Nos. 20-15398, 20-15399, 20-16045, 20-35044

United States Court of Appeals
for the
Ninth Circuit

CITY AND COUNTY OF SAN FRANCISCO,

Plaintiff-Appellee,

– v. –

ALEX M. AZAR II, Secretary of U.S. Department of Health and Human Services; ROGER T. SEVERINO, Director, Office for Civil Rights, Department of Health and Human Services; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
DISTRICT COURT CASE NO. 3:19-cv-02405-WHA

BRIEF OF LEADING MEDICAL ORGANIZATIONS AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFF-APPELLEE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the undersigned counsel certifies that none of the *amici* is a publicly-held corporation, issues stock, or has a parent corporation.

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I. Interests of *Amici Curiae*

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

- The American College of Obstetricians and Gynecologists ("ACOG") is the nation's premier professional membership organization for obstetrician-gynecologists dedicated to the improvement of women's health. Representing more than 90% of board-certified ob-gyns in the United States, ACOG is dedicated to the advancement of women's health care, including the core value of access for all women to high quality safe health care.
- The American Medical Association ("AMA") is the largest professional association of physicians, residents, and medical students in the United States. Through the AMA's House of Delegates, substantially all U.S. physicians, residents, and medical students are represented in the AMA's policymaking process. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health.

[1] All parties consent 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*, their members, or their counsel, contributed money that was intended to fund the preparation or submission of this brief.

The AMA, CMA and WSMA appear on their own behalves and as representatives of the AMA Litigation Center. The AMA Litigation Center is a coalition among the AMA and the medical societies of every state to represent the interests of the medical profession in the courts.

- 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 pediatric specialists, the AAP is a powerful voice for child and adolescent health through education, research, advocacy, and the provision of expert advice.
- The American College of Emergency Physicians ("ACEP") represents more than 41,000 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. ACEP continually strives to improve the quality of emergency medical services.
- The American College of Osteopathic Obstetricians and Gynecologists ("ACOOG") is a 2,500-member organization dedicated exclusively to women's healthcare. ACOOG provides education,

training, and community to its osteopathic obstetricians-gynecologists throughout the United States.

- The American Society for Reproductive Medicine ("ASRM") is a multidisciplinary not-for-profit organization with approximately 8,000 professionals dedicated to the advancement of the science and practice of reproductive medicine.
- 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. NPWH's mission is to ensure quality primary and specialty healthcare to women of all ages by women's health and women's health-focused nurse practitioners.
- The Society for Maternal-Fetal Medicine ("SMFM") is a non-profit, membership organization with more than 5,000 physicians, scientists and women's health professionals around the world. SMFM supports the clinical practice of maternal-fetal medicine by providing education, promoting research and engaging in advocacy to optimize the health of high-risk pregnant women and their babies.
- The American College of Nurse-Midwives ("ACNM") works to advance the practice of midwifery to achieve optimal health for

women through their lifespan, with expertise in well woman and gynecologic care. Its members include approximately 7,000 certified nurse-midwives and certified 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 a diverse membership including gynecologists, adolescent medicine specialists, pediatric endocrinologists, and other medical specialties.
- The American Muslim Health Professionals ("AMHP") is a national nonprofit organization representing the voice of Muslim health professionals in the U.S. to advance the public health of the entire American community. AMHP supports all efforts that improve access to healthcare and provide education to Americans on healthcare issues.
- The World Professional Association for Transgender Health ("WPATH") is a non-profit interdisciplinary medical professional and educational organization devoted to transgender health, with over 2,100 members engaged in clinical and academic research to develop

evidence-based medicine and promote high quality care for transsexual, transgender, and gender-nonconforming individuals internationally.

- The California Medical Association ("CMA") is a professional organization representing California physicians. CMA serves more than 50,000 physician members in all modes of practice and specialties.
- Washington State Medical Association ("WSMA") is the largest medical professional association in Washington, representing physicians, residents, medical students and physician assistants from nearly all specialties and practice settings throughout the state.
- Kaiser Permanente is an integrated healthcare delivery system that provides coverage for more than 12 million members, and in which 22,000 physicians, 59,000 nurses, and 217,000 employees provide the full range of necessary healthcare services for members.

