Exhibit 1

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, et al.,	
Plaintiffs,	1:19-cv-4676 (PAE) 1:19-cv-5433 (PAE) 1:19-cv-5435 (PAE)
v.	
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,	
Defendants.	

BRIEF OF LEADING MEDICAL ORGANIZATIONS AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION AND CROSS-MOTION FOR SUMMARY JUDGMENT

Shannon Rose Selden
DEBEVOISE & PLIMPTON LLP
919 Third Avenue
New York, NY 10022

Anna A. Moody
DEBEVOISE & PLIMPTON LLP
801 Pennsylvania Ave, NW
Washington, D.C. 20004

Counsel for Amici Curiae

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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, ACOG is dedicated to the advancement of women's health care, including advancing the core value of access for all women to high quality safe health care. ACOG has a long and strong history of supporting access to health care for all women.

- 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, 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.

- The American Academy of Pediatrics ("AAP") was founded in 1930 and 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 AAP has become a powerful voice for child and adolescent health through education, research, advocacy, and the provision of expert advice. AAP has worked with the federal and state governments, healthcare providers, and parents on behalf of America's families to ensure the availability of safe and effective reproductive health services.

- 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. ACEP continually strives to improve the quality of emergency medical services through the development of evidence-based clinical policies, funding emergency medicine research, providing public education on emergency care and disaster preparedness,

[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*, their members, or their 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.

legislative and regulatory advocacy efforts, providing industry-leading continuing medical education ("CME") in the form of educational conferences, online training, professional references and news magazines, and publishing Annals of Emergency Medicine, the specialty's leading peer-reviewed scientific journal.

- The American College of Osteopathic Obstetricians and Gynecologists ("ACOOG") was founded in 1934 and is a 2,500- member organization dedicated exclusively to women's healthcare. An osteopathic obstetrician-gynecologist is committed to the physical, mental, and emotional health of women. 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 dedicated to the advancement of the science and practice of reproductive medicine. Its members include approximately 8,000 professionals. ASRM accomplishes its mission through the pursuit of excellence in education and research and through advocacy on behalf of patients, physicians, and affiliated healthcare providers. ASRM is committed to facilitating and sponsoring educational activities for the lay public and continuing medical education activities for professionals who are engaged in the practice of and research in 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 since its inception in 1980. Its members champion state-of-the-science healthcare that holistically addresses the unique needs of women across their lifetimes. NPWH's mission is to ensure the provision of quality primary and specialty healthcare to women of all ages by women's health and women's health-focused nurse practitioners, including by protecting and promoting a woman's right to make her own choices regarding her health within the context of her personal, religious, cultural, and family beliefs.

- The Society for Maternal-Fetal Medicine ("SMFM") supports the clinical practice of maternal-fetal medicine ("MFM") by providing education, promoting research, and engaging in advocacy to optimize the health of high-risk pregnant women and their babies. Founded in 1977, 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 who care for high-risk pregnant women, SMFM works to increase promotion of high-quality MFM research and expand access to MFM services to reduce healthcare disparities for high-risk pregnant women.

- The American College of Nurse-Midwives ("ACNM") works to advance the practice of midwifery in order 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. ACNM and its members respect each woman's right to dominion over her own health and care and ACNM advocates on behalf of women and families, its members, and the midwifery profession to eliminate health disparities and increase access to evidence-based, quality care.

- 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. With its diverse membership including gynecologists, adolescent medicine specialists, pediatric endocrinologists, and other medical specialties, its focus is to be the leading provider in pediatric and adolescent gynecology ("PAG") education, research, and clinical care; conduct and encourage multidisciplinary and interprofessional programs of medical education and research in the field of PAG; and advocate for the reproductive well-being of children and adolescents and the provision of unrestricted, unbiased, and evidence-based practice of PAG.

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

- The World Professional Association for Transgender Health ("WPATH") is a non-profit professional and educational organization devoted to transgender health, with professional, supporting, and student 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.

