EXHIBIT 1

UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

MAYOR AND CITY COUNCIL OF BALTIMORE, Plaintiff, v. ALEX M. AZAR II, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES; and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	Civil Action No: 1:19-cv-01672-GLR

BRIEF OF LEADING MEDICAL ORGANIZATIONS AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, MOTION FOR SUMMARY JUDGMENT

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I. Interests of *Amici Curiae*

The following medical organizations respectfully submit this brief as *Amici Curiae* in support of Plaintiffs:[1]

- The American College of Obstetricians and Gynecologists ("ACOG") is the specialty's premier professional membership organization dedicated to the improvement of women's health, with more than 58,000 members representing more than 90% of board certified ob-gyns in the United States.

- The American Medical Association ("AMA") is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in the AMA's House of Delegates, substantially all U.S. physicians are represented in the AMA's policymaking process.

- The American Academy of Pediatrics ("AAP") is a national, not-for-profit organization dedicated to furthering the interests of child and adolescent health, representing more than 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists.

- The American College of Emergency Physicians ("ACEP") represents more than 38,000 emergency physicians, emergency medicine residents and medical students. ACEP promotes the highest quality of emergency care and is the leading advocate for emergency physicians, their patients, and the public.

- The American College of Osteopathic Obstetricians and Gynecologists ("ACOOG") is a 2,500-member organization dedicated exclusively to the physical, mental, and emotional health of women.

- The American Society for Reproductive Medicine ("ASRM") is a multidisciplinary not-for-profit organization dedicated to the advancement of the science and practice of reproductive medicine, representing approximately 8,000 professionals.

- The National Association of Nurse Practitioners in Women's Health ("NPWH") is a national professional membership organization for advanced-practice registered nurses dedicated to women and their health.

[1] All parties have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part, and no counsel for a party, nor any person other than the *amici curiae*, its members, or its counsel, contributed money that was intended to fund the preparation or submission of this brief. Pursuant to Federal Rule of Civil Procedure 7.1, the undersigned counsel certifies that none of the *amici* has a parent corporation and no publicly held corporation owns 10% or more of their respective stock.

- The Society for Maternal-Fetal Medicine ("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.

- The American College of Nurse-Midwives ("ACNM") represents approximately 7,000 certified nurse-midwives and certified member midwives who provide primary and maternity care services to help women of all ages and their newborns attain, regain, and maintain health.

- The North American Society for Pediatric and Adolescent Gynecology ("NASPAG") is dedicated to providing multidisciplinary leadership in education, research, and gynecologic care to improve the reproductive health of youth through the provision of unrestricted, unbiased, and evidence-based practice, and has a diverse membership of gynecologists, adolescent medicine specialists, pediatric endocrinologists, and other medical specialties.

- The American Muslim Health Professionals ("AMHP") is a national nonprofit organization focused on professional development, health education and advocacy centered around the unique needs of American Muslims.

- The World Professional Association for Transgender Health ("WPATH") is an interdisciplinary professional and educational organization devoted to transgender health. Its members engage in clinical and academic research to develop evidence-based medicine and strive to promote a high quality of care for transsexual, transgender, and gender-nonconforming individuals internationally.

II. Introduction

Amici are the leading medical organizations representing physicians and health practitioners in the United States. *Amici* are dedicated to healthcare, to research, and to evidence-based health policy. *Amici* are opposed to all forms of discrimination, and are committed to preserving access to healthcare for all ages and populations.

All patients are entitled to prompt, complete, and unbiased healthcare. All patients should have access to care that is medically and scientifically sound, and unaffected by the personal preferences or religious beliefs of those who provide it. *Amici* believe that respect for individual conscience is important. But one individual's personal convictions cannot and should not be used to deprive another person—*a patient*—of medically sound treatment, information, and services. In medicine, the patient is paramount.