II. Introduction

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 of those who provide it. *Amici* believe that respect for individual conscience is important. But one individual's convictions

cannot and should not be used to deprive 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") completely disregards the ethical obligations and medical standards that are the bedrock of contemporary patient-centered care.[2] 84 Fed. Reg. 23170 (May 21, 2019) (to be codified at 45 C.F.R. pt. 88); *see* E. D. Wash Dist. Ct. Order ("Wash. Op."), Excerpts of Record, Dkt. 18, at ER32. As the district courts found, the Rule represents a dramatic departure from statutory standards and agency interpretation and stands contrary to established law and practice. N. D. Cal. Dist. Ct. Order ("Cal. Op."), Excerpts of Record, Dkt. 18, at ER44-63; Wash. Op. at ER30-32. They accordingly and rightfully vacated the Rule before it could take effect. Cal. Op. at ER63-64; Wash. Op. at ER33.

These decisions should be affirmed. If the Rule were to take effect, it would disrupt medical care and endanger patients. Where professional ethics recognize that the patient is paramount, the Rule prioritizes an objector's personal beliefs, beyond any accommodation intended by Congress. It permits objectors to hold their beliefs secret and to refuse care without prior notice, without disclosing their

[2] Appellants received comments from several *Amici* during the notice-and-comment period asking that the Rule be withdrawn because the Rule endangers their patients, but Appellants ignored the view of the established medical community *Amici* represent.

refusal, and without arranging or referring for alternative care. The Rule would allow individuals to refuse medically appropriate care *even when their refusal jeopardizes another's life*. The Rule 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. For already-vulnerable populations in need of critical care, the Rule promises to be especially devastating, perpetuating racial and socioeconomic inequalities. These concerns are even more acute during the COVID-19 pandemic, which has strained hospitals, exacerbated health inequities, and heightened the need for emergency rooms to nimbly respond to patient needs.

Amici, as the nation's leading medical organizations, whose policies and guidance represent the considered judgment of many physicians and clinicians in this country, write in full support of Appellees. *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 provision of quality health care services on a non-discriminatory basis, and threatens the effective functioning of health care institutions, which will be subject to penalties for noncompliance with vague standards they cannot parse. *Amici* thus urge this Court to affirm and uphold vacatur of the Rule.

III. Principles of Medical Ethics

The moral imperative to care for patients and alleviate suffering is the foundational principle of medical ethics. In medicine, all who provide care have an overarching ethical commitment to serve the best interests of patients. Patient welfare is paramount. That clear and simple premise is reflected in the medical professions' Codes of Ethics and derives from the bedrock principles of beneficence, nonmaleficence, autonomy, and justice. Any analysis of the Rule should compare its disregard for patient well-being with the fundamental ethics governing medical practice.

These ethical rules unequivocally place the patient first. AMA policy provides that a physician is required to use sound medical judgment, ***holding the best interests of the patient as paramount***. AMA Principles of Medical Ethics VIII. "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 . . . and to advocate for their patients' welfare." Code of Medical Ethics of the AMA ("AMA Code"),[3] Opinion 1.1.1. Similarly, ACOG's Code of Professional Ethics states that the "***welfare of the patient***

[3] The first modern national medical ethics code, the AMA Code is the most well-respected code for physicians worldwide and is regularly cited by the federal judiciary, including the Supreme Court. *See, e.g.*, *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 593 (2012) (Ginsburg, J., concurring); *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997); *Roe v. Wade*, 410 U.S. 113, 144 n.39 (1973).

(beneficence) is central to all considerations in the patient–physician relationship." ACOG Code of Professional Ethics, Ch. I (2018). Under the ACEP Code of Ethics for Emergency Physicians, "***physicians assume a fundamental duty to serve the best interests of their patients***." ACEP Code of Ethics for Emergency Physicians ("ACEP Code"), Ch. II.B.1 (2017). In pediatric care, "***[p]atient well-being should be the primary motivating factor in patient care, ahead of physicians' own interests and needs***." AAP, Committee on Bioethics, *Professionalism in Pediatrics: Statement of Principles*,120 Pediatrics 895, 896 (2007). Other medical professionals represented by *Amici* make similar pledges to patient well-being.

Beneficence and Nonmaleficence. Beneficence and nonmaleficence require medical professionals to help and not hurt those they care for. Beneficence is the obligation to promote the well-being of others; nonmaleficence is the obligation not to harm or cause injury. *See* ACOG Committee Opinion No. 385, *The Limits of Conscientious Refusal in Reproductive Medicine*, at 3 (2007, reaff'd 2016) ("CO 385").

