EXHIBIT 40



March 27, 2018

Submitted electronically

Department of Health and Human Services Office for Civil Rights Hubert H. Humphrey Building, Room 509F 200 Independent Avenue SW Washington, DC 20201

Attn: Conscience NPRM, RIN 0945-ZA03

Re: Proposed New 45 CFR Part 88 Regarding Refusals of Medical Care

The New York Civil Liberties Union submits these comments on the proposed rule published at 83 FR 3880 (January 28, 2018), RIN 0945-ZA03, with the title "Ensuring that the Department of Health and Human Services [the "Department"] Does Not Fund or Administer Programs or Activities that Violate Conscience and Associated Anti-Discrimination Laws" (the "Proposed Rule" or "Rule").

The New York Civil Liberties Union (NYCLU), a nonprofit, nonpartisan organization with eight chapters, regional offices, and more than 200,000 members and supporters across the state, works to defend and promote the fundamental principles, rights and constitutional values embodied in the Bill of Rights of the U.S. Constitution and the Constitution of the State of New York. The NYCLU has a long history of vigorously defending religious liberty. We are equally vigilant in our efforts to safeguard reproductive rights and to end discrimination against those who have historically been excluded or diminished by more powerful actors in society, including in health care settings. The Proposed Rule implicates a host of health care services, including reproductive health services, end-of-life care, HIV/AIDS counseling and treatment, reproductive technology and fertility treatments, and post-sexual assault care. The NYCLU is particularly well-positioned to comment on the Proposed Rule and the serious concerns it raises about access to reproductive and other health care, based on the religious or other beliefs of institutions or individual providers. We steadfastly protect the right to religious freedom. But that right does not include a right to harm others as this Proposed Rule contemplates.

The NYCLU strongly advocates solutions that balance the protection of public health, patient autonomy, and gender equality with the protection of individual religious belief and institutional religious worship. To achieve this balance, we believe it is often possible to

accommodate an individual health care professional's religiously-based refusal to provide a particular health service so long as the professional takes steps to ensure that the patient can receive that service elsewhere. However, because health care providers serve patients and customers of all faiths and backgrounds, a provider's wholesale refusal to provide services poses a much greater risk of harm to those who do not share in those religious beliefs and should not be allowed to trump all other important societal interests.

The proposed regulation threatens to upset the careful balance between the religious freedom of health care providers and patients' ability to access health care services—a balance that has been carefully struck in both New York State and federal law. Since the founding of our Nation, freedom of religion has been one of our most highly prized liberties, and protections for that freedom are enshrined in both the United States and New York State Constitutions. Congress, as well as the state legislatures, have enacted numerous laws to add force to those protections. Both Title VII of the 1964 Civil Rights Act and the New York State Human Rights Law currently protect against discrimination on the basis of religion and in employment.¹ However, in codifying and applying these laws, courts and legislatures have been careful to ensure that in protecting religious liberty, other fundamental rights and freedoms are not unduly burdened. The proposed regulation fails to take the same precautions. New York State, in particular, has a history of balancing these sometimes competing interests to ensure seamless delivery of health care and protect individuals' religious liberty rights. Indeed, the New York Civil Rights Law prevents discrimination against individuals who refuse to perform abortions as against their religious beliefs.² Even in the insurance context, New York has created explicit carve outs for religious employers who wish to exclude contraception or abortion from their employees' health plan.³ These laws represent important steps toward ending gender discrimination, ensuring access to health care that meets the standard of care, as well as ensuring religious objectors have the opportunity to honor their private beliefs.

Without any regulatory authority, the Department has proposed a rule that vastly expands narrow statutory sections in ways Congress never intended, in a manner unsupportable by the terms of the statutes, and in a way that upsets the careful balance struck by other federal laws, all in an effort to grant health care providers unprecedented license to refuse to provide care and information to patients. In so doing, the Proposed Rule does not mention, much less grapple with, the consequences of refusals to provide full information and necessary health care to patients. The denials that the Rule proposes to protect will have significant consequences for individuals in terms of their health and well-being, in addition to financial costs. And, because the Proposed Rule is tied to entities that receive federal funding, those consequences will fall most heavily on poor and low-income people who must rely on government-supported programs and institutions for their care and who will have few, if any, other options if they are denied appropriate care. The Proposed Rule amounts to a license to discriminate, made all the worse because the federal purse will be used to further that discrimination.

¹ 42 U.S.C. § 2000e et seq. (2008); N.Y. Executive Law § 296.

² N.Y. Civil Rights Law 79-i.

³ E.g., N.Y. Ins. Law § 3221(l)(16), 4303(cc) (the New York Women's Health and Wellness Act contains an exemption from a contraceptive insurance coverage requirement for religious employers).

The Proposed Rule is not only extremely detrimental to patient health, it is also entirely unnecessary. Individual providers' religious and moral beliefs are already strongly protected by federal and state law that, among other things, forbids religious discrimination and requires employers to provide reasonable accommodation of an employee's religious objections.

Because the Proposed Rule harms patient health, encourages discrimination against patients, and exceeds the Department's rulemaking authority, it should be withdrawn. If the Department refuses to do so, it must, at a minimum, revise the Proposed Rule so that it aligns with the statutory provisions it purports to implement, makes clear that it is not intended to conflict with or preempt other state or federal laws that protect and expand access to health care, and mitigates the Rule's harm to patients' health and well-being.

