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10 UNITED STATES DISTRICT COURT

11 NORTHERN DISTRICT OF CALIFORNIA, SAN FRANCISCO DIVISION

12 CITY AND COUNTY OF SAN FRANCISCO,

13 Plaintiff,

14 vs.

15 ALEX M. AZAR II, et al.,

16 Defendants.

17 STATE OF CALIFORNIA, by and through
18 ATTORNEY GENERAL XAVIER
19 BECERRA,

20 Plaintiff,

21 vs.

22 ALEX M. AZAR, et al.,

23 Defendants.

24 COUNTY OF SANTA CLARA, et al.

25 Plaintiffs,

26 vs.

27 U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, et al.

28 Defendants.

Case No. 3:19-cv-02405-WHA
Related to
Case No. 3:19-cv-02769-WHA
Case No.: 3:19-cv-02916-WHA

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

Judge: Hon William Alsup.
Department: 12

Date: October 30, 2019
Time: 8:00 a.m.
Courtroom: Philip Burton Federal Building &
United States Courthouse
450 Golden Gate Ave., 19th Floor
San Francisco, CA 94102

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1 **I. Interests of Amici Curiae**

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

- 4 • The American College of Obstetricians and Gynecologists (“ACOG”) is the
5 specialty’s premier professional membership organization dedicated to the
6 improvement of women’s health, with more than 58,000 members representing
7 more than 90% of board certified ob-gyns in the United States.
- 8 • The American Medical Association (“AMA”) is the largest professional association
9 of physicians, residents, and medical students in the United States. Additionally,
10 through state and specialty medical societies and other physician groups seated in
11 the AMA’s House of Delegates, substantially all U.S. physicians are represented in
12 the AMA’s policymaking process.
- 13 • The American Academy of Pediatrics (“AAP”) is a national, not-for-profit
14 organization dedicated to furthering the interests of child and adolescent health,
15 representing more than 67,000 primary care pediatricians, pediatric medical
16 subspecialists, and pediatric surgical specialists.
- 17 • The American College of Emergency Physicians (“ACEP”) represents more than
18 38,000 emergency physicians, emergency medicine residents and medical students.
19 ACEP promotes the highest quality of emergency care and is the leading advocate
20 for emergency physicians, their patients, and the public.
- 21 • The American College of Osteopathic Obstetricians and Gynecologists (“ACOOG”) is
22 a 2,500-member organization dedicated exclusively to the physical, mental, and
23 emotional health of women.
- 24 • The American Society for Reproductive Medicine (“ASRM”) is a multidisciplinary
25

26 ¹ All parties have consented to the filing of this brief. No counsel for a party authored this brief in
27 whole or in part, and no counsel for a party, nor any person other than the *amici curiae*, its
28 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.

1 not-for-profit organization dedicated to the advancement of the science and practice
2 of reproductive medicine, representing approximately 8,000 professionals.

- 3 • The National Association of Nurse Practitioners in Women’s Health (“NPWH”) is a
4 national professional membership organization for advanced-practice registered
5 nurses dedicated to women and their health.
- 6 • The Society for Maternal Fetal Medicine (“SMFM”) is the medical professional
7 society for obstetricians who have additional training in the area of high-risk,
8 complicated pregnancies, representing over 4,000 members.
- 9 • The American College of Nurse-Midwives (“ACNM”) represents approximately
10 7,000 certified nurse-midwives and certified members midwives who provide
11 primary and maternity care services to help women of all ages and their newborns
12 attain, regain, and maintain health.
- 13 • The North American Society for Pediatric and Adolescent Gynecology
14 (“NASPAG”) is dedicated to providing multidisciplinary leadership in education,
15 research, and gynecologic care to improve the reproductive health of youth through
16 the provision of unrestricted, unbiased, and evidence-based practice, and has a
17 diverse membership of gynecologists, adolescent medicine specialists, pediatric
18 endocrinologists, and other medical specialties.
- 19 • The American Muslim Health Professionals (“AMHP”) is a national nonprofit
20 organization focused on professional development, health education and advocacy
21 centered around the unique needs of American-Muslims.
- 22 • The California Medical Association (“CMA”) is a professional organization
23 representing California physicians. CMA serves more than 44,000 physician
24 members in all modes of practice and specialties.
- 25 • Kaiser Permanente is an integrated health care delivery system that provides
26 coverage for more than 12 million members, and in which 22,914 physicians,
27 59,127 nurses, and 217,712 employees provide the full range of necessary health
28 care services for our members.