Beneficence and nonmaleficence are individual and communal obligations: as trustees of patients' wellbeing, medical professionals assume an obligation not only to care for patients themselves, but also "to support continuity of care for their patients"—to ensure that when they cannot personally perform needed services,

they refer the patient to another who can. AMA Code, Opinion 1.1.5. These duties mean that "[p]atients should be able to expect that their physician will cooperate in coordinating medically indicated care with other health care professionals, and that the physician will not discontinue treating them when further treatment is medically indicated without giving them sufficient notice and reasonable assistance in making alternative arrangements for care." AMA Code, Opinion 1.1.3; AMA Code, Opinion 1.2.3 ("Physicians' fiduciary obligation to promote patients' best interests and welfare can include . . . referring patients to other professionals to provide care."). This duty to the patient is primary; where conscience implores physicians to deviate from standard practices, "[p]hysicians' freedom to act according to conscience is not unlimited," AMA Code, Opinion 1.1.7, and they should provide patients with accurate prior notice of their personal commitments. *See* CO 385 at 5.

Autonomy. Respect for autonomy holds that patients should be free to act without controlling constraints imposed by others. *See* CO 385 at 1–3; ACEP Code, Ch. II.B.3. Respect for autonomy likewise undergirds important ethical principles of informed consent. ACOG Committee Opinion No. 439, *Informed Consent*, at 2 (2009) ("CO 439"). "[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." *Id.* at 3.

Physicians who refuse information or care based on their personal convictions fail in their fundamental duty to enable patients to make decisions for themselves. *Id*. Patient autonomy requires medical professionals also to commit to scientific integrity and evidence-based practice, out of respect for patients' personhood and ability to make free and informed choices based on relevant and accurate information provided to them. *See id.*; AMA Code, Opinion 2.1.1.

Justice. In medical ethics, justice concerns both the obligation to treat patients with respect and the physician's role in the allocation of limited medical resources in the community. ACOG Committee Opinion No. 390, *Ethical Decision Making in Obstetrics and Gynecology*, at 4 (2007). *See also* AMA Code, Opinion 11.1.3, 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. Medical professionals have an ethical obligation to advocate "for patients' needs and rights[, and neither] create [n]or reinforce racial or socioeconomic inequalities in society." CO 385 at 4. In addition, the AMA Code requires "[p]hysicians . . . not to discriminate against a prospective patient on the basis of…personal or social characteristics that are not clinically relevant to the individual's care." AMA Code, Opinion 1.1.2; *see also* ACEP Code Ch. I.2 ("Emergency physicians shall respond promptly and expertly, without prejudice or partiality, to the need for emergency medical care."); 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 or injury, or ability to pay is unethical.").

IV. Argument

A. The Rule Undermines Fundamental Principles of Medical Ethics.

The Rule cannot be reconciled with these bedrock principles of medical ethics. The ethical practice of medicine puts the patient first: it seeks to alleviate suffering and to avoid harm. The Rule turns that fundamental obligation on its head. The Rule purports to permit anyone involved in patient care to ignore another's suffering and to refuse to provide care, even when that refusal endangers the patient. It compels institutions to certify that they will prioritize 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 medical providers or others in health care settings receiving federal funds to refuse patients basic health care services and information, without regard to medical necessity and including in emergency situations, based solely on individual views. Objecting employees need not notify their employers or the patient of their objection before refusing to provide care, information, or a referral. Instead, the Rule puts the onus on the employer to ask whether an employee is likely to object to certain services, but allows the employer to do so only *once a*

year, after hiring, absent a "persuasive justification." 84 Fed. Reg. at 23263, § 88.2(5); *New York v. HHS,* 414 F. Supp. 3d 475 (S.D.N.Y. 2019), *reasoning adopted by* Wash Op. at ER30 ("N.Y. Op.") at 36, 50. It extends this latitude to virtually any employee working in any capacity for the broad array of providers subject to the Rule. N.Y. Op. at 35–36, 52. By purportedly permitting essentially anyone involved in the provision of health care to refuse help to those who need it, without warning, the Rule eviscerates the paramount ethical commitment 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 Promote the Well-being of the Patient.