1. The Proposed Rule Ignores Its Impact on Patients' Health and Invites Harms That Will Disproportionately Fall on Women and Marginalized Populations

The Proposed Rule seeks to immunize refusals of health care, yet utterly fails to consider the harmful impact it would have on patients' health. But this failure to address the obvious consequences of giving federally subsidized providers *carte blanche* to decide whom to treat or not treat based on religious or moral convictions—or indeed, based on any reasoning or none at all⁴—does not mean the harm does not exist. In fact, the harms would be substantial. For example, the Proposed Rule:

- Appears to provide immunities for health care institutions that receive federal funding and professionals who work in federally funded programs to refuse to provide complete information to patients about their condition and treatment options;
- Purports to create new "exemptions," so that patients who rely on federally subsidized health care programs, such as Title X, may be unable to obtain services those programs are required by law to provide;
- Causes confusion about whether hospitals can prevent staff from providing emergency care to pregnant women who are suffering miscarriages or otherwise need emergency abortion care; and
- Invites health care providers to discriminate against individuals based on who they are, for example, by refusing to provide otherwise available services to a patient for the sole reason that the patient is transgender or by refusing to provide medical services to the children of a same sex couple or by refusing care for patients living with HIV, including the option of pre-exposure prophylaxis (PrEP) for those people who are in a sexual relationship with an HIV-positive partner.

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⁴ Although the Notice of Proposed Rulemaking highlights religious freedom and rights of conscience, a number of the referenced statutes—and the proposed expansions of those in the Rule—do not turn on the existence of any religious or moral justification. The Proposed Rule would empower not only those acting based on conscience, but others acting, for example, out of bare animus toward a patient's desired care or any aspect of their identity.

 Permits health care providers to refuse to honor the advance health care directives of patients who choose a DNR/DNI order or who refuse artificial nutrition or other lifesustaining medical treatment.

These harms would fall most heavily on historically disadvantaged groups and those with limited economic resources. As the ACLU and NYCLU's own cases and requests for assistance reflect, women, LGBT (lesbian, gay, bisexual and transgender) individuals, people of color, immigrants, young people, and members of other groups who continue to struggle for equal rights are those who most often experience refusals of care. Likewise, poor and low-income people will also suffer acutely under the Proposed Rule. They are more likely to rely on health care that is in some manner tied to federal funding, and less likely to have other options at their disposal if they are denied access to care or information. Because it will limit access to health care, harm patients' outcomes, and undermine the central, public health mission of the Department, the Proposed Rule should be withdrawn.

2. The Department Lacks the Authority to Issue the Proposed Rule

The Proposed Rule references the Church Amendments, 42 U.S.C. § 300a-7, the Coats-Snowe Amendment, 42 U.S.C. § 238n, the Weldon Amendment, Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, Tit. V, § 507(d), and other similar "protections" or "exemptions," *see* 83 FR 3880, that sometimes allow, under narrow circumstances, health care professionals to avoid providing certain medical procedures or that limit the actions that may be taken against them if they refuse to provide care (collectively, the "Refusal Statutes"). The Preamble to the Rule focuses most extensively on the Church, Coats, and Weldon Amendments (the "Amendments"), and the Rule itself purports to establish extraordinarily expansive new substantive requirements, compliance steps, and enforcement authority under them.

But the Department does not possess *any* legislative rulemaking powers under those Amendments and wholly lacks the authority to promulgate the Proposed Rule as it applies to them. None of those Amendments includes, or references, any explicit delegation of regulatory authority. *Compare*, *e.g.*, 42 U.S.C. § 2000d-1 (expressly directing all relevant federal agencies to issue "rules, regulations, or orders of general applicability" to achieve the objectives of Title VI). Nor does any implicit delegation of legislative rulemaking authority exist for these provisions. For this reason alone, the Department cannot properly proceed to adopt the Proposed Rule or any similar variation of it.

3. The Proposed Rule Impermissibly Expands the Narrow Referenced Statutes and Does So In Ways That Ignore The Statutes' Limited Terms and Purposes

Even if the Department had the necessary rulemaking authority (which it does not), the Proposed Rule's virtually unbounded definition of certain terms and expansions of the Refusal Statutes' reach would broaden the Refusal Statutes beyond reason and recognition, create conflict with federal law, and lead to denials of appropriate care to patients. While we do not attempt to catalogue each way in which the Proposed Rule impermissibly expands the Refusal Statutes, a few examples follow.

A. Assist in the Performance

For example, Subsection (c)(1) of the Church Amendments prohibits recipients of certain federal funds from engaging in employment discrimination against health care providers who have objected to performing or "assist[ing] in the performance of" an abortion or sterilization. 42 U.S.C. § 300a-7(c)(1). Under the Proposed Rule, however, the Department defines "assist in the performance" of an abortion or sterilization to include not only assistance in the performance of those actual procedures – the ordinary meaning of the phrase – but also to participation in any other activity with "an articulable connection to a procedure[.]" 83 FD 8892, 3923. Through this expanded definition, the Department explicitly aims to include activities beyond "direct involvement with a procedure" and to provide "broad protection"—despite the fact that the statutory references are limited to "assistance in the performance of" an abortion or sterilization procedure itself. 83 FR 3892; cf. e.g., 42 U.S.C. § 300a-7(c)(1).

This means, for example, that simply admitting a patient to a health care facility, filing her chart, transporting her from one part of the facility to another, or even taking her temperature could conceivably be considered "assist[ing] in the performance" of an abortion or sterilization, as any of those activities could have an "articulable connection" to the procedure. As described more fully below, the Proposed Rule could even be cited by health care providers who withhold basic information from patients seeking information about abortion or sterilization on the grounds that "assist[ing] in the performance" of a procedure "includes but is not limited to counseling, referral, training, and other arrangements for the procedure." 83 FR 3892, 3923.

But the term "assist in the performance" simply does not have the virtually limitless meaning the Department proposes ascribing to it. The Department has no basis for declaring that Congress meant anything beyond actually "assist[ing] in the performance of" the specified procedure—given that it used that phrasing, 42 U.S.C. §§ 300a-7(c)(1)—and instead meant any activity with any connection that can be articulated, regardless of how attenuated the claimed connection, how distant in time, or how non-procedure-specific the activity.