II. Introduction

Amici are the leading medical organizations representing physicians and health practitioners in the United States. They include the AMA, the largest professional association of physicians, residents, and medical students in the country; ACOG, the nation's leading organization of physicians who provide health services unique to women; the AAP, representing more than 67,000 pediatricians and pediatric subspecialists; ACEP, the leading advocate for emergency physicians and their patients, and many others. *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 advocating for the public health and 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. 84 Fed. Reg. 23170 (May 21, 2019) (to be codified at 45 C.F.R. pt. 88). It represents a dramatic departure from statutory standards and prior agency interpretation, is unworkably vague, and creates dangerous uncertainty.[2]

Amici are deeply concerned that the Rule will radically disrupt medical care and endanger the lives and health of patients. Where professional ethics recognize that the patient is paramount, the Rule prioritizes an individual's personal beliefs. 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 medically appropriate care *even when their refusal jeopardizes another's life and safety*. The Rule protects objectors and endangers patients in every conceivable context—from infancy through end-of-life,

[2] 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.

in rural clinics and urban hospitals, from preventative care to life-or-death emergencies. Patients will inevitably 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' urgent request for preliminary relief. In addition to Plaintiff's detailed arguments, *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 wellbeing, impedes the provision of quality health care services on a non-discriminatory basis, and critically threatens the effective functioning of health care institutions, which will be subject to extreme penalties for noncompliance with vague standards they cannot parse. These injuries are irreparable. *Amici* urge the Court to grant Plaintiffs' motion for summary judgment and hold the Rule to be invalid, or, in the alternative, enjoin the Rule before it takes effect.

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 foundational ethics that govern the practice of medicine.

The ethical rules unequivocally place the patient first. AMA policy provides that a physician is ethically required to use sound medical judgment, ***holding the best interests of the***

patient as paramount. Code of Medical Ethics of the American Medical Association ("AMA Code of Medical Ethics"),[3] Opinion 1.1.1; *see also id*. ("The practice of medicine . . . is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering."); AMA Code of Medical Ethics, Opinion 1.1.3 ("[P]atients' rights" include "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 . . . and to advocate for their patients' welfare." AMA Code of Medical Ethics, Opinion 1.1.1. Similarly, ACOG's Code of Professional Ethics states that the "***welfare of the patient (beneficence) is central to all considerations in the patient–physician relationship***." ACOG Code of Professional Ethics ("ACOG Code"), *December 2018*, Ch. I (emphasis added). Under the American College of Emergency Physicians Code of Ethics for Emergency Physicians "***physicians assume a fundamental duty to serve the best interests of their patients***." American College of Emergency Physicians Code of Ethics for Emergency Physicians, *January 2017*, ("ACEP Code"), Ch. II.B.1 (emphasis added). In pediatric care, providers make a particular ethical commitment to protecting young patients from serious harm and ensuring child health and well-being. American Academy of Pediatrics, Committee on Bioethics,

[3] The AMA has published its Code of Medical Ethics since 1847. This was the first modern national medical ethics code in the world, and continues to be the most comprehensive and well-respected code for physicians world-wide. The federal judiciary, including the United States Supreme Court, has repeatedly cited the AMA Code of Medical Ethics. *See, e.g.*, *Lilly v. Commissioner*, 343 U.S. 90, 97 n.9 (1952); *Roe v. Wade*, 410 U.S. 113, 144 n.39 (1973); *Bates v. State Bar of Ariz.*, 433 U.S. 350, 369 n.20 (1977); *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 288 & 308 (1990) (O'Connor, J., concurring & Brennan, J., dissenting); *Rust v. Sullivan*, 500 U.S. 173, 214 (1991) (Blackmun, J., dissenting); *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997); *Vacco v. Quill*, 521 U.S. 793, 800 n.6 & 801 (1997); *Ferguson v. City of Charleston*, 532 U.S. 67, 81 (2001); *Baze v. Rees*, 553 U.S. 35, 64 & 112 (2008) (Alito, J., concurring & Breyer, J., concurring); *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 592-93 (2012) (Ginsburg, J., dissenting in part).

