience confirms that the Final Rule will cause an immediate and steep decline both in the number of Title X providers and the quality of care they can provide. The Court should affirm the district court's injunction order, given the nature and magnitude of the immediate harm if the Final Rule were to go into effect.

First, as described *supra*, the Final Rule's restrictions contravene medical ethics and best practices. When a regulation imposes significant constraints on a medical provider's ability to provide continued quality care for his or her patients, irreparable harm has been demonstrated sufficient to justify a preliminary injunction.[35] Here, the Final Rule's restrictions on providers' ability to provide care consistent with best practices and ethical norms warrant a preliminary injunction.

Second, the Final Rule will undermine the patient-provider relationship, which is the cornerstone of ethical medical practice. The Final Rule's restrictions on doctors' communication will likely undermine patients' trust, making patients

[35] *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 N.Y. 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").

less likely to turn to medical professionals for other critical care, such as timely cancer screenings or obtaining effective contraceptive care.[36]

Third, if the Final Rule is implemented, it will exacerbate the ongoing shortage of providers of necessary medical care. Currently, there is a nationwide shortage of obstetrician-gynecologists.[37] This trend is expected to worsen: leading groups predict that by 2030 there will be an 18% nationwide shortage of obstetrician-gynecologists,[38] and a shortfall of as many as 55,200 primary care physicians ("PCPs") and 65,800 non-primary care physicians by 2032.[39] 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.[40] If the Final

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[36] 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).

[37] *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).

[38] *Id*.

[39] TIM DALL ET AL., COMPLEXITIES OF PHYSICIAN SUPPLY AND DEMAND: PROJECTIONS FROM 2017 TO 2032 at viii (2019). 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).

[40] 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 June 29, 2019); TIM DALL ET AL., *supra* note 39, at 6. *See generally* STEPHEN

Rule goes into effect and practitioners are forced to forego Title X funds in order to comply with medical best practices and ethical duties, these shortages will only worsen. This will 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.[41] 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.[42]

Contrary to HHS's unsupported speculation, the harmful impacts of the Final Rule will affect millions of lives.

CONCLUSION

For the foregoing reasons, *Amici* respectfully request that this Court affirm the preliminary injunction order of the lower court.

(Signature page follows)

PETTERSON ET AL., ROBERT GRAHAM CENTER, THE STATE OF PRIMARY CARE PHYSICIAN WORKFORCE (2019).

[41] CHRISTINA FOWLER ET AL., OFFICE OF POPULATION AFFAIRS, TITLE X FAMILY PLANNING ANNUAL REPORT: 2017 NATIONAL SUMMARY at ES-1 (Aug. 2018).

[42] *Id.*

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 29, I certify that:

This brief complies with the type-volume limitation of Fed. R. App. P. 29 (a)(5), 32(a)(7)(b), and Circuit Rule 32-1(a) because this brief contains 5,106 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionately spaced typeface using Microsoft Word 2016 Times New Roman 14-point font.

Date: July 5, 2019

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CERTIFICATE OF SERVICE

On July 5, 2019, the undersigned caused the foregoing document to be filed electronically by using the Court's CM/ECF system. All parties are represented by registered CM/ECF users and will be served by the appellate CM/ECF system.

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