B. Referral or Refer for

Others of the Refusal Statutes provide limited protections to certain health care entities and individuals that refuse to, among other things, "refer for" abortions. For those statutes, the Proposed Rule expands "referral or refer for" beyond recognition, by proposing to define a referral as "the provision of *any* information ... by any method ... pertaining to a health care service, activity, or procedure ... that could provide *any assistance* in a person obtaining, assisting, ... financing, or performing" it, where the entity (including a person) doing so "sincerely understands" the service, activity, or procedure to be a "possible outcome[.]" 83 FR 3894-95 (emphasis added), 3924. This wholesale re-definition of the concept of "referral" could have dire consequences for patients. For example, a hospital that prohibits its doctors from even discussing abortion as a treatment option for certain serious medical conditions could attempt to claim that the Rule protects this withholding of critical information because the hospital "sincerely understands" the provision of this information to the patient may provide some assistance to the patient in obtaining an abortion.

Providing a green light for the refusal to provide information that patients need to make informed decisions about their medical care not only violates basic medical ethics, but also far exceeds Congress's language and intent. A referral—as used in common parlance and the underlying statutes—has a far more limited meaning than providing *any* information that *could* provide *any assistance whatsoever* to a person who may ultimately decide to obtain, assist, finance, or perform a given procedure sometime in the future. The meaning of "referral or refer for" in the health care context is to *direct* a patient elsewhere for care. *See* Merriam-Webster, https//www.merriam-webster.com/dictionary/referral ("referral" is "the process of directing or redirecting (as a medical case or a patient) to an appropriate specialist or agency for definitive treatment").

C. Discriminate or Discrimination

These expansive definitions are all the more troubling given the Proposed Rule's definition of "discrimination," which purports to provide unlimited immunity for institutions that receive some federal funds to deny abortion care, to block coverage for such care, or to stop patients' access to information, no matter what the patients' circumstances or the mandates of state or federal law. Likewise, the definition appears aimed at providing immunity for employees who refuse to perform central parts of their job, regardless of the impact on the ability of a health care entity to provide appropriate care to its patients. This expansion of "discrimination" would apparently treat virtually any adverse action – including government enforcement of a patient non-discrimination or access-to-care law – against a health care facility or individual as *per se* discrimination. But "discrimination" does not mean any negative action, and instead requires an assessment of context and justification, with the claimant showing unequal treatment on prohibited grounds under the operative circumstances. The Proposed Rule abandons, for example, the nuanced and balanced approach required by Title VII, and also ignores other federal laws, state laws, and providers' ethical obligations to their patients. *See infra* Parts 4-6.

D. Other Expansions of the Scope of the Refusal Statutes

The Proposed Rule not only distorts the definitions of words in the statutes, but also alters the statutes' substantive provisions in other ways to attempt to expand the ability of individuals and entities to deny care in contravention of legal and ethical requirements and to the severe detriment of patients. Again, these comments do not attempt to exhaustively catalogue all of the unauthorized expansions but instead provide a few illustrative examples.

For example, Congress enacted Subsection (d) of the Church Amendment in 1974 as part of Public Law 93-348, a law that addressed biomedical and behavioral research, and appended that new Subsection (d) to the pre-existing subsections of Church from 1973, which all are codified within 42 U.S.C. § 300a-7: the "Sterilization or Abortion" section within the code subchapter that relates to "Population Research and Voluntary Family Planning Programs." Despite this explicit context for Subsection (d), and Congress' intent that it apply narrowly, however, the Proposed Rule attempts to import into this Subsection an unduly broad definition of "health service program," along with the expansive definitions discussed above, to purportedly transform it into a much more general prohibition that would apply to any programs or services administered by the Department, and that would assertedly prevent any entity that receives

federal funding through those programs or services from requiring individuals to perform or assist in the performance of actions contrary to their religious beliefs or moral convictions. *See* 83 FR 3894, 3906, 3925. This erroneous expansion of Church (d), as described in this attempted rule-making, could prevent health care institutions from ensuring that their employees provide appropriate care and information. It would purportedly prevent institutions taking action against members of their workforce who refuse to provide any information or care that they "sincerely understand" may have an "articulable connection" to some eventual procedure to which they object—no matter what medical ethics, their job requirements, Title VII or laws directly protecting patient access to care may require.

The Rule similarly attempts to expand the Coats Amendment beyond its limited provisions, which apply to certain "governmental activities regarding training and licensing of physicians," 42 U.S.C. § 238n (quoting title), to apply regardless of context. Thus, rather than being confined to residency training programs as Congress intended, the Proposed Rule purports to give all manner of health care entities, including insurance companies and hospitals, a broad right to refuse to provide abortion and abortion-related care. In addition, the Rule's expansion of the terms "referral" and "make arrangements for" extends the Coats Amendment to shield any conduct that would provide "any information ... by any method ... that could provide any assistance in a person obtaining, assisting, ... financing, or performing" an abortion or that "render[s] aid to anyone else reasonably likely" to make an abortion referral. 83 FR 3894-95 (emphasis added), 3924. This expansive interpretation not only goes far beyond congressional intent and the terms of the statute, it also could have extremely detrimental effects on patient health. For example, it would apparently shield, against any state or federal government penalties, a women's health center that required any obstetrician-gynecologist practicing there who diagnosed a pregnant patient as having a serious uterine health condition to refuse to provide her with even the name of an appropriate specialist, because that specialist "is reasonably likely" to provide the patient with information about abortion.

Similarly, as written, the Weldon Amendment is no more than a bar on particular appropriated funds flowing to a "Federal agency or program, or State or local government," if any of those government institutions discriminate on the basis that a health care entity does not provide, pay for, provide coverage of, or refer for abortion. Pub. L. No. 115-31, Div. H, Tit. V, § 507(d)(1). Yet again, however, the Proposed Rule attempts to vastly increase its reach by (i) expanding the scope of the federal funding streams to which the Weldon Amendment prohibition reaches and (ii) binding "any entity" that receives such funding—not just the government entities listed in the Amendment—to its proscriptions. 83 FR 3925. These unauthorized expansions, combined with the expansive definitions discussed *supra*, can lead to broad and harmful denials of care. For example, under this unduly expansive interpretation of Weldon, an organization that refuses to discuss the option of abortion with people who discover they are pregnant may claim a right to participate in the Title X program, despite the fact that both federal law and medical ethics require that Title X patients be provided with counseling about all of their options. *See*, *e.g.*, 42 C.F.R. § 59.5(a)(5).