Professionalism in Pediatrics: Statement of Principles, 120 Pediatrics 895, 896 (2007) ("***Patient well-being should be the primary motivating factor in patient care, ahead of physicians' own interests and needs***."). 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 is the obligation to promote the well-being of others; it 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, best known in the ancient maxim, *primum non nocere* ("First, do no harm"). *See* ACOG Committee Opinion No. 385, *The Limits of Conscientious Refusal in Reproductive Medicine*, Nov. 2007, ("CO 385") at 3.

Beneficence and non maleficence are individual and communal obligations: as trustees of patients' wellbeing, medical professionals assume an obligation not only to care for patients themselves, but also "an obligation to support continuity of care for their patients"—*i.e.*, to ensure that when they cannot personally perform the services a patient needs, they refer the patient to another health care provider who can. AMA Code of Medical Ethics, Opinion 1.1.5. The ethical obligations to help and not harm means 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 of Medical Ethics, Opinion 1.1.3 ("patients' rights" include "continuity of care"); *see also* AMA Code of Medical Ethics, 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, and where conscience implores physicians to deviate from standard practices, "[p]hysicians' freedom to act according to conscience is not unlimited," AMA Opinion 1.1.7, and they should provide patients with accurate and prior notice of their personal commitments. *See* CO 385 at 5.

Autonomy. Respect for patient autonomy holds that persons should be free to choose and act without controlling constraints imposed by others. *See* CO 385 at 1-3; AMA Code of Medical Ethics, Opinion 2.1.1; ACEP Code, Ch. II.B.3. 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 solely as means or instruments for another's purposes or goals. ACOG Committee Opinion No. 439, *Informed Consent*, Aug. 2009, ("CO 439") at 3. Respect for autonomy undergirds important ethical principles of informed consent and free decision-making. *Id.* at 2. "[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. Providers who refuse to provide information or care on the grounds of their religious objections fail in their fundamental duty to enable patients to make decisions for themselves. *Id*. True patient autonomy requires medical professionals 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. *See id*; AMA Code of Medical Ethics, Opinion 2.1.1.

Justice. In the context of medical ethics, justice concerns both the obligation to render to a patient the care and respect that is owed to them and the physician's role in the allocation of limited medical resources in the broader community. ACOG Committee Opinion No. 390, *Ethical Decision Making in Obstetrics and Gynecology*, Dec. 2007, ("CO 390") at 4. *See also* AMA Code of Medical Ethics, 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. Medical professionals have an affirmative 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 of Medical Ethics 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 of Medical Ethics, 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 bedrock principles of medical ethics. The ethical practice of medicine puts the patient first: it seeks to alleviate suffering and to avoid causing harm. The Rule turns that fundamental moral obligation on its head. The Rule purports to permit anyone involved in patient care to ignore another's suffering and to affirmatively refuse to

assist in their care, even when that refusal endangers or harms the patient. 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 health care providers or other individuals working in a health care setting receiving federal funds to refuse to provide patients basic health care services and information, without regard to medical necessity and including potentially in emergency situations, based solely on personal religious views. *See* 84 Fed. Reg. at 23263, § 88.2. 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. *Id*. Instead, the Rule puts the onus on the employer to ask whether an employee is likely to lodge an objection to certain medical services, and restricts the employer from doing so to *once a year, after hiring,* absent a "persuasive justification." *Id*. The Rule extends this permission to virtually any employee working in any capacity for the broad array of health care providers subject to the Rule. By purportedly permitting doctors, nurses, emergency medical technicians, and virtually every other individual involved in the provision of health care to refuse help to those who need it, without warning, the Rule eviscerates the paramount ethical commitment of medical ethics to respect and care for patients.

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

The duties of beneficence and nonmaleficence at the very core of the practice of medicine require medical professionals to act in good faith to protect patient health, even when a patient's health interests conflict with a physician's personal views. CO 385 at 3. 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 access to and maintain continuity of care for all

patients; and (3) permits individuals without medical training to impede the course of patient treatment.