The Rule is fundamentally irreconcilable with medical ethics because the Rule: (1) permits refusal to provide necessary services, even in emergencies; (2) fails to protect access to and maintain continuity of care for all patients; and (3) permits virtually any employee in a health care setting to impede patient treatment.

1. The Rule Endangers Patients in Emergency Situations.

In a repudiation of medical ethics, the Rule purports to permit medical professionals to deny patients necessary care, even in emergencies in which referral is impossible or might harm the patient's physical or mental health. *See* 84 Fed. Reg. at 23263–64, §§ 88.1–88.2 (lacking carve-out for emergencies); N.Y. Op.

at 76–77, 103–106; Wash. Op. at ER28.[4] By prioritizing an employee's moral views over a patient's prompt receipt of emergency care, the Rule endangers patients and eviscerates the premise of emergency rooms as a place where those with urgent, often life-threatening needs can seek immediate care. *See* ACEP Code Ch. I.2 ("Emergency physicians shall respond promptly and expertly, without prejudice or partiality, to the need for emergency medical care."); ACOG, Letter Re: RIN 0945-A03; Protecting Statutory Conscience Rights in Health Care (March 27, 2018)[5] ("In an emergency in which referral is not possible or might negatively impact the patient's physical or mental health, providers have an obligation to provide medically indicated and requested care.").

The Rule also violates settled law: it irreconcilably conflicts with the Emergency Medical Treatment and Labor Act ("EMTALA"). N.Y. Op. at 74–78, 126; *see also* 42 U.S.C. §1395dd; 84 Fed. Reg. at 23170, 23183. Appellants' response—maintaining that "EMTALA requires emergency medical care only 'within the staff and facilities *available* at the hospital,'" and that any objector is simply not "available," even if the result is a patient receiving no care—makes clear that the Rule puts objectors first and patients last, fundamentally undermining

[4] *See* N.Y. Op. at 77 (rejecting attempts to minimize the Rule's impact and stating that HHS's claim to "view complaints involving emergencies with lenity does not, in the crucible, give [providers] certainty that favoring the patient's needs over the employee's objections will not result in a loss of funding").
[5] https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70647.

EMTALA's promise that emergency care will be provided when needed. *See* Appellants' Br. (Dkt. 15) at 45 ("If no staff are available because every staff member has a valid statutory conscience objection . . . , there is no violation of EMTALA . . . ."); San Francisco's Answering Br. (Dkt. 48) at 41-44.

Emergency medical situations, by definition, pose urgent threats to patient health. Patients arrive in emergency rooms with dangerous conditions and require immediate attention to stabilize, remain conscious and, in many cases, remain alive. Emergency rooms rely on numerous employees to assist with providing urgently needed care to these patients, including at the intake stage, when patients are often at their most vulnerable. The Rule disregards that patients with life-threatening injuries do not have time to wait for replacement staff to be found or to be transferred. Nor can an emergency department anticipate every possible basis for an 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, for both standard emergency room readiness and emergency preparedness. *See* ACEP, Letter Re: Protecting Statutory Conscience Rights in Health Care (March 27, 2018);[6] N.Y. Op. at 77 (dismissing over-staffing as "a non-starter" because hospitals cannot "assure that a conscience-cleared platoon is

[6] https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71219.

present or on call for every urgent scenario. And in an emergency, patients 'may not have time to wait to be referred . . . .'").

It is difficult to overestimate the effect of the Rule. The kinds of "conscience objections" the Rule permits are objections to the completely legal and scientifically sound practice of medicine and provision of health care. For example, the medical profession recognizes that women may face life-threatening conditions in which termination of a pregnancy is advisable or necessary, such as ectopic pregnancy or severe preeclampsia. *See, e.g.*, ACOG Practice Bulletin No. 193, *Tubal Ectopic Pregnancy* (March 2018).[7] Yet the Rule protects a physician who refuses to terminate a pregnancy under these circumstances, even in an emergency when no other clinician is available. That patient's doctor could, under the Rule, simply decline to inform her (or an alternative clinician) of her condition. 84 Fed. Reg. at 23263, § 88.2. Experiencing extreme pain, she could call for an ambulance but, under the Rule, the ambulance driver, made aware of or suspecting the potential for termination, could refuse to transport her to the hospital and refuse to refer her to other transportation or tell a supervisor of the refusal. *See* 84 Fed. Reg. at 23188; Cal. Op. at ER47-49; N.Y. Op. at 35, 76, 105. Assuming she makes it to the emergency room on her own, she will need to be admitted, which a clerk could, under the Rule, refuse to do. *See* N.Y. Op. at 35, 52. The patient will then need