- 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 health care, to research, and to evidence-based health policy. *Amici* are opposed to all forms of discrimination, and are committed to preserving access to health care for all ages and populations.

All patients are entitled to prompt, complete, and unbiased health care. 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. Whereas professional ethics recognize that the patient is paramount, the Rule prioritizes the personal beliefs of individuals other than the patient. It permits

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.

1 objectors to hold their beliefs secret and to refuse care without prior notice, without disclosing their
2 refusal, and without arranging or referring for alternative care. The Rule allows individuals to
3 refuse to administer medically appropriate care *even when their refusal jeopardizes a patient's life*
4 *and safety*. The Rule protects objectors and endangers patients in every conceivable context—from
5 infancy through end-of-life, in rural clinics and urban hospitals, from preventative care to life-or-
6 death emergencies. Patients will suffer as a result. For already-vulnerable populations in need of
7 critical care, the Rule promises to be especially devastating, perpetuating racial and socioeconomic
8 inequalities.

9 *Amici*, whose policies and guidance represent the considered judgment of the many
10 physicians and other clinicians in this country, write in full support of Plaintiffs' opposition to
11 HHS's attempt to dismiss the Plaintiffs' request to permanently enjoin the Rule. *Amici* believe it is
12 imperative that the Court consider the incredibly damaging effect of the Rule on patients and the
13 practice of medicine. *Amici* write to alert the Court to the many ways that the Rule undermines
14 principles of medical ethics, intrudes into the patient-provider relationship, compromises patient
15 safety and wellbeing, impedes the non-discriminatory provision of quality health care services, and
16 critically threatens the effective functioning of health care institutions, which will be subject to
17 extreme penalties for noncompliance with vague standards they cannot parse. *Amici* urge the Court
18 to reject HHS's attempts to dismiss the Plaintiffs' action so it may go forward with the Rule.

19 **III. Principles of Medical Ethics**

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

23 The ethical rules unequivocally place the patient first. The Code of Medical Ethics of the
24 American Medical Association ("AMA Code")⁴ provides that a physician is ethically required to

26 ⁴ The federal judiciary, including the United States Supreme Court, has repeatedly cited the AMA
27 Code. *See, e.g., Baze v. Rees*, 553 U.S. 35, 64 & 112 (2008) (Alito, J., concurring & Breyer, J.,
28 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,

1 use sound medical judgment, holding the best interests of the patient as paramount.⁵ ACOG’s
 2 Code of Professional Ethics (“ACOG Code”) states that the “*welfare of the patient (beneficence) is*
 3 *central to all considerations in the patient–physician relationship.*”⁶ Under the American College
 4 of Emergency Physicians Code of Ethics for Emergency Physicians (“ACEP Code”) “*physicians*
 5 *assume a fundamental duty to serve the best interests of their patients.*”⁷ In pediatric care,
 6 “[p]atient well-being should be the primary motivating factor in patient care, ahead of physicians’
 7 own interests and needs.”⁸ Other medical professionals represented by *amici* make similar pledges
 8 to patient well-being.

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

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

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 21 144 n.39 (1973); *Lilly v. Commissioner*, 343 U.S. 90, 97 n.9 (1952).

22 ⁵ AMA Code, Opinion 1.1.1; *see also* AMA Code, Opinion 1.1.3 (“[P]atients’ rights” includes
 23 “respect, dignity,” and “to make decisions about [their care] . . . and to have those decisions
 24 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.

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

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

27 ⁸ M. E. Fallat, J. Glover, & the Committee on Bioethics, *Professionalism in Pediatrics: Statement*
 28 *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.

1 **Autonomy.** Respect for patient autonomy holds that persons should be free to choose and
 2 act without controlling constraints imposed by others.¹¹ The principle of patient autonomy is an
 3 aspect of the broader ethical commitment of respect for persons, and the commitment to treat
 4 persons as “ends in themselves,” not as instruments for another’s goals.¹² Informed consent by a
 5 patient to a particular course of medical treatment “is fundamental in both ethics and law” as a
 6 necessary safeguard of patient autonomy.¹³ “[I]t is ordinarily an ethically unacceptable violation of
 7 who and what persons are to manipulate or coerce their actions or to refuse their participation in
 8 important decisions that affect their lives.”¹⁴ True patient autonomy requires medical professionals
 9 to also commit to scientific integrity and evidence-based practice, again, out of respect for their
 10 patients’ personhood and ability to make free and informed choices.¹⁵

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

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 21 _____
 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.