1. The Rule Endangers Patients in Emergency Situations.

In a total repudiation of established medical ethics, the Rule purports to permit medical providers 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. *See* 84 Fed. Reg. at 23263-685, §§ 88.1-88.2 (containing no carve-out for emergency situations).[4] By prioritizing the religious views of employees over a patient's prompt receipt of emergency medical care, the Rule eviscerates the premise of emergency rooms as a place where those with urgent, often life-or-death medical needs can seek immediate medical care and endangers the physical safety of patients. AMA Code of Medical Ethics, 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, to the need for emergency medical care."); Letter from ACOG to Sec. Azar, March 27, 2018, (on 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 physical or mental health, providers have an obligation to provide medically indicated and requested care."). The Rule also appears to violate settled law: the Emergency Medical Treatment and Labor Act (EMTALA) requires clinicians to screen and stabilize patients who come to the emergency department. 42 U.S.C. §1395dd. HHS contends that the Rule is consistent with EMTALA, but

[4] 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 well-defined carveout specifying that one may not refuse treatment in emergency situations.

the two are patently irreconcilable. 84 F.R. at 23170, 23183. 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. *See* Letter from ACEP to Sec. Azar, March 27, 2018, (on file with Dep't of Health and Human Serv., Office for Civil Rights, RIN 0945-ZA03; Protecting Statutory Conscience Rights in Health Care; Delegations of Authority) ("ACEP Comment Letter").

Emergency medical situations, by definition, pose urgent threats to a patient's health and safety. Patients arrive in emergency rooms with dangerous, often life-threatening conditions and require immediate medical attention to stabilize, remain conscious, and in many cases, remain alive. Emergency rooms rely on a number of different staff members to assist with providing urgently-needed medical care to these patients, including at the intake stage, when patients are often in their most vulnerable state, and operate on tight budgets that make over-staffing unfeasible. ACEP Comment Letter, at 2. The Rule disregards the fact that patients with life-threatening injuries do not have time to wait for a replacement staff member to be found, or to be transferred to another physician or provider.

It is difficult to overestimate the effect of this change. 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 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. ACOG Practice Bulletin No. 193*: Tubal Ectopic Pregnancy*, March 2018, available at https://www.acog.org/Clinical-Guidance-and-Publications/Practice-

Bulletins/Committee-on-Practice-Bulletins-Gynecology/Tubal-Ectopic-Pregnancy. Yet the Rule protects a provider who refuses to terminate an ectopic pregnancy, even in an emergency in which no alternative provider is available. That patient's primary care doctor could, under the Rule, simply decline to inform her (or an alternate provider) of her condition. 84 Fed. Reg. at 23263, § 88.2 (permitting health care provider employees subject to the Rule to refuse to "assist in [the] performance" of any health care activity, including "counseling, referral**,** training, or otherwise making arrangements for the procedure," without regard to medical necessity). 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 to either refer her to alternate transportation or to tell his supervisor of his refusal. *See id*. Assuming she makes it to the emergency room under her own power, she will need to be admitted, which a clerk could refuse to do. *See id*. The patient will then need a surgery involving, on average, fifteen medical staff members, or face a high risk of death.[5] Allen Decl. ¶ 28. The Rule includes each of these employees, and many more, within the category of individuals who may lodge an objection and refuse to "assist in the performance of" the procedure without *any* prior notice, potentially costing the patient her life. 84 Fed. Reg. at 23263, § 88.2. HHS acknowledges that the Rule will lead to harm to patients, but promulgated the Rule anyhow. 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.").

[5] These staff members include registration clerks, triage nurses, patient care associates, laboratory technicians, emergency room physicians, operating room technicians, clerical staff, radiologists, radiology technicians, staff nurses, housekeeping staff, scrub nurses, circulating nurses, anesthesiologists, and certified registered nurse anesthetists. Corrected Declaration of Dr. Machelle Allen, Senior Vice President and System Chief Medical Officer, New York City Health + Hospitals, Dkt. 44-1 ¶ 29 ("Allen Decl.").