The Department should withdraw the Rule to prevent it from impeding health care and harming patients. But if it does not do so, each of the definitions must be clarified and revert to

the terms' proper meaning, and each of the substantive requirements should track only those provisions actually found in the Refusal Statutes themselves.

4. The Rule Undermines Legal and Ethical Requirements of Fully Informed Consent

The Proposed Rule appears to allow institutional and individual health care providers to manipulate and distort provider-patient communications and deprive patients of critical health care information about their condition and treatment options. While the Proposed Rule's Preamble suggests the Rule will improve physician-patient communication because it will purportedly "assist patients in seeking counselors and other health-care providers who share their deepest held convictions," 83 FR 3916-17, the notion that empowering health care providers to deny care to and withhold information from some patients is somehow necessary to enable other patients to identify like-minded providers strains credulity: Patients are already free to inquire about their providers' views and patients' own expressions of faith and decisions based on that faith must already be honored. *Cf. id.* Allowing *providers* to decide what information to share—or not share—with patients, regardless of the patient's needs or the requirements of informed consent and professional ethics would gravely harm trust and open communication in health care, rather than aiding it.

New York State Public Health Law requires physicians to obtain informed consent before provision of any procedure, and defines informed consent as including advice as to the foreseeable risks and benefits of a proposed treatment, as well as any alternatives. And, as the American Medical Association's Code of Medical Ethics ("AMA Code") explains, the relationship between patient and physician "gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own self-interest[.]" AMA Code § 1.1.1. Even in instances where a provider's beliefs are opposed to a particular course of action, the provider must "[u]phold standards of informed consent and inform the patient about all relevant options for treatment, including options to which the physician morally objects." *Id.* § 1.1.7(e).

By erroneously expanding the meaning of "assist in the performance of," "refer for" and "make arrangements for," as described above, however, the Proposed Rule purports to allow health care providers to refuse to provide basic information to patients in ways that were never contemplated by the underlying statutes. As described above, these broad definitions may be used to immunize the denial of basic information about a patient's condition as well as her treatment options.

Withholding this vital information from patients violates fundamental legal and ethical principles, deprives patients of the ability to make informed decisions, and leads to negligent care. If the Department moves forward with the Proposed Rule, it should, among other necessary changes, modify it to make clear that it does not subvert basic principles of medical ethics and does not protect withholding information from a patient about her condition or treatment options.

5. By Failing to Acknowledge Other Federal Laws, the Proposed Rule Will Lead to Confusion, Denials for Care, and Harm to Patients

⁵ See N.Y. Public Health Law § 2805(d).

A. Title VII

The Proposed Rule is not only unauthorized and harmful to patients, it is also unnecessary to accommodate individual workers—federal law already amply protects individuals' religious freedom in the workplace. For more than four decades, Title VII has required employers to make reasonable accommodations for current and prospective employers' religious beliefs so long as doing so does not pose an "undue hardship" to the employer. 42 U.S.C. §§ 2000e(j), 2000e-(2)(a); *Trans World Airlines, Inc. v. Hardison*, 432 U.S. 63, 84 (1977); EEOC Guidelines, 29 C.F.R. § 1605.2(e)(1).⁶ Thus, Title VII—while protecting freedom of religion—establishes an essential balance. It recognizes that an employer cannot subject an employee to less favorable treatment because of that individual's religion and that generally an employer must accommodate an employee's religious practices. However, it does not require accommodation when the employee objects to performing core job functions, particularly when those objections harm patients, depart from the standard of care, or otherwise constitute an undue hardship. *Id.* This careful balance between the needs of employees, patients, and employers is critical to ensuring that religious beliefs are respected while at the same time health care employers are able to provide quality health care to their patients.

The New York State Human Rights and Civil Rights laws similarly afford protection against religious discrimination by employers, including on the grounds that a health care provider refuses to provide abortion. However, the New York courts have also applied a balancing test, and have stopped short of requiring employers to offer accommodations that would impede their mission or interfere with their ability to conduct business. In the health care context, this has meant that employers whose mission is providing health care to the public have not been required to accommodate the religious beliefs of their employees if the accommodation sought would impede their ability to serve patients promptly and respectfully.

⁶ Religion for purposes of Title VII includes not only theistic beliefs, but also non-theistic "moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views." Equal Employment Opportunity Commission ("EEOC") Guidelines, 29 C.F.R. §1605.1.

⁷ See N.Y. Executive Law § 296; N.Y. Civil Rights Law § 79-I; Larson v. Albany Med. Ctr., 252 A.D.2d 936 (N.Y. App. Div., 3d Dep't 1998).

⁸ See Eastern Greyhound Lines v. New York State Div. of Human Rights, 27 N.Y.2d 279, 284 (1970) (holding uniformly applied policy requiring all employees to be clean-shaven was not an unlawful discriminatory practice as applied to a Muslim employee whose religion required him to have a beard); Harmon v. General Electric Co., 72 A.D.2d 903, 904 (N.Y. App. Div., 3d Dep't 1979) (finding termination of employee who refused to continue working in employer's machinery apparatus operation based on pacifist views, which are part of his Catholic faith, was not an unlawful discriminatory practice). While the NYCLU may not agree with the outcome in each of these cases, we cite them merely to illustrate that the courts have adopted a balancing test that appears to be completely absent from the proposed regulation's terms.