The Department of Health and Human Services ("HHS") rule entitled "Protecting Statutory Conscience Rights in Health Care" (the "Rule")—adopted over *amici's* opposition—completely disregards the ethical obligations and medical standards that are the bedrock of contemporary patient-centered care.[2] It represents a dramatic departure from statutory standards and prior agency interpretation, is unworkably vague, and creates dangerous uncertainty.[3]

Amici are deeply concerned that the Rule will radically disrupt medical care and endanger the lives and health of patients. Professional ethics recognize that the patient is paramount. In contrast, the Rule prioritizes the personal beliefs of individuals other than the patient. It permits objectors to hold their beliefs secret and to refuse care without prior notice, without disclosing their refusal, and without arranging or referring for alternative care. The Rule allows individuals to refuse to administer medically appropriate care *even when their refusal jeopardizes a patient's life and safety*. The Rule protects objectors and endangers patients in every conceivable context—from infancy through end-of-life, in rural clinics and urban hospitals, from preventative care to life-or-death emergencies. Patients will suffer as a result. For already-vulnerable populations in need of critical care, the Rule promises to be especially devastating, perpetuating racial and socioeconomic inequalities.

Amici, whose policies and guidance represent the considered judgment of the many physicians and other clinicians in this country, write in full support of Plaintiffs' opposition to HHS's attempt to dismiss the Plaintiffs' request to permanently enjoin the Rule. *Amici* believe it is imperative that the Court consider the incredibly damaging effect of the Rule on patients and the practice of medicine. *Amici* write to alert the Court to the many ways that the Rule undermines principles of medical ethics, intrudes into the patient-provider relationship, compromises patient safety and well-being, impedes the non-discriminatory provision of quality

[2] 84 Fed. Reg. 23170 (May 21, 2019) (to be codified at 45 C.F.R. pt. 88).

[3] Defendants received comments from several *amici* during the notice and comment period asking that the Rule be withdrawn, and detailing the particular ways the Rule endangers their primary patient constituencies, but Defendants ignored the view of the established medical community *amici* represent.

healthcare services, and critically threatens the effective functioning of healthcare institutions, which will be subject to extreme penalties for noncompliance with vague standards they cannot parse. *Amici* urge the Court to reject HHS's attempts to dismiss the Plaintiffs' action so it may go forward with the Rule.

III. Principles of Medical Ethics

The moral imperative to serve the best interests of patients and alleviate suffering is the foundational principle of medical ethics. Any analysis of the Rule should compare its disregard for patient well-being with the foundational ethics that govern the practice of medicine.

The ethical rules unequivocally place the patient first. The Code of Medical Ethics of the American Medical Association ("AMA Code")[4] provides that a physician is ethically required to use sound medical judgment, holding the best interests of the patient as paramount.[5] ACOG's Code of Professional Ethics ("ACOG Code") states that the "*welfare of the patient (beneficence) is central to all considerations in the patient–physician relationship.*"[6] Under the American College of Emergency Physicians Code of Ethics for Emergency Physicians ("ACEP Code"), "*physicians assume a fundamental duty to serve the best interests of their patients.*"[7] In pediatric care, "*[p]atient well-being should be the primary motivating factor in patient care, ahead of*

[4] The federal judiciary, including the United States Supreme Court, has repeatedly cited the AMA Code. *See, e.g.*, *Baze v. Rees*, 553 U.S. 35, 64 & 112 (2008) (Alito, J., concurring & Breyer, J., concurring); *Ferguson v. City of Charleston*, 532 U.S. 67, 81 (2001); *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997); *Vacco v. Quill*, 521 U.S. 793, 800 n.6 & 801 (1997); *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 288 & 308 (1990) (O'Connor, J., concurring & Brennan, J., dissenting); *Bates v. State Bar of Ariz.*, 433 U.S. 350, 369 n.20 (1977); *Roe v. Wade*, 410 U.S. 113, 144 n.39 (1973); *Lilly v. Commissioner*, 343 U.S. 90, 97 n.9 (1952).

[5] AMA Code, Opinion 1.1.1; *see also* AMA Code, Opinion 1.1.3 ("[P]atients' rights" includes "respect, dignity," and "to make decisions about [their care] . . . and to have those decisions respected."). "The relationship between a patient and a physician is based on trust, which gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own self-interest," AMA Code, Opinion 1.1.1.

[6] ACOG Code, *December 2018*, Ch. I (emphasis added).

[7] ACEP Code, *January 2017*, Ch. II.B.1 (emphasis added).

physicians' own interests and needs."[8] Other medical professionals represented by *Amici* make similar pledges to patient well-being.