The risks of refusal hurts patients at every possible turn, from a young adult who develops cancer as a result of her doctor's refusal to provide her with the HPV vaccine, to a transgender individual denied hormone therapy, to a patient whose pharmacist refuses to provide prescribed HIV-preventative medication. Patients whose request for contraceptive care is denied or delayed may face the irreparable effect of unintended pregnancy. *See Pennsylvania v. Trump*, 351 F. Supp. 3d 791, 828 (E.D. Pa. 2019). Delays and denials of medical care, particularly in urgent or emergency situations, due to a single individual's refusal to participate (which may be disclosed, if at all, at the last minute) endanger patients and may cause unnecessary complications, injury, or even death. Many transgender patients require cross-hormone therapy, gender affirmation surgery and/or mental health support services—safe and effective treatments needed to help alleviate cross-gender identity issues that are not issues of choice for these individuals and cannot be reversed with psychiatric treatment. ACOG Committee Opinion No. 512, *Health Care for Transgender Individuals*, Dec. 2011, at 1. When these treatments are unavailable to transgender patients, the consequences of inadequate treatment are staggering: 54% of transgender youth have attempted suicide and 21% resort to self-mutilation. *Id*. at 2. More than 50% of persons identified as transgender have used injected hormones that were obtained illegally or used outside of conventional medical settings. *Id.*

Transgender patients need and deserve complete and respectful care and it is imperative that health care providers who are morally opposed to providing care to this population should refer them elsewhere for care. But under the Rule, they can simply decline to do so.

The harms the Rule threatens to cause are the very definition of irreparable. *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 effective medication).

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 health care provider who could provide such services. 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 . . .."). Objecting employees need not facilitate the transfer of patient care to another provider who could accommodate the patient's requests, *or even inform other staff at the relevant institution that they have refused to provide such services or a referral to the patient*. Rather, the Rule relies on health care 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 ("[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.").

The Rule improperly shifts the burden of ensuring health care continuity from health care 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 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. 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. Moreover, if the female patient proactively asks about HPV and is refused this information on the basis of a religious objection, she may be discouraged from seeking this information elsewhere. *See* Section IV.C, *infra*.

Unsurprisingly, this aspect of the Rule is also irreconcilable with medical professionals' ethical obligations. Medical professionals' "fiduciary responsibility to patients entails an obligation to support continuity of care for their patients"—*i.e.*, to ensure that when they cannot personally perform the services a patient needs, they refer the patient to another health care provider who can perform such services. AMA Code of Medical Ethics, Opinion 1.1.5. When considering withdrawing from a case, therefore, 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." *Id.* *See also id.* at 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 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"); *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.").

The disruption of the patient-provider relationship is its own form of irreparable harm. *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").

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

As noted above, the Rule permits virtually any individual employee to lodge an objection that must be accommodated, without any affirmative obligation to provide notice to his or her employer in advance, and only permitting certain employers to ask whether its employee is likely to object to certain procedures once a year absent a "persuasive justification." 84 Fed. Reg. at 23263, § 88.2. This includes any and all employees of a health care provider—from surgeons, to clerks, to laboratory technicians, to janitors. *See id*. 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 unnecessarily and unethically endangers patient health.

Many medical procedures require the participation of several, if not dozens, of individual employees.[6] This includes many employees occupying roles that do not require medical training,

[6] For example, in the context of a hysterectomy, at least twelve different employees are involved in delivering direct care to the patient, including nurses, operating room technicians, and others. Allen Decl. ¶ 23. If clerical staff and housekeepers are included in that figure, the number

such as receptionists, janitors, and security guards—all of whom are potential objectors under the Rule. 84 Fed. Reg. at 23264, § 88.2. As Plaintiffs have explained, "[i]t 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." Allen Decl. ¶ 23. "In such an instance, the procedure may not be able to be rescheduled for weeks or months," *id*., with potentially life-threatening consequences. Thus, the Rule makes patient care subject to critical disruption by objecting employees who lack the medical training necessary to understand the gravity of a patient's need for certain services.