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.”).

1 **IV. Argument**

2 **A. The Rule Undermines Fundamental Principles of Medical Ethics.**

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

9 The Rule's complete disregard for medical ethics is evident on its face. It expressly permits
10 health care providers or virtually any employee working in any capacity in a health care setting
11 receiving federal funds to refuse to provide patients basic health care services and information,
12 without regard to medical necessity and including potentially in emergency situations, based solely
13 on personal religious views.¹⁸ The objecting employee need not notify his employer or the patient
14 of his objection before asserting it and refusing to provide care, information, or a referral.¹⁹
15 Instead, the Rule puts the onus on the employer to ask whether an employee is likely to lodge an
16 objection to certain medical services.²⁰ By purportedly permitting doctors, nurses, emergency
17 medical technicians, and virtually every other individual involved in the provision of health care to
18 refuse help to those who need it, without warning, the Rule eviscerates the paramount commitment
19 of medical ethics to respect and care for patients.

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

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

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27 ¹⁸ See 84 Fed. Reg. at 23263, § 88.2.

28 ¹⁹ *Id.*

²⁰ *Id.*

1 *I. The Rule Endangers Patients in Emergency Situations.*

2 In a total repudiation of established medical ethics, the Rule purports to permit health care
 3 employees to deny patients access to necessary care, even in emergencies in which referral is not
 4 possible or might negatively impact the patient’s physical or mental health.²¹ By prioritizing the
 5 religious views of employees over a patient’s prompt receipt of emergency medical care, the Rule
 6 endangers the physical safety of patients.²² The Rule also appears to violate settled law: the
 7 Emergency Medical Treatment and Labor Act (EMTALA) requires clinicians to screen and
 8 stabilize patients who come to the emergency department.²³ HHS contends, without sufficient
 9 support, that the Rule is consistent with EMTALA,²⁴ but the two are patently irreconcilable. An
 10 emergency department cannot anticipate every possible basis for a religious or moral objection,
 11 survey its employees to ascertain on which basis they might object, and staff accordingly. This is
 12 an impossible task that jeopardizes the ability to provide care, both for standard emergency room
 13 readiness and for emergency preparedness.²⁵

14 It is difficult to overestimate the effect of this Rule. The kind of “conscience objections”
 15 the Rule permits are objections to the completely legal and scientifically sound practice of
 16 medicine and provision of health care. For example, the medical profession recognizes that an
 17 ectopic pregnancy—a condition in which a fertilized egg implants outside of a woman’s uterus and
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20 ²¹ See 84 Fed. Reg. at 23263-685, §§ 88.1-88.2 (containing no carve-out for emergency situations).
 21 While the HHS has specified in comments that it will permit exceptions to its broad prohibition on
 22 discrimination on a “case by case basis”, this vague representation does not adequately replace a
 23 clear statement that one may not refuse treatment in emergency situations.

24 ²² AMA Code, Opinion 1.1.7 (“Physicians’ freedom to act according to conscience is not
 25 unlimited”). See also ACEP Code Ch. I.2 (“Emergency physicians shall respond promptly and
 26 expertly, without prejudice or partiality”); Letter from ACOG to Sec. Azar, March 27, 2018, (on
 27 file with Dep’t of Health and Human Serv., Office for Civil Rights, RIN 0945-A03; Protecting
 28 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”).

1 cannot develop normally—can be a life-threatening emergency requiring immediate surgery.²⁶ Yet
 2 the Rule protects a provider who refuses to terminate an ectopic pregnancy, even in an emergency.
 3 That patient’s primary care doctor could, under the Rule, simply decline to inform her (or an
 4 alternate provider) of her condition.²⁷ Experiencing extreme abdominal pain, the patient could call
 5 for an ambulance, but under the Rule, the ambulance driver, suspecting her condition, could refuse
 6 to transport her to the hospital and refuse either to refer her to alternate transportation or to tell his
 7 or her supervisor of his or her refusal. If she makes it to the emergency room by her own means,
 8 she will need to be admitted, which a clerk could refuse to do. The patient will then need a surgery
 9 involving multiple medical staff members, or face a high risk of death. Every employee involved is
 10 within the category of individuals who, under the Rule, may lodge an objection and refuse to
 11 “assist in the performance of” the procedure without *any* prior notice, potentially costing the patient
 12 her life.²⁸ HHS acknowledges that the Rule will harm patients, but promulgated the Rule
 13 anyway.²⁹ The harms the Rule threatens to cause are the very definition of irreparable.³⁰

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

15 In cases where a provider objects to the care a patient needs or desires, the Rule goes so far
 16 as to suggest that employers may not require employees to refer these patients to another health
 17 care provider who could provide such services, *or even inform other staff at the relevant institution*
 18 *that they have refused to provide such services.*³¹ Rather, the Rule relies on health care providers
 19

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

22 ²⁷ 84 Fed. Reg. at 23263, § 88.2.

23 ²⁸ 84 Fed. Reg. at 23263, § 88.2.

24 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...”).

25 ³⁰ *See, e.g., Blum v. Caldwell*, 446 U.S. 1311, 1314 (1980) (Marshall, J.) (“[T]he *very survival* of
 26 these individuals and those class members . . . is threatened by a denial of medical assistance
 27 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).

28 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

1 to post public notices with general indications that alternatives are available,³² improperly shifting
 2 the burden of ensuring health care continuity from health care provider to patient, with potentially
 3 devastating consequences. For example, if a primary care physician has a religious objection to
 4 informing his patient, a minor woman on Medicaid, about the availability of the HPV vaccine, he
 5 need not do so, and he has no obligation to alert her or refer her to an alternate provider. She may
 6 never learn of the vaccine, which protects against a virus that can cause cervical cancer. Nearly
 7 11,000 women in the United States are diagnosed with cervical cancer each year, and nearly half
 8 that number die from it.³³

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

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

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

21
 22 additional action by . . . the objecting protected entity . . .").

23 ³² 84 Fed. Reg. at 23192 ("[A]n employer may post such a notice and a phone number in a
 24 reception area or at a point of sale, but may not list staff with conscientious objections by name if
 such singling out constitutes retaliation.").

25 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.

26 ³⁴ AMA Code, Opinion 1.1.5.

27 ³⁵ *Id.* See also *id.* at Opinion 1.1.3 (acknowledging that "patients' rights" include "continuity of
 28 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.

1 Many medical procedures require the participation of several, if not dozens, of individual
 2 employees. It may be impossible to perform the procedure when even one of them—for example, a
 3 scrub nurse or certified registered nurse anesthetist—lodges a last minute objection to providing
 4 care. In such an instance, the procedure may not be able to be rescheduled for weeks or months,
 5 with potentially life-threatening consequences. Thus, the Rule makes patient care subject to critical
 6 disruption by objecting employees who lack sufficient medical training to understand the gravity of
 7 a patient’s need for certain services.

8 **C. The Rule Undermines Patient Autonomy and Informed Consent.**

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

12 The Rule subverts the principle of informed consent by limiting the information health care
 13 employees must provide to patients. Specifically, as set forth in Section I.A, *supra*, the Rule
 14 permits an objecting employee to refuse to make a “referral” for certain services, which in turn is
 15 defined to include “the provision of information . . . where the purpose or reasonably foreseeable
 16 outcome of provision of the information is to assist a person in . . . obtaining . . . a particular health
 17 care service, program, activity, or procedure.”³⁹ This broad mandate reaches well beyond
 18 safeguarding conscience rights, and instead allows any individual or entity involved with patient
 19 care to virtually assure that a patient does not receive a particular course of treatment—or even
 20 know options exists. For example, the Rule would permit an objecting employee to decline to
 21 provide a female patient with information about her reproductive health—such as the availability of
 22 abortions or contraceptive procedures—or notify her that she is not receiving all available
 23 information. Women cannot make fundamental decisions about sexual activity or pregnancy
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27 ³⁷ See *supra* at 4; CO 385 at 3; AMA Code, Opinion 1.1.3.

28 ³⁸ AMA Code, Opinion 1.1.3; see also AMA Code, Opinion 2.1.1.

³⁹ 84 Fed. Reg. at 23263-64, § 88.2.

1 absent that information. This is especially concerning given the time limits that many states place
2 on the availability of abortion.⁴⁰

3 **D. The Rule Creates and Exacerbates Unequal Access to Health Care.**

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

9 *First*, the Rule imposes constraints upon medical service providers that will incentivize
10 them to limit or eliminate altogether certain health care services, posing additional hurdles to
11 complete care for certain populations, such as rural women, minorities, and LGBTQIA individuals,
12 that already lack access to adequate care. Most rural women, for example, find themselves at least
13 a 30-minute drive from reproductive care.⁴³ Minority women already face significant and
14 persistent disparities in health care as compared to the general population, including disparities in
15 access to healthcare.⁴⁴ In 2010, there were 26 black maternal deaths for every seven white
16 maternal deaths in California.⁴⁵ Healthcare refusals will have a disproportionate impact on black
17 women’s lives. In a recent study, nearly 20% of LGBTQIA people—and 31% of transgender
18 people—stated that it would be very difficult or impossible to receive certain medical services they
19 need if they were unable to receive such services from their existing provider.⁴⁶ The Rule will
20 force patients in need of health services to overcome increased barriers to pursue them, such as
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22 ⁴⁰ See, e.g., Neb. Rev. Stat. §§ 28-3102 to 28-3111 (2019) (prohibiting abortions after 20 weeks
23 into a pregnancy, with limited exceptions for rape, incest, and the health of the mother).

24 ⁴¹ CO 385 at 4.

25 ⁴² AMA Code, Opinion 1.1.2.

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

27 ⁴⁴ ACOG Committee Opinion No. 649, *Racial and Ethnic Disparities in Obstetrics and
28 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>.

1 driving longer distances or longer wait times. Faced with these additional challenges, these
 2 individuals are likely to accept substandard care or forego medical services entirely.

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

8 **E. The Rule Employs Language That Is Impermissibly Vague and Stymies Effective**
 9 **Functioning of Health Care Systems.**

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

14 The Rule poses broad operational and implementation challenges for providers, including
 15 integrated health care provider systems like Kaiser Permanente, which must balance support for
 16 employees against the needs of patients. The Rule’s absolute accommodation standard will make it
 17 difficult, if not impossible, for Kaiser Permanente both to comply with the rule and be confident
 18 that patient care needs will be met. That standard is all the more problematic in combination with
 19 the broad definition of “discrimination” against an employee asserting a religious or moral
 20 objection, which prevents an employer from knowing for certain in advance which employees
 21 object to which services and therefore prevents integrated health care providers systems like Kaiser
 22 Permanente from hiring and staffing to avoid conflicts between patient needs and employees’
 23 individual religious or moral objections. Because of this shift in the balance of rights away from
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26 ⁴⁷ Injuries to one’s “mental health and overall well-being”, including feelings of stigmatization,
 27 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.*
 28 *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.

1 patients, the Final Rule will introduce substantial uncertainty and new patient risks to the delivery
2 of health care.

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

14 **V. Conclusion**

15 *Amici* urge the Court to reject HHS’ motion to dismiss. The Rule will cause grave harm to
16 patients and the public health, is inconsistent with principles of medical ethics, and is
17 impermissibly vague. The Rule represents a dangerous intrusion into the patient-provider
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20 ⁴⁹ 83 Fed. Reg. 3880, 3898.

21 ⁵⁰ 84 Fed. Reg. at 23180 (emphasizing that remedies may include “termination of relevant funding,
22 in whole or in part” and “funding claw backs to the extent permitted by law”); 84 Fed. Reg. at
23 23271, § 88.7(i) (remedies for noncompliance with the Rule include withholding, denying, or
24 terminating federal funding and denying or withholding new federal funding).

25 ⁵¹ See *Fairfield Cty. Med. Ass’n v. United Healthcare of New England*, 985 F. Supp. 2d 262, 271-
26 72 (D. Conn. 2013), *aff’d as modified sub nom. Fairfield Cty. Med. Ass’n v. United Healthcare of*
27 *New England, Inc.*, 557 F. App’x 53 (2d Cir. 2014) (finding irreparable injury to physicians where
28 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).

1 relationship and will compromise patient health and safety for the personal views and beliefs of an
2 individual health care employee.

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1 Dated: September 12, 2019

Respectfully submitted,

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