The primacy of the patient reflected in the Codes derives from first principles. It reflects an abiding commitment to the moral imperatives of beneficence and nonmaleficence, autonomy, and justice. Those moral imperatives were wholly disregarded by HHS in its rule-making process; but they are familiar and straightforward:

Beneficence and Nonmaleficence. Beneficence and nonmaleficence require providers to help and not hurt those they care for. Beneficence requires a physician to act in a way that is likely *to benefit* the patient. Nonmaleficence is the obligation not to harm or cause injury.[9] This duty to the patient is primary, and where conscience implores physicians to deviate from standard practices, "[p]hysicians' freedom to act according to conscience is not unlimited."[10]

Autonomy. Respect for patient autonomy holds that persons should be free to choose and act without controlling constraints imposed by others.[11] The principle of patient autonomy is an aspect of the broader ethical commitment of respect for persons, and the commitment to treat persons as "ends in themselves," not as instruments for another's goals.[12] Informed consent by a patient to a particular course of medical treatment "is fundamental in both ethics and law" as a necessary safeguard of patient autonomy.[13] "[I]t is ordinarily an ethically unacceptable violation of who and what persons are to manipulate or coerce their actions or to refuse their participation in important decisions that affect their lives."[14] True patient autonomy requires medical

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[8] M. E. Fallat, J. Glover, & the Committee on Bioethics, *Professionalism in Pediatrics: Statement of Principles*, 120 Pediatrics 895, 896 (2007).

[9] ACOG Committee Opinion No. 385, *The Limits of Conscientious Refusal in Reproductive Medicine*, Nov. 2007, ("CO 385") at 3.

[10] AMA Code, Opinion 1.1.7.

[11] *See* CO 385 at 1-3; AMA Code, Opinion 2.1.1; ACEP Code, Ch. II.B.3.

[12] ACOG Committee Opinion No. 439, *Informed Consent*, Aug. 2009, ("CO 439") at 3.

[13] AMA Code, Opinion 2.1.1.

[14] CO 439 at 3.

professionals to also commit to scientific integrity and evidence-based practice, again, out of respect for their patients' personhood and ability to make free and informed choices.[15]

Justice. In the context of medical ethics, justice concerns both the obligation to render to patients the care and respect that is owed to them and an affirmative ethical obligation to advocate "for patients' needs and rights[, and neither] create nor reinforce racial or socioeconomic inequalities in society."[16] In addition, the AMA Code requires "[p]hysicians . . . not to discriminate against a prospective patient on the basis of race, gender, sexual orientation or gender identity, or other personal or social characteristics that are not clinically relevant to the individual's care."[17]

IV. Argument

A. The Rule Undermines Fundamental Principles of Medical Ethics.

The Rule cannot be reconciled with bedrock principles of medical ethics. The ethical practice of medicine puts the patient first. The Rule turns that fundamental moral obligation on its head. It permits anyone involved in patient care to ignore others' suffering and to affirmatively refuse to assist in their care, even when that refusal endangers or harms patients. It compels institutions to certify that they will prioritize the objectors over their patients. The Rule puts the patient last.

The Rule's complete disregard for medical ethics is evident on its face. It expressly permits healthcare providers or virtually any employee working in any capacity in a healthcare setting receiving federal funds to refuse to provide patients basic healthcare services and

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[15] *Id.*; *see also* AMA Code, Opinion 2.1.1.

[16] CO 385 at 4. See also, ACOG Committee Opinion No. 390, *Ethical Decision Making in Obstetrics and Gynecology*, Dec. 2007, ("CO 390"); AMA Code, Opinion 11.1.4 ("[P]hysicians individually and collectively have an ethical responsibility to ensure that all persons have access to needed care regardless of their economic means."); ACEP Code Ch. II.B.4.

[17] AMA Code, Opinion 1.1.2; *see also* ACEP Code, Ch. II.D.3.a ("Denial of emergency care or delay in providing emergency services on the basis of race, religion, sexual orientation, gender identity, ethnic background, social status, type of illness of injury, or ability to pay is unethical.").

information, without regard to medical necessity and including potentially in emergency situations, based solely on personal religious views.[18] The objecting employee need not notify his employer or the patient of his objection before asserting it and refusing to provide care, information, or a referral.[19] Instead, the Rule puts the onus on the employer to ask whether an employee is likely to lodge an objection to certain medical services.[20] By purportedly permitting doctors, nurses, emergency medical technicians, and virtually every other individual involved in the provision of healthcare to refuse help to those who need it, without warning, the Rule eviscerates the paramount commitment of medical ethics to respect and care for patients.