⁹ See Shelton v. Univ. of Med. & Dentistry of N.J., 223 F.3d 220, 228 (3d Cir. 2000) (finding hospital's offer to move nurse who objected to performance of abortions from labor and delivery to infant ICU constituted reasonable accommodation of religious beliefs); Noesen v. Med. Staffing Network, Inc., 232 Fed. Appx. 581, 584, 2007 WL 1302118, at *3 (7th Cir. 2007) (finding that pharmacy was not required to offer accommodation to pharmacist who objected to provision of birth control removing him from all contact with patients because such accommodation would pose undue hardship on employer); Grant v. Fairview Hosp. and Healthcare Servs., 2004 WL 326694, at *5 (D. Minn. 2004) (holding hospital had offered reasonable accommodation to ultrasound technician who disapproved of abortion by taking steps to avoid him coming into contact with patients contemplating abortion, but that it was not required to permit him to provide pastoral counseling to all pregnant patients receiving ultrasounds).

Despite this long-standing balance and the lack of any evidence that Congress intended the Refusal Statutes to disrupt it, the Proposed Rule does not even mention these basic federal or New York State legal standards or the need to ensure patient needs are met. Instead, by presenting a seemingly unqualified definition of what constitutes "discrimination," 83 FR 3892-93, 3923-24, and expansive refusal rights, the Department appears to attempt to provide complete immunity for religious refusals in the workplace, no matter how significantly those refusals undermine patient care, informed consent, or the essential work of institutions established for the purpose of promoting health. Indeed, the Rule is explicit in seeking not simply a "level playing field" and reasonable accommodation, but rather an unlimited ability for individuals to "be[] free not to act contrary to one's beliefs," regardless of the harm it causes others and without any repercussions. Id. Such an interpretation could have a drastic impact on the nation's safety-net providers' ability to provide high quality care by requiring, for example, a family planning provider to hire a counselor to provide pregnancy options counseling even if the counselor refuses to comply with ethical and legal obligations to inform patients of the availability of abortion. If the Department does not withdraw the entire Rule, therefore, it should explicitly limit its reach and make clear that Title VII provides the governing standard for employment situations.

B. EMTALA

The Proposed Rule also puts patients at risk by ignoring the federal Emergency Medical Treatment and Labor Act ("EMTALA") and hospitals' obligations to care for patients in an emergency. As Congress has recognized, a refusal to treat patients facing an emergency puts their health and, in some cases, their lives at serious risk. Through EMTALA, Congress has required hospitals with an emergency room to provide stabilizing treatment to any individual experiencing an emergency medical condition or to provide a medically beneficial transfer. 42 U.S.C. § 1395dd(a)-(c). New York also has many protections in place to ensure medical care for patients in need, such as professional misconduct laws prohibiting abandonment of a patient in need of care, ¹⁰ and state laws requiring emergency treatment for patients at hospital emergency rooms. ¹¹ The proposed rule casts doubt on the State's continued authority to enforce such provisions.

The Refusal Statutes do not override the requirements of EMTALA or similar state laws, such as EMSRA, that require health care providers to provide abortion care to a woman facing an emergency. *See, e.g., California v. U.S.*, Civ. No. 05-00328, 2008 WL 744840, at *4 (N.D. Cal. March 18, 2008) (rejecting notion "[t]hat enforcing [a state law requiring emergency departments to provide emergency care] or the EMTALA to require medical treatment for emergency medical conditions would be considered 'discrimination' under the Weldon Amendment if the required medical treatment was abortion related services").

It is particularly troubling, therefore, to have the Department use attempts to require hospitals to comply with their obligations under EMTALA in its Preamble as *justification* for

¹⁰ See 8 NYCRR § 29.2 (2008) (including abandoning patient in need of care in definition of professional misconduct for medical professionals).

¹¹ See New York State Emergency Medical Services Reform Act (EMSRA), N.Y. Public Health Law §2805-b; 10 NYCRR Part 800.

expanding the Refusal Statutes. 83 FR 3888-89. For example, the Preamble discusses the case brought by the ACLU on behalf of Tamesha Means who at 18 weeks of pregnancy began to miscarry and sought care, not once but three times, at her local hospital. 83 FR 3888-89. Despite the fact that she was bleeding, in severe pain, and had developed a serious infection, the hospital repeatedly sent her away and never told her that her health was at risk and that having an abortion was the safest course for her. *See* Health Care Denied 9-10 (May 2016), *available at* https://www.aclu.org/report/report-health-care-denied?redirect=report/health-care-denied. But the ethical imperative is the opposite: "In an emergency in which referral is not possible or might negatively affect a patient's physical or mental health, providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections." 83 FR 3888 (quoting American Congress of Obstetricians and Gynecologists ("ACOG") Committee Opinion No. 365) (reaffirmed 2016).

The Proposed Rule suggests that hospitals like the one who put Ms. Means' health at risk should be given a free pass. Yet doing so would not only violate EMTALA, but also other legal, professional, and ethical principles governing access to health care in this country. For that reason, if not withdrawn in its entirety, the Proposed Rule should, at minimum, clarify that it does not disturb health care providers' obligations to provide appropriate care in an emergency.

C. Section 1557

The Proposed Rule also puts patients at risk by ignoring the federal Patient Protection and Affordable Care Act ("ACA"), which explicitly confers on patients the right to receive nondiscriminatory health care in any health program or activity that receives federal funding. 42 U.S.C. § 18116. Incorporating the prohibited grounds for discrimination described in other federal civil rights laws, the ACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability. *Id.* at § 18116(a).

The Refusal Statutes must be read to coexist with the statutory nondiscrimination requirements of the ACA and similar state nondiscrimination laws. If a nondiscrimination requirement has any meaning in the healthcare context, it must mean that a patient cannot be refused care simply because of her race, color, national origin, sex, age, or disability. And as courts have recognized, the prohibition on sex discrimination under the federal civil rights statutes should be interpreted to prohibit discrimination against transgender people. See Whitaker by Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ., 858 F.3d 1034, 1049-50 (7th Cir. 2017) (discrimination against transgender students violates Title IX, which is the basis for the ACA's prohibition on sex discrimination);); see also EEOC v. R.G. & G.R. Funeral Homes, Inc., 2018 WL 1177669 at *5-12 (6th Cir. Mar. 7, 2018) (Title VII). Notwithstanding these protections, as well as explicit statutory protections from discrimination based on gender identity and sexual orientation in many states (as discussed below), the Proposed Rule invites providers to discriminate against LGBT patients, particularly transgender people.