People with complex medical needs will be particularly vulnerable to such disruption in their care. For example, individuals with disabilities face an increased risk of sexual abuse and assault as compared to the general population. *See* National Public Radio, *The Sexual Assault Epidemic No One Talks About*. Jan. 8, 2018, available at https://www.npr.org/2018/01/08/570224090/the-sexual-assault-epidemic-no-one-talks-about, (unpublished DOJ data shows "people with intellectual disabilities . . . are the victims of sexual assaults at rates more than seven times those for people without disabilities."); Disability Justice: *Sexual Abuse* (accessed June 29, 2019), available at https://disabilityjustice.org/sexual-abuse/, ("In general, people with disabilities experience domestic and sexual violence at higher rates than people who do not have a form of disability"). These individuals have a particularly strong need for reproductive care. For example, 60% of respondents to a 2005 survey of disabled individuals had been subjected to some form of unwanted sexual activity, but almost half never reported the assault. *Id*. These individuals may be unable to effectively pursue appropriate services if, for example, a clerk

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increases to at least fifteen different people. *Id*. Importantly, under the Rule, the pool of potential objectors includes those employees occupying roles that do not require medical training, such as receptionists, janitors and security guards. 84 Fed. Reg. at 23264, § 88.2. Many of these individuals are scheduled to perform services weeks or months in advance. Allen Decl. ¶ 23.

refuses to refer a patient for an abortion, or a provider declines to provide emergency contraception, particularly if they have cognitive or intellectual disabilities that may impede effective self-advocacy. *See also* Declaration of Sarah Adelman, Deputy Commissioner, New Jersey Department of Human Services, Dkt. 43, Ex. 1, ¶ 12.

C. The Rule Undermines Patient Autonomy and Informed Consent.

The protection of patient autonomy—*i.e.* the patient's ability and freedom to make decisions about his or her own health care without controlling constraints imposed by others—is at the very heart of the medical ethical standards. *See supra* at Section III; CO 385 at 3; AMA Code of Medical Ethics, Opinion 1.1.3. Patient autonomy therefore requires that patients "receive information from their physicians . . . including the risks, benefits and costs of forgoing treatment," AMA Code of Medical Ethics, 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 of Medical Ethics, Opinion 2.1.1. 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. *Id.*

The Rule subverts the principle of informed consent by limiting the information health care employees must provide to patients. Specifically, as set forth in Section IV.B, *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 health care service, program, activity, or procedure." 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. 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. As noted above, the Rule also discourages policies or practices that would require "additional action" by an objecting employee, such as policies that would require an objecting employee to inform another staff member at the relevant institution that he or she has declined to provide a patient with medical information that would permit the patient to pursue medical treatments the objector condemns. *See* 84 Fed. Reg. at 23263, § 88.2.

Without access to all the relevant medical information pertaining to their condition, or even the fact that they lack all the relevant medical information, patients cannot provide informed consent to or participate in any decision-making with respect to their care. 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, whether and when to become pregnant, or whether and how to terminate a pregnancy absent that information. This is especially concerning given the time limits that many states place on the availability of abortion. *See, e.g.*, Neb. Rev. Stat. §§ 28-3, 102 to 28-3, 111 (2019) (prohibiting abortions after 20 weeks into a pregnancy, with limited exceptions for rape, incest, and the health of the mother).

By permitting virtually any health care employee to withhold often critical medical information from patients, 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 of Medical Ethics 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 upon them new barriers to health care services.

First, the Rule will create additional hurdles to complete care for already-vulnerable populations, such as women, minorities, and LGBTQIA individuals. As set forth in Section IV.E, *infra*, the Rule imposes constraints upon medical service providers that will incentivize them to limit or eliminate altogether health care service offerings which employees may find morally or religiously objectionable. Moreover, the socioeconomic restraints faced by those who rely on federally-funded health care services will magnify the negative effect of health care provider closures on these vulnerable populations. As a result, patients in need of these services will have to overcome increased barriers to pursue them, such as driving longer distances to the nearest institution offering such services, or waiting longer to receive the care they need. These are the same patients who have the fewest viable options for health care providers, 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.