B. The Rule Is Inconsistent with Patient Well-being and Medical Professionals' Duty to Do No Harm and to Act to Promote the Well-being of the Patient.

To enforce the Rule would be a breach of these fundamental ethical obligations in every respect. The Rule and the ethics are irreconcilable because the Rule: (1) permits refusal to provide necessary services, even in cases of emergency; (2) fails to protect continuity of care for all patients; and (3) permits individuals without medical training to impede patient treatment.

1. The Rule Endangers Patients in Emergency Situations.

In a total repudiation of established medical ethics, the Rule purports to permit healthcare employees to deny patients access to necessary care, even in emergencies in which referral is not possible or might negatively impact the patient's physical or mental health.[21] By prioritizing the religious views of employees over a patient's prompt receipt of emergency medical care, the Rule endangers the physical safety of patients.[22] The Rule also appears to violate settled law:

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[18] *See* 84 Fed. Reg. at 23263, § 88.2.

[19] *Id.*

[20] *Id.*

[21] *See* 84 Fed. Reg. at 23263-685, §§ 88.1-88.2 (containing no carve-out for emergency situations). While the HHS has specified in comments that it will permit exceptions to its broad prohibition on discrimination on a "case-by-case basis", this vague representation does not adequately replace a clear statement that one may not refuse treatment in emergency situations.

[22] AMA Code, Opinion 1.1.7 ("Physicians' freedom to act according to conscience is not unlimited"). *See also* ACEP Code Ch. I.2 ("Emergency physicians shall respond promptly and expertly, without prejudice or partiality"); Letter from ACOG to Sec. Azar, March 27, 2018, (on

the Emergency Medical Treatment and Labor Act ("EMTALA") requires clinicians to screen and stabilize patients who come to the emergency department.[23] HHS contends, without sufficient support, that the Rule is consistent with EMTALA,[24] yet the two are patently irreconcilable. An emergency department cannot anticipate every possible basis for a religious or moral objection, survey its employees to ascertain on which basis they might object, and staff accordingly. This is an impossible task that jeopardizes the ability to provide care, both for standard emergency room readiness and for emergency preparedness.[25]

It is difficult to overestimate the effect of this Rule. The kind of "conscience objections" the Rule permits are objections to the completely legal and scientifically sound practice of medicine and provision of healthcare. For example, the medical profession recognizes that an ectopic pregnancy—a condition in which a fertilized egg implants outside of a woman's uterus and cannot develop normally—can be a life-threatening emergency requiring immediate surgery.[26] Yet the Rule protects a provider who refuses to terminate an ectopic pregnancy, even in an emergency. That patient's primary care doctor could, under the Rule, simply decline to inform her (or an alternate provider) of her condition.[27] Experiencing extreme abdominal pain, the patient could call for an ambulance, but under the Rule, the ambulance driver, suspecting her condition, could refuse to transport her to the hospital and refuse either to refer her to alternate transportation or to tell his or her supervisor of his or her refusal. If she makes it to the

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file with Dep't of Health and Human Serv., Office for Civil Rights, RIN 0945-A03; Protecting Statutory Conscience Rights in Health Care; Delegations of Authority) ("ACOG Comment Letter") at 2 ("In an emergency in which referral is not possible or might negatively impact the patient's…health, providers have an obligation to provide…care.").

[23] 42 U.S.C. §1395dd.

[24] 84 F.R. at 23170, 23183.

[25] *See* Letter from ACEP to Sec. Azar, March 27, 2018, (on file with Dep't of Health and Human Serv., Office for Civil Rights, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority) ("ACEP Comment Letter").

[26] ACOG Practice Bulletin No. 193*: Tubal Ectopic Pregnancy,* 131 Obstetrics & Gynecology 91 (March 2018), available at https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Bulletins/Committee-on-Practice-Bulletins-Gynecology/Tubal-Ectopic-Pregnancy.