[7] https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Bulletins/Committee-on-Practice-Bulletins-Gynecology/Tubal-Ectopic-Pregnancy.

surgery involving multiple medical staff members, or face a high risk of death. Every employee involved is within the category of individuals who, under the Rule, may refuse to "assist in the performance of" the procedure without *any* prior notice, potentially costing the patient her life. 84 Fed. Reg. at 23188 .

Delays and denials of medical care, particularly in emergency situations, due to one individual's objection (which may be disclosed, if at all, at the last minute) endanger patients. Appellants acknowledged that the Rule will harm patients, but promulgated the Rule anyway. 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 he or she seeks.").

The harms the Rule poses to emergency medicine are only exacerbated by the COVID-19 pandemic. That crisis has strained emergency rooms and hospitals, leaving institutions short-staffed and placing limitations on non-COVID care. Amid shutdowns, patients have foregone preventive care, potentially leading to more medical crises and further stressing already-taxed providers.[8] During a pandemic, institutions that "typically operate[] at maximum capacity" do not have staff to spare and cannot afford to risk more lives, either by calling on depleted

[8] *See, e.g.*, Katia Hetter, *Getting to medical appointments during a pandemic*, CNN (May 11, 2020), https://www.cnn.com/2020/05/11/health/getting-to-medical-appointments-pandemic-wellness/index.html; Reis Thebault, et al., *Heart conditions drove spike in deaths beyond those attributed to COVID-19, analysis shows*, Wash. Post (July 2, 2020), https://www.washingtonpost.com/graphics/2020/investigations/coronavirus-excess-deaths-heart/.

backup employees or by further delaying or denying emergency care due to strained resources.[9] For example, when a registered nurse anesthetist lodges a last-minute objection to assisting a patient with an urgent need, and s/he cannot be replaced because all colleagues are in COVID-19 ICUs, the patient may die. The COVID-19 crisis thus heightens the dangers the Rule threatens to the provision of necessary and urgent care.

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

Where an employee objects to the care a patient needs or desires, the Rule goes so far as to prevent employers from requiring employees to refer patients to another professional who could provide such services. 84 Fed. Reg. at 23263, § 88.2(6). Objecting employees need not facilitate the transfer of care, *or even inform other staff that they have refused to provide such services or a referral to the patient*. Rather, the Rule relies on providers to post public notices with general indications that alternatives are available, and leaves it up to the patient to pursue these alternatives. 84 Fed. Reg. at 23192.

The Rule improperly shifts the burden of ensuring health care continuity from clinician to patient, with potentially devastating consequences. For example, if a primary care physician has a religious objection to informing a patient, such as

[9] *See, e.g.*, Frances Stead Sellers, *As coronavirus invades, emergency rooms look to keep people at a safe distance*, Wash. Post (Mar. 20, 2020), https://www.washingtonpost.com/national/coronavirus-emergency-room-hospital/2020/03/19/3b6e0d94-685b-11ea-abef-020f086a3fab_story.html.

a minor on Medicaid, about the HPV vaccine, s/he need not do so under the Rule and would have no legal obligation to make a referral to another clinician. The patient 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. AAP, Letter to HHS, Office for Civil Rights, RIN 0945-ZA0 (March 27, 2018).[10] Moreover, if the patient proactively asks about HPV and is refused information on the basis of a clinician's personal objection, the patient may be discouraged from seeking this information elsewhere. *See* Section IV.C.

The risk of refusal hurts patients at every turn, from a young adult who develops cancer following denial of the HPV vaccine to a patient whose pharmacist denies prescribed HIV-preventative medication. Patients whose requests for contraceptive care are denied or delayed may face the irreparable effect of unintended pregnancy. Many transgender patients require cross-hormone therapy, gender affirmation surgery and/or mental health support services—safe and effective treatments that are necessary for patient health and well-being. ACOG Committee Opinion No. 512, *Health Care for Transgender Individuals*, at 1 (2011). When these treatments are unavailable, the consequences are staggering: 54% of transgender youth have attempted suicide and 21% resort to self-mutilation.

[10] https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71022.

Id. at 2. Under the Rule, clinicians can simply decline to offer or even refer patients to the care they need.

Individuals' reluctance to seek medical care during the pandemic may exacerbate the harms of an employee's refusal to direct a patient to, or even inform a patient of, needed care or clinicians. For example, a patient who, despite fear of contracting COVID-19, garners the courage to seek contraceptive care at a nearby clinic may be discouraged from seeking it elsewhere when the clinic nurse denies care without informing her of other options. Seeking to avoid exposure to the virus, and without any assurance of receiving the care she needs, the patient may simply give up.

This aspect of the Rule is also irreconcilable with medical ethics. Medical professionals' "fiduciary responsibility to patients entails an obligation to support continuity of care for their patients"—*i.e.*, that when they cannot perform the services a patient needs, they refer the patient to another who can." AMA Code, Opinion 1.1.5. Medical ethics require that physicians considering withdrawing from a case "(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." *Id.* *See also* AMA Code, Opinion 1.1.3 (acknowledging that "patients' rights" include "continuity of care" and that "[p]atients should be able to expect that their physician will cooperate in

coordinating medically indicated care…, and that the physician will not discontinue treating them…without giving them sufficient notice and reasonable assistance in making alternative arrangements"); Opinion 1.2.3 ("Physicians' fiduciary obligation to promote patients' best interests and welfare can include . . . referring patients to other professionals to provide care.").

3. The Rule Sanctions Interference in Patient Care by Virtually Any Employee.

As noted above, the Rule permits virtually any employee to make an objection that must be accommodated, without any obligation to provide advance notice to the employer, while only permitting employers to ask whether their employee is likely to object to certain procedures once a year absent a "persuasive justification." 84 Fed. Reg. at 23263, § 88.2(5). This includes any and all employees—from surgeons, to laboratory technicians, to janitors. *See* N.Y. Op. at 35, 52.

Several, if not dozens, of employees can impact one medical procedure. It may be impossible to perform the procedure when even one of them lodges a last minute objection to providing care. In such an instance, the procedure may not be able to be rescheduled for weeks, with potentially life-threatening consequences. This includes even employees seemingly far-removed from the procedure itself, such as receptionists and elevator operators—all of whom are potential objectors under the Rule. *See* 84 Fed. Reg. at 23264, § 88.2(1); N.Y. Op. at 35, 52. The

Rule thus makes patient care subject to critical disruption by virtually any employee who objects to certain services.

C. The Rule Undermines Patient Autonomy and Informed Consent.

The protection of patient autonomy is at the heart of medical ethics. *See* CO 385 at 3; AMA Code, Opinion 1.1.3. Patient autonomy requires that patients "receive information from their physicians . . . including the risks, benefits and costs of forgoing treatment," AMA Code, Opinion 1.1.3, and have the "right to receive information and ask questions about recommended treatments so that they can make well-considered decisions." AMA Code, Opinion 2.1.1. A patient's informed consent to a particular course of medical treatment "is fundamental in both ethics and law" as a necessary safeguard of patient autonomy. *Id.*

The Rule subverts the principle of informed consent by permitting an employee to withhold critical information from a patient. The Rule permits an 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 health care service...." 84 Fed. Reg. at 23263-64, § 88.2. The Rule permits objecting employees to refuse to provide any information for which "the purpose" or even "reasonably foreseeable outcome" would be to allow a patient to receive certain life-saving health services, simply

because the objector opposes such services. *Id.* at 23264. This broad mandate reaches well beyond safeguarding conscience rights, allowing any individual touching on patient care to virtually assure that a patient does not receive a particular course of treatment. The Rule also prevents policies or practices that would require "additional action" by an objecting employee, such as policies requiring an objecting employee to inform staff that s/he has declined to provide a patient with information. *See* 84 Fed. Reg. at 23263, § 88.2(6).

Without access to all relevant medical information concerning their condition, or even the fact that they lack all relevant medical information, patients cannot give informed consent to or participate in decision-making with respect to their care. For example, the Rule permits an employee to decline to provide a patient with information about her reproductive health—such as the availability of abortion or contraception—or notify her that she is not receiving all available information. Women cannot make fully informed decisions absent that information. This is especially concerning given the time limits many states place on the availability of abortion. *See, e.g.*, Neb. Rev. Stat. §§ 28-3,102–28-3,111 (2019) (prohibiting abortions after 20 weeks, with limited exceptions).

By permitting virtually any employee in a health care setting to withhold critical medical information, the Rule prevents patients' participation in important

decisions that affect their lives and amounts to "an ethically unacceptable violation of who and what persons are[.]" CO 439 at 3.

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

"Justice . . . requires medical professionals and policy makers to treat individuals fairly and to provide medical services in a nondiscriminatory manner." CO 385 at 4. 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." AMA Code, Opinion 1.1.2. Rather than promote equal access, however, the Rule targets individuals who rely on federal funding for health care and imposes new barriers to their health care services. Wash. Op. at ER31-32.

First, the Rule creates additional hurdles for already-vulnerable populations, such as women, people of color, LGBTQIA individuals, and individuals with disabilities. As detailed in Section IV.E, the Rule imposes constraints upon providers that will incentivize them to limit or eliminate health care offerings that employees may find morally or religiously objectionable. At the same time, the socioeconomic constraints faced by those who rely on federally-funded health care services will magnify the negative effect of closures on these vulnerable populations. Patients in need of these services will have to overcome increased

barriers to pursue them, such as driving longer distances or waiting longer to receive needed care. These are the same patients who have the fewest viable options for care, being unable to pay premiums for more convenient private services. Faced with these additional challenges, these individuals are likely to accept substandard care or forego medical services entirely.

Rural women, for example, are "more likely to be poor, lack health insurance or rely substantially on Medicaid and Medicare" and must "travel longer distances to receive care." ACOG Committee Opinion No. 586, *Health Disparities in Rural Women*, at 2 (2014). As a result, women in rural communities are more likely to be deterred from seeking abortion care or prenatal care, and may not even be able to access a hospital when they need to give birth. *See id.* at 1, 2. The Rule's impact on emergency care, *see* Section IV.B.1, also poses disproportionate harm to low-income and rural communities, where "emergency rooms are the first stop in the search for health care."[11]

People of color are also likely to be disproportionately disadvantaged by the Rule, given that many already face significant and persistent inequities in health care compared to the general population. ACOG Committee Opinion No. 649, *Racial and Ethnic Disparities in Obstetrics and Gynecology*, at 1 (2015). This is all the more true during the COVID-19 crisis, which has taken an outsize toll on

[11] Sellers, *supra* note 6 ("[I]n rural areas, some 60 million Americans rely on hospitals exclusively for their care").

communities of color.[12] The pandemic heightens the need to ensure access to care is provided without the disruptions threatened by the Rule, as "historic inequities in access to health care and other resources" continue to "contribute to disproportionate rates of comorbidities in communities of color, which place individuals at higher risk of severe illness from COVID-19."[13]

LGBTQIA individuals would face greater constraints on the already-limited pool of medical professionals offering services they need as a result of the Rule. In a recent study, nearly 20% of LGBTQIA—and 31% of transgender—people stated that it would be very difficult or impossible to receive certain necessary medical services if they were unable to receive them from their existing provider.[14] When narrowed to individuals in non-metropolitan areas, 41% of people said it would be very difficult or impossible.[15]

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[12] *See* ACEP, *ACEP Diversity, Inclusion, and Health Equity Initiative*, https://www.emergencyphysicians.org/article/covid19/ acep-diversity-inclusion-and-health-equity-covid19-initiative ("Data shows disproportionate rates of infection and death within communities of color, with the disparity in death rates up to 40 percent in some communities.") (last accessed October 19, 2020).

[13] ACOG, *Addressing Health Equity During the COVID-19 Pandemic* (May 11, 2020), https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2020/addressing-health-equity-during-the-covid-19-pandemic.

[14] Shabab Ahmed Mirza, et al., *Discrimination Prevents LGBTQ People from Accessing Health Care*, Center for American Progress (Jan 18, 2018), https://www.americanprogress.org/issues/lgbtq-rights/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/.

[15] *Id.*

People with disabilities and complex medical needs will likewise be disproportionately harmed by the Rule. Many rely on health care services, including home and community-based services, to facilitate their daily activities, making them particularly vulnerable to disruptions in care. *See* National Association of Councils on Developmental Disabilities, Letter re: Protecting Statutory Conscience Rights in Health Care (Mar. 22, 2018).[16] The Rule poses additional burdens for individuals whose group homes are operated by faith-based entities, which could, for instance, refuse to facilitate reproductive care services.[17] Given that individuals with disabilities face an increased risk of sexual abuse compared to the general population, these individuals have a particularly strong need for reproductive care, but may be unable to pursue needed services if they are refused care or referrals.[18]

Second, in addition to compromising patients' physical health, subjecting vulnerable populations to discrimination and dignitary harm is unethical and likely to have life-long repercussions. For instance, studies have concluded that

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[16] https://www.regulations.gov/document?D=HHS-OCR-2018-0002-66494.
[17] Courtney Perkes, *Disability Advocates Worry 'Conscience Rule' Could Spell Trouble*, Disability Scoop (May 28, 2019), https://www.disabilityscoop.com/2019/05/28/disability-advocates-conscience-rule-trouble/26687/.
[18] *See* Joseph Shapiro, *The Sexual Assault Epidemic No One Talks About*, NPR (Jan. 8, 2018), https://www.npr.org/2018/01/08/ 570224090/the-sexual-assault-epidemic-no-one-talks-about; Disability Justice, *Sexual Abuse*, https://disabilityjustice.org/sexual-abuse/ (last accessed October 19, 2020).

transgender people already delay or avoid medical services to avoid discrimination and harassment, resulting in serious lifelong health risks.[19] The Rule exacerbates these harms. For example, a patient who seeks Post-exposure Prophylaxis—a medication that can prevent the contraction of HIV—but is turned away by a clinic employee who objects to his or her gender identity is likely to feel stigmatized and dissuaded from seeking the medication from another clinic during the time within which it would be effective.

E. The Rule Is Impermissibly Vague and Stymies Effective Functioning of Health Care Systems.

That the Rule is irreconcilable with principles of medical ethics is clear. Remarkably unclear, however, are the Rule's directives that dictate how providers would comply with its legal obligations. Because of its many ambiguities and its inconsistency with other laws, the Rule does not offer adequate guidance as to what conduct is prohibited and encourages arbitrary enforcement. Providers are left to parse the Rule's ambiguous language under threat of draconian penalties.

Among the many problematic ambiguities addressed by Appellees, *Amici* are particularly concerned by the Rule's overbroad and vague language concerning its enforcement mechanisms. For example, the preamble to the proposed Rule asserted that HHS may regulate an unspecified "broader range of funds or broader

[19] *See* Kristie L. Seelman et al., *Transgender Noninclusive Healthcare and Delaying Care Because of Fear: Connections to General Health and Mental Health Among Transgender Adults*, Transgender Health 2(1):17-28, at 25 (2017).

categories of covered entities" for "noncompliant entities," without any indication as to the limit of this regulation. 83 Fed. Reg. 3880, 3898 (Jan. 26, 2018). And Appellants admit that all HHS funds for a certain organization may be at risk for violations of the Rule. *See* Appellants' Br. (Dkt. 15) at 24 ("[W]here a recipient's violation might extend to each funding stream it receives, it is entirely reasonable . . . to include a provision 'reserv[ing] the right'…to terminate all HHS funds . . . for such a violation."). When combined with draconian penalties for noncompliance—including cutting off or clawing back all federal funding, even funding unrelated to the area in which the alleged discrimination occurred[20]—providers may 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 both the Rule and obligations to patients will face feasibility issues of daunting complexity and cost.

V. Conclusion

Amici urge the Court to affirm the district courts' decisions. For the reasons explained above and outlined more fully in Appellees' briefs, the Rule, if implemented, would cause grave harm to patients and public health, conflict with

[20] 84 Fed. Reg. at 23180 (remedies include "termination of relevant funding, in whole or in part" and "funding claw backs to the extent permitted by law"); 84 Fed. Reg. at 23271-72, § 88.7(i) (remedies include withholding, denying, or terminating existing funding; denying or withholding new funding; and suspending award activities).

principles of medical ethics, and be impermissibly vague. The Rule distorts the patient-provider relationship and compromises patient health and safety for the personal beliefs of an individual.

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CERTIFICATE OF COMPLIANCE WITH F.R.A.P. 32(a)

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B). It contains 6,457 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2. 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). It has been prepared in a proportionally spaced typeface using Microsoft Word in 14 point Times New Roman.

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