6. The Rule Also Appears Aimed at Pre-Empting State Laws That Expand Access to Health Care or Otherwise Immunizing Violations of State Law

The Proposed Rule creates even more concern with regard to its intended effect on state law. The Preamble devotes extensive discussion to "Recently Enacted State and Local health Government Health Care Laws" that have triggered some litigation by "conscientious objectors," 83 FR 3888, characterizing those disputes as part of the rationale for the Rule. Although the Department states it "has not opined on or judged the legal merits of any of the" catalogued state and local laws, it uses these laws "to illustrate the need for clarity" concerning the Refusal Statutes that are the subject of the Proposed Rule. 83 FR 3889.

But no clarity, only more questions ensue, because the Proposed Rule does not explain how its requirements interact with state and local law (nor does it provide any statutory authority on which those requirements rest under federal law, as discussed above). The Rule's expansion of definitions, covered entities, and enforcement mechanisms appears to impermissibly invite institutions and individuals to violate state law, and to attempt somehow to inhibit states from enforcing their own laws that require institutions to provide care, coverage, or even just information. The Proposed Rule also includes a troubling preemption provision, which specifies only that state and local laws that are "equally or more protective of religious freedom" should be saved from preemption, 83 FR 3931, and ignores the importance of maintaining the protection of other state laws, such as laws mandating non-discrimination in the provision of health care or requiring that state funding be available for certain procedures.

Thus, the Proposed Regulation and its treatment of state and local laws puts at risk provisions of New York State and local laws that prohibit medical facilities and providers from discriminating against anyone on the basis of certain characteristics, such as race, sex, sexual orientation, marital status or disability. 12

The Rule, if it survives in any fashion, should clarify that it creates no new preemption of state or local laws. That is because any preemption must be limited to that which already existed, if any, by virtue of the extremely limited, pre-existing Refusal Statutes. These regulations cannot create some new gutting of state and local mandates.

7. The Rule Would Violate the Establishment Clause Because It Forces Unwilling Third Parties to Bear Serious Harms From Others' Religious Exercise

The Proposed Rule imposes the significant harms on patients identified above in service of institutional and individual religious objectors. It purports to mandate that their religious choices take precedence over providing medical information and health care to patients. But the First Amendment forbids government action that favors the free exercise of religion to the point of forcing unwilling third parties to bear the burdens and costs of someone else's faith. As the Supreme Court has emphasized, "[t]he principle that government may accommodate the free exercise of religion does not supersede the fundamental limitation imposed by the Establishment Clause." *Lee v. Weisman*, 505 U.S. 577, 587 (1992); *accord Bd. of Educ. of Kiryas Joel Village School Dist. v. Grumet*, 512 U.S. 687, 706 (1994) ("accommodation is not a principle without limits").

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¹² See e.g. N.Y. Human Rights Law, N.Y. Executive Law Article 15, § 290 et seq. and N.Y.C. Human Rights Law, N.Y.C. Admin. Code Title 8, § 8-801 et seq..

Because the Rule attempts to license serious patient harms in the name of shielding others' religious conduct, it is incompatible with our longstanding constitutional commitment to separation of church and state. *See Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 708-10 (1985) (rejecting, as Establishment Clause violation, law that freed religious workers from Sabbath duties, because the law imposed substantial harms on other employees); *see also Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 14, 18 n.8 (1989) (plurality opinion) (invalidating sales tax exemption for religious periodicals, in part because the exemption "burden[e]d nonbeneficiaries markedly" by increasing their tax bills). The Department should withdraw the Rule to avoid its violation of the Establishment Clause.

8. The Rule Unnecessarily Expands Compliance Tools, Without Clear Due Process Protections, and Risks Overzealous Enforcement That Would Harm Patient Care

Finally, the Department provides no evidence that existing enforcement mechanisms are insufficient to educate providers, investigate and conduct compliance reviews, and address any meritorious complaints under the Refusal Statutes. Yet the Department itself, in a woefully inadequate and low estimation, concedes that at least hundreds of millions of dollars will be spent by health care providers to attempt to comply with the new requirements the Proposed Rule purports to create. Moreover, the Rule proposes ongoing reporting requirements for five years after any investigation of a complaint or compliance review, regardless of its outcome; purports to empower the Department to revoke federal funding before any opportunity for voluntary compliance occurs; allows punishment of grantees for acts, no matter how independent, of sub-recipients; and lacks clarity as to any procedural protections that a grantee may have in contesting enforcement actions. If the entire Rule is not withdrawn, its enforcement powers and obligations should be substantially scaled back, and full due process protections should clearly be identified and provided if any funding impact is threatened, *see*, *e.g.*, 45 C.F.R. §§ 80.8-80.10 (Title VI due process protections).

The Rule contemplates an enormous outlay of funds to implement a complex, extreme compliance scheme that will only serve to divert funds away from the provision of high-quality health care to those who need it most.

* * *

For all these reasons, the Department should withdraw the Proposed Rule. If it fails to do

so, it must substantially modify the Proposed Rule so as, at a minimum, not to exceed the terms of and congressional intent behind the underlying statutes.