[27] 84 Fed. Reg. at 23263, § 88.2.

emergency room by her own means, she will need to be admitted, which a clerk could refuse to do. The patient will then need a surgery involving multiple medical staff members, or she will face a high risk of death. Every employee involved is within the category of individuals who, under the Rule, may lodge an objection and refuse to "assist in the performance of" the procedure without *any* prior notice, potentially costing the patient her life.[28] HHS acknowledges that the Rule will harm patients, but promulgated the Rule anyway.[29] The harms the Rule threatens to cause are the very definition of irreparable.[30]

2. The Rule Violates the Duty to Provide a Continuity of Care.

In cases where a provider objects to the care a patient needs or desires, the Rule goes so far as to suggest that employers may not require employees to refer these patients to another healthcare provider who could provide such services, *or even inform other staff at the relevant institution that they have refused to provide such services.*[31] Rather, the Rule relies on healthcare providers to post public notices with general indications that alternatives are available,[32] improperly shifting the burden of ensuring healthcare continuity from healthcare provider to patient, with potentially devastating consequences. For example, if a primary care physician has a religious objection to informing his patient, a minor woman on Medicaid, about the availability

[28] 84 Fed. Reg. at 23263, § 88.2.

[29] 84 Fed. Reg. at 23251 ("[T]he patient's health might be harmed if an alternative is not readily found . . . . [T]he patient may experience distress associated with not receiving a procedure...").

[30] *See, e.g.*, *Blum v. Caldwell*, 446 U.S. 1311, 1314 (1980) (Marshall, J.) ("[T]he *very survival* of these individuals and those class members . . . is threatened by a denial of medical assistance benefits.") (emphasis added) (internal quotation omitted); *Harris v. Bd. of Supervisors*, 366 F.3d 754, 766 (9th Cir. 2004) (irreparable harm from pain, complications, and other adverse effects due to delayed medical treatment); *Medina v. Buther*, No. 15-1955, 2017 WL 700744, at *11 (S.D.N.Y. Feb. 3, 2017) (irreparable harm includes unnecessary pain from lack of medication).

[31] 84 Fed. Reg. at 23263, § 88.2(6) ("The taking of steps by an entity subject to prohibitions in this part to use alternate staff or methods to provide or further any objected-to conduct . . . would not, by itself, constitute discrimination or a prohibited referral, if such entity does not require any additional action by . . . the objecting protected entity . . . .").

[32] 84 Fed. Reg. at 23192 ("[A]n employer may post such a notice and a phone number in a reception area or at a point of sale, but may not list staff with conscientious objections by name if such singling out constitutes retaliation.").

of the HPV vaccine, he need not do so, and he has no obligation to alert her or refer her to an alternate provider. She may never learn of the vaccine, which protects against a virus that can cause cervical cancer. Nearly 11,000 women in the United States are diagnosed with cervical cancer each year, and nearly half that number die from it.[33]

This aspect of the Rule is irreconcilable with medical professionals' ethical obligations of beneficence and nonmaleficence. Medical professionals' "fiduciary responsibility to patients entails an obligation to support continuity of care for their patients."[34] When considering withdrawing from a case, medical ethics require that physicians "(a) [n]otify the patient (or authorized decision maker) long enough in advance to permit the patient to secure another physician, [and] (b) [f]acilitate transfer of care when appropriate."[35]

3. The Rule Sanctions Interference in Patient Care by Non-Medically Trained Staff.

As noted above, the Rule permits virtually any individual employee, including clerks, laboratory technicians, and janitors, to lodge an objection that must be accommodated, without any affirmative obligation to provide notice to his or her employer in advance.[36] That a non-medically trained staff member may, at any point and without any notice, halt a medical procedure or otherwise thwart the provision of appropriate care unethically endangers patients.

Many medical procedures require the participation of several, if not dozens, of individual employees. It may be impossible to perform the procedure when even one of them—for example, a scrub nurse or certified registered nurse anesthetist—lodges a last-minute objection to providing care. In such an instance, the procedure may not be able to be rescheduled for weeks or months, with potentially life-threatening consequences. Thus, the Rule makes patient care

[33] Letter from AAP to Dir. Severino, March 27, 2018 (on file with Dep't of Health and Human Serv., Office for Civil Rights, RIN 0945-ZA03; Docket ID No. HHS-OCR-2018-0002), at 4.