Most rural women, for example, find themselves at least a 30-minute drive from reproductive care. ACOG Committee Opinion No. 586, *Health Disparities in Rural Women*, Feb. 2014 ("CO 586"), at 2 (citing William F. Rayburn, Michael E. Richards, and Erika C. Elwell, *Drive times to hospitals with perinatal care in the United States*, 119 Obstetrics & Gynecology

611 (2012)). 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. CO 586 at 2 (noting that, in 2006, home births were higher in rural counties (0.87%) than in counties with a population size of 100,000 or more (0.50%)); *see also id.* at 1 (reporting that proportionately fewer rural women receive recommended preventive screening services for breast and cervical cancer).

Minority women are also likely to be disproportionately disadvantaged by the Rule, given that many already face significant and persistent disparities in health care as compared to the general population, including accessibility of health care. ACOG Committee Opinion No. 649, *Racial and Ethnic Disparities in Obstetrics and Gynecology*, Dec. 2015, at 1. And in 2010, there were 26 black maternal deaths for every seven white maternal deaths in California. *Id*. at 2. Healthcare refusals will have a disproportionate impact on African American women's lives.

As a result of the rule, individuals in the LGBTQIA community are likely to face even greater constraints on the already-limited pool of health care institutions offering many services they need. 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. Declaration of Dr. Rachel L. Levine, Secretary of Health for the Commonwealth of Pennsylvania and Professor of Pediatrics and Psychiatry at the Penn State College of Medicine, Dkt. 43, Ex. 28, ¶ 31. When narrowed to LGBTQIA individuals living in non-metropolitan areas, 41% said it would be very difficult or impossible to find a replacement provider of such services. *Id*.

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 likely to have life-long repercussions for those populations.[7] For example, a patient who seeks Post-exposure Prophylaxis—a medication that can prevent the contraction of HIV either before or after coming into contact with the virus—but is turned away by a clinic employee who objects to his or her gender identity or expression is likely to feel stigmatized and be discouraged from seeking the medication from another provider, let alone within the window of time during which it would be effective. *See* Declaration of Dr. Adena Greenbaum, Assistant Commissioner, Bureau of Clinical Services, Baltimore City Health Department, Dkt. 43, Ex. 21. Moreover, this individual would be unlikely to seek other HIV-related medications or contraceptive devices, even from other health care providers, for fear of discrimination. *See id.*

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

That the Rule is baldly irreconcilable with several core principles of medical ethics is clear. Remarkably unclear, however, are the directives in the Rule that 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 health care service providers with adequate guidance as to what conduct is prohibited and encourages arbitrary enforcement. Absent clear guidance, providers are left to parse the Rule's ambiguous language under threat of draconian penalties, erecting yet one more barrier to complete medical care.

Among the many problematic ambiguities addressed by Plaintiffs, *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

[7] 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).

"noncompliant entities," without any specification as to the limit of this regulation. 83 Fed. Reg. 3880, 3898 (Jan. 26, 2018). When combined with the draconian penalties for noncompliance—which include cutting off or clawing back all federal funding, including funding unrelated to the area in which the alleged discrimination occurred[8]—health care 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.

In addition to disrupting the effective functioning of health care systems, the changes to policies, scheduling, and personnel management practices the Rule imposes will result in financial expenditures that amount to irreparable harm. *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 grant Plaintiffs' cross-motion for summary judgment and hold the Rule to be invalid, or in the alternative, enjoin the Rule before it goes into effect. For the reasons explained above and outlined more fully in the Plaintiffs' briefs, 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

[8] 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 23271-72, § 88.7(i) (remedies for noncompliance with the Rule include withholding, denying, or terminating existing federal funding; denying or withholding new federal funding; and suspending award activities).

relationship and will compromise patient health and safety for the personal views and beliefs of an individual provider.

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Respectfully submitted,

/s/ Shannon Rose Selden
Shannon Rose Selden
DEBEVOISE & PLIMPTON LLP
919 Third Avenue
New York, NY 10022
(212) 909-6000
srselden@debevoise.com

Anna A. Moody
DEBEVOISE & PLIMPTON LLP
801 Pennsylvania Ave, NW
Washington, D.C. 20004
(202) 383-8000
amoody@debevoise.com

Counsel for Amici Curiae