Sincerely,

Katharine Bodde Senior Policy Counsel

Beth Haroules

Senior Staff Attorney

Fer Haires

EXHIBIT 41



JAMES L. MADARA, MD

EXECUTIVE VICE PRESIDENT, CEO

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March 27, 2018

The Honorable Alex M. Azar, II Secretary U.S. Department of Health & Human Services Hubert H. Humphrey Building 200 Independence Avenue, SW Washington, DC 20201

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (RIN 0945-ZA03), 83 Fed. Reg. 3880 (January 26, 2018)

Dear Secretary Azar:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to provide comments to the Department of Health and Human Services (HHS) in response to the Notice of Proposed Rulemaking (Proposed Rule or Proposal) on "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," issued by the Office of Civil Rights (OCR). In its Proposed Rule, OCR proposes to revise existing regulations and create new regulations to interpret and enforce more than 20 federal statutory provisions related to conscience and religious freedom. Under OCR's broad interpretation of these provisions, individuals, health care organizations, and other entities would be allowed to refuse to provide or participate in medical treatment, services, information, and referrals to which they have religious or moral objections. This would include services related to abortion, contraception (including sterilization), vaccination, end-of-life care, mental health, and global health support, and could include health care services provided to patients who are lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ).

For the reasons discussed below, the AMA believes the Proposed Rule would undermine patients' access to medical care and information, impose barriers to physicians' and health care institutions' ability to provide treatment, impede advances in biomedical research, and create confusion and uncertainty among physicians, other health care professionals, and health care institutions about their legal and ethical obligations to treat patients. We are very concerned that the Proposed Rule would legitimize discrimination against vulnerable patients and in fact create a right to refuse to provide certain treatments or services. Given our concerns, we urge HHS to withdraw this Proposal.

The AMA supports conscience protections for physicians and other health professional personnel. We believe that no physician or other professional personnel should be required to perform an act that violates good medical judgment, and no physician, hospital, or hospital personnel should be required to perform any act that violates personally held moral principles. As moral agents in their own right, physicians are informed by and committed to diverse cultural, religious, and philosophical traditions and beliefs. According to the <u>AMA Code of Medical Ethics</u>, "physicians should have considerable latitude to practice in accord with well-considered, deeply held beliefs that are central to their self-identities."

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Conscience protections for medical students and residents are also warranted. The AMA supports educating medical students, residents, and young physicians about the need for physicians who provide termination of pregnancy services, the medical and public health importance of access to safe termination of pregnancy, and the medical, ethical, legal, and psychological principles associated with termination of pregnancy, while maintaining that the observation of, attendance at, or any direct or indirect participation in abortion should not be required.

Nonetheless, while we support the legitimate conscience rights of individual health care professionals, the exercise of these rights must be balanced against the fundamental obligations of the medical profession and physicians' paramount responsibility and commitment to serving the needs of their patients. As advocates for our patients, we strongly support patients' access to comprehensive reproductive health care and freedom of communication between physicians and their patients, and oppose government interference in the practice of medicine or the use of health care funding mechanisms to deny established and accepted medical care to any segment of the population.

According to the AMA *Code of Medical Ethics*, physicians' freedom to act according to conscience is not unlimited. Physicians are expected to provide care in emergencies, honor patients' informed decisions to refuse life-sustaining treatment, and respect basic civil liberties and not discriminate against individuals in deciding whether to enter into a professional relationship with a new patient. Physicians have stronger obligations to patients with whom they have a patient-physician relationship, especially one of long standing; when there is imminent risk of foreseeable harm to the patient or delay in access to treatment would significantly adversely affect the patient's physical or emotional well-being; and when the patient is not reasonably able to access needed treatment from another qualified physician. The Code provides guidance to physicians in assessing how and when to act according to the dictates of their conscience. Of key relevance to the Proposed Rule, the *Code* directs physicians to:

- Take care that their actions do not discriminate against or unduly burden individual patients or populations of patients and do not adversely affect patient or public trust.
- Be mindful of the burden their actions may place on fellow professionals.
- Uphold standards of informed consent and inform the patient about all relevant options for treatment, including options to which the physician morally objects.
- In general, physicians should refer a patient to another physician or institution to provide treatment the physician declines to offer. When a deeply held, well-considered personal belief leads a physician also to decline to refer, the physician should offer impartial guidance to patients about how to inform themselves regarding access to desired services.
- Continue to provide other ongoing care for the patient or formally terminate the patient-physician relationship in keeping with ethics guidance.

The ethical responsibilities of physicians are also reflected in the AMA's long-standing policy protecting access to care, especially for vulnerable and underserved populations, and our anti-discrimination policy, which opposes any discrimination based on an individual's sex, sexual orientation, gender identity, race, religion, disability, ethnic origin, national origin or age. We are concerned that the Proposed Rule, by attempting to allow individuals and health care entities who receive federal funding to refuse to provide *any* part of a health service or program based on religious beliefs or moral convictions, will allow discrimination against patients, exacerbate health inequities, and undermine patients' access to care.

We would like to note that no statutory provision requires the promulgation of rules to implement various conscience laws that have been in existence for years. We believe physicians are aware of their legal obligations under these requirements and do not think that the promulgation of this rule is necessary to enforce the conscience provisions under existing law. OCR has failed to provide adequate reasons or a satisfactory explanation for the Proposed Rule as required under the Administrative Procedure Act (APA). As OCR itself acknowledges, between 2008 and November 2016, OCR received 10 complaints alleging violations of federal conscience laws; OCR received an additional 34 similar complaints between November 2016 and January 2018. In comparison, during a similar time period, from fall 2016 to fall 2017, OCR received over 30,000 complaints alleging violations of either HIPAA or civil rights. These numbers demonstrate that the Proposed Rule to enhance enforcement authority over conscience laws is not necessary.

OCR's stated purpose in revising existing regulations is to ensure that persons or entities are not subjected to certain practices or policies that violate conscience, coerce, or discriminate, in violation of federal laws. We believe that several provisions and definitions in the Proposed Rule go beyond this stated purpose and are ambiguous, overly broad, and could lead to differing interpretations, causing unnecessary confusion among health care institutions and professionals, thereby potentially impeding patients' access to needed health care services and information. The Proposed Rule attempts to expand existing refusal of care/right of conscience laws—which already are used to deny patients the care they need—in numerous ways that are directly contrary to the stated purpose of the existing laws. For example, one provision of the Church Amendments allows individuals who work for or with entities receiving grants or contracts for biomedical or behavioral research entities to refuse to participate in "any lawful health services or research activity" based on religious beliefs or moral convictions specifically related to the service or research activity to which they object. But the Proposed Rule attempts to broaden this provision to allow individuals to refuse to perform aspects of their jobs based on a mere reference to a religious or moral belief regardless of whether it relates to the specific biomedical or behavioral service or research activity they are working on. Such an attempted expansion goes beyond what the statute enacted by Congress allows.

We are concerned that the scope of the services and programs that would be covered under the Proposed Rule is broader than allowed by existing law. While OCR claims that it is trying to clarify key terms in existing statutes, it appears that they are actually redefining many terms to expand the meaning and reach of these laws. For example, "health program or activity" is defined in the proposed regulatory text to include "the provision or administration of any health-related services, health service programs and research activities, health-related insurance coverage, health studies, or any other service related to health or wellness whether directly, through payments, grants, contracts, or other instruments, through insurance, or otherwise." Likewise, "health service program" is defined in the proposed regulatory text to include "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded, in whole or in part, by [HHS]." These definitions make clear that OCR intends to interpret these terms to include an activity related in any way to providing medicine, health care, or any other service related to health or wellness, including programs where HHS provides care directly, grant programs such as Title X, programs such as Medicare where HHS provides reimbursement, and health insurance programs where federal funds are used to provide access to health coverage, such as Medicaid and CHIP. The definitions inappropriately expand the scope of the conscience provisions to include virtually any medical treatment or service, biomedical and behavioral research, and health insurance.

Furthermore, the Proposed Rule's new and expanded definitions often exceed, or are not in accordance with, existing definitions contained within the existing laws OCR seeks to enforce. For example, "health care entity" is defined under the Coats and Weldon Amendments to include a limited and specific range of individuals and entities involved in the delivery of health care. However, the Proposed Rule attempts to combine separate definitions of "health care entity" found in different statutes and applicable in different circumstances into one broad term by including a wide range of individuals, e.g., not just health care professionals, but any personnel, and institutions, including not only health care facilities and insurance plans, but also plan sponsors and state and local governments. This impermissibly expands statutory definitions and will create confusion.

We are also concerned that the proposed rule expands the range of health care institutions and individuals who may refuse to provide services, and broadens the scope of what qualifies as a refusal under the applicable law beyond the actual provision of health care services to information and counseling about health services, as well as referrals. For example, "assist in the performance" is defined as "participating in any program or activity with an articulable connection to a given procedure or service." The definition also states that it includes "counseling, referral, training, and other arrangements for the procedure, health service, or research activity." While "articulable connection" is not further explained, OCR states in the preamble that it seeks to provide broad protection for individuals and that a narrower definition, such as a definition restricted to those activities that constitute direct involvement with a procedure, health service, or research activity, would not provide sufficient protection as intended by Congress.

However, this definition goes well beyond what was intended by Congress. Specifically, the Church Amendments prohibit federal funding recipients from discriminating against those who refuse to perform, or "assist in the performance" of, sterilizations or abortions on the basis of religious or moral objections, as well as those who choose to provide abortion or sterilization. The statute does not contain a definition for the phrase "assist in the performance." Senator Church, during debate on the legislation, stated that, "the amendment is meant to give protection to the physicians, to the nurses, to the hospitals themselves, if they are religious affiliated institutions. There is no intention here to permit a frivolous objection from someone unconnected with the procedure to be the basis for a refusal to perform what would otherwise be a legal operation." Read in conjunction with the rest of the proposed rule, it is clear this definition is intended to broaden the amendment's scope far beyond what was envisioned when the amendment was enacted. It allows any entity involved in a patient's care—from a hospital board of directors to the receptionist that schedules procedures—to use their personal beliefs to determine a patient's access to care.

In a similar fashion, the proposed definition of "workforce" extends the right to refuse not only to an entity's employees but also to volunteers and trainees. When both of these definitions are viewed together, this language seems to go well beyond those who perform or participate in a particular service to permit, for example, receptionists or schedulers to refuse to schedule or refer patients for medically necessary services or to provide patients with factual information, financing information, and options for medical treatment. It could also mean that individuals who clean or maintain equipment or rooms used in procedures to which they object would have a new right of refusal and would have to be accommodated. We believe this could significantly impact the smooth flow of health care operations for physicians, hospitals, and other health care institutions and could be unworkable in many circumstances.

The AMA is concerned that the Proposed Rule fails to address the interaction with existing federal and state laws that apply to similar issues, and thus is likely to create uncertainty and confusion about the rights and obligations of physicians, other health care providers, and health care institutions. Most notably, the Proposal is silent on the interplay with Title VII of the Civil Rights Act of 1964 and guidance by the Equal Employment Opportunity Commission, which along with state laws govern religious discrimination in the workplace. Title VII provides an important balance between employers' need to accommodate their employees' religious beliefs and practices—including their refusal to participate in specific health care activities to which they have religious objections—with the needs of the people the employer must serve. Under Title VII, employers have a duty to reasonably accommodate an employee or applicant's religious beliefs or practices, unless doing so places an "undue hardship" on the employer's business. It is unclear under the Proposed Rule if, for example, hospitals would be able to argue that an accommodation to an employee is an undue hardship in providing care. The Proposed Rule also could put hospitals, physician practices, and other health care entities in the impossible position of being forced to hire individuals who intend to refuse to perform essential elements of a job. Under Title VII, such an accommodation most likely would not be required.

Additional concerns exist for physicians with respect to their workforce under this Proposal. The Proposed Rule is unclear about what a physician employer's rights are in the event that an employee alleges discrimination based on moral or religious views when in fact there may be just cause for adverse employment decisions. For example, if a physician declines to hire an individual based on a lack of necessary skill, compensation and/or benefit requests out