[34] AMA Code, Opinion 1.1.5.

[35] *Id. See also id.* at Opinion 1.1.3 (acknowledging that "patients' rights" include "continuity of care"); *id.* at Opinion 1.2.3 ("Physicians' fiduciary obligation to promote patients' best interests and welfare can include . . . referring patients to other professionals to provide care.").

[36] 84 Fed. Reg. at 23264, § 88.2.

subject to critical disruption by objecting employees who lack sufficient medical training to understand the gravity of a patient's need for certain services.

C. The Rule Undermines Patient Autonomy and Informed Consent.

The protection of patient autonomy is at the very heart of the medical ethical standards.[37] Patient autonomy requires that patients "receive information from their physicians . . . including the risks, benefits and costs of forgoing treatment."[38]

The Rule subverts the principle of informed consent by limiting the information healthcare employees must provide to patients. Specifically, as set forth in Section I.A, *supra*, the Rule permits an objecting employee to refuse to make a "referral" for certain services, which in turn is defined to include "the provision of information . . . where the purpose or reasonably foreseeable outcome of provision of the information is to assist a person in . . . obtaining . . . a particular healthcare service, program, activity, or procedure."[39] This broad mandate reaches well beyond safeguarding conscience rights, and instead allows any individual or entity involved with patient care to virtually assure that a patient does not receive a particular course of treatment—or even know options exist. For example, the Rule would permit an objecting employee to decline to provide a female patient with information about her reproductive health—such as the availability of abortions or contraceptive procedures—or notify her that she is not receiving all available information. Women cannot make fundamental decisions about sexual activity or pregnancy absent that information. This is especially concerning given the time limits that many states place on the availability of abortion.[40]

[37] *See supra* at 4; CO 385 at 3; AMA Code, Opinion 1.1.3.

[38] AMA Code, Opinion 1.1.3; *see also* AMA Code, Opinion 2.1.1.

[39] 84 Fed. Reg. at 23263-64, § 88.2.

[40] *See, e.g.*, Neb. Rev. Stat. §§ 28-3102 to 28-3111 (2019) (prohibiting abortions after 20 weeks into a pregnancy, with limited exceptions for rape, incest, and the health of the mother).

D. The Rule Creates and Exacerbates Unequal Access to Healthcare.

"Justice . . . requires medical professionals and policy makers to treat individuals fairly and to provide medical services in a nondiscriminatory manner."[41] The AMA Code requires "[p]hysicians . . . not to discriminate against a prospective patient."[42] Rather than promote equal access, however, the Rule targets individuals who rely on federal funding for healthcare and imposes upon them new barriers to healthcare.

First, the Rule imposes constraints upon medical service providers that will incentivize them to limit or eliminate altogether certain healthcare services, posing additional hurdles to complete care for certain populations, such as rural women, minorities, and LGBTQIA individuals, that already lack access to adequate care. Most rural women, for example, find themselves at least a 30-minute drive from reproductive care.[43] Minority women already face significant and persistent disparities in healthcare as compared to the general population, including disparities in access to healthcare.[44] In 2010, there were 26 black maternal deaths for every seven white maternal deaths in California.[45] Healthcare refusals will have a disproportionate impact on black women's lives. In a recent study, nearly 20% of LGBTQIA people—and 31% of transgender people—stated that it would be very difficult or impossible to receive certain medical services they need if they were unable to receive such services from their existing provider.[46] The Rule will force patients in need of health services to overcome increased barriers to pursue them, such as longer driving distances or longer wait times. Faced

[41] CO 385 at 4.

[42] AMA Code, Opinion 1.1.2.

[43] ACOG Committee Opinion No. 586, *Health Disparities in Rural Women*, Feb. 2014, at 2.

[44] ACOG Committee Opinion No. 649, *Racial and Ethnic Disparities in Obstetrics and Gynecology*, Dec. 2015, at 1.

[45] *Id*. at 2.

[46] Letter from the Center for American Progress to Sec. Azar, March 29, 2018, (on file with Dep't of Health and Human Serv., Office for Civil Rights, Protecting Statutory Conscience Rights in Health Care) https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71744.

with these additional challenges, these individuals are likely to accept substandard care or forego medical services entirely.

Second, in addition to compromising patients' physical health by refusing to provide care, subjecting vulnerable populations to additional discrimination, stigma, and dignitary harm is unethical and may have life-long repercussions.[47] A patient who seeks medical care but is turned away by an employee who objects to his or her sexual orientation or gender identity is likely to feel stigmatized and be discouraged from seeking care, even from another provider.[48]

E. The Rule Employs Language That Is Impermissibly Vague and Stymies Effective Functioning of Healthcare Systems.

The Rule is remarkably unclear in its attempt to dictate how providers may comply with the Rule's legal obligations. Because of its many ambiguities, and its inconsistency with other federal laws, the Rule does not provide healthcare service providers with adequate guidance as to what conduct is prohibited and encourages arbitrary enforcement.

The Rule poses broad operational and implementation challenges for providers, including integrated healthcare provider systems like Kaiser Permanente, which must balance support for employees against the needs of patients. The Rule's absolute accommodation standard will make it difficult, if not impossible, for Kaiser Permanente both to comply with the rule and be confident that patient care needs will be met. That standard is all the more problematic in combination with the broad definition of "discrimination" against an employee asserting a religious or moral objection, which prevents an employer from knowing for certain in advance which employees object to which services and therefore prevents integrated healthcare providers systems like Kaiser Permanente from hiring and staffing to avoid conflicts between patient needs

[47] Injuries to one's "mental health and overall well-being", including feelings of stigmatization, amount to irreparable injury. *Whitaker By Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1045 (7th Cir. 2017), cert. dismissed sub nom. *Kenosha Unified Sch. Dist. No. 1 Bd. of Educ. v. Whitaker ex rel. Whitaker*, 138 S. Ct. 1260 (2018) (mem).

[48] Human Rights Watch, *All We Want is Equality*, Administrative Record, 000538505 – 000538552.

and employees' individual religious or moral objections. Because of this shift in the balance of rights away from patients, the Final Rule will introduce substantial uncertainty and new patient risks to the delivery of healthcare.

Amici are particularly concerned that the Rule uses overbroad and vague language in outlining its enforcement mechanisms. For example, the preamble to the proposed Rule asserted that HHS may regulate an unspecified "broader range of funds or broader categories of covered entities" for "noncompliant entities," without any specification as to the limit of this regulation.[49] When combined with the draconian penalties for noncompliance,[50] healthcare service providers will be effectively coerced into adopting overbroad and costly policies or cutting off certain services altogether for fear of discriminating on the basis of religion. Providers seeking to comply with the Rule and obligations to patients will face feasibility issues of daunting complexity and cost, including double staffing arrangements. The disruption of the patient-provider relationship is its own form of irreparable harm,[51] as are the required changes to policies, scheduling, and personnel management practices and their associated costs.[52]

[49] 83 Fed. Reg. 3880, 3898.

[50] 84 Fed. Reg. at 23180 (emphasizing that remedies may include "termination of relevant funding, in whole or in part" and "funding claw backs to the extent permitted by law"); 84 Fed. Reg. at 23271, § 88.7(i) (remedies for noncompliance with the Rule include withholding, denying, or terminating federal funding and denying or withholding new federal funding).

[51] *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 Medicare Advantage patients" and noting that "several district and circuit courts have found that disruption of the physician-patient relationship . . . can cause irreparable harm"); *New York v. Schweiker*, 557 F. Supp. 354, 360 (S.D.N.Y. 1983) (HHS regulation causing physicians to breach ethical duty to maintain patient confidentiality was an irreparable harm because "their reputation for trust among their adolescent clientele will be damaged severely, if not effaced").

[52] *California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) (administrative costs required by federal rules that are not recoverable, such as those required by regulations propagated under the Administrative Procedures Act, amount to irreparable injury).

V. Conclusion

Amici urge the Court to reject HHS' motion to dismiss. The Rule will cause grave harm to patients and the public health, is inconsistent with principles of medical ethics, and is impermissibly vague. The Rule represents a dangerous intrusion into the patient-provider relationship and will compromise patient health and safety for the personal views and beliefs of an individual healthcare employee.

Dated: September 26, 2019

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/s/ Michael J. O'Leary_____
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**pro hac vice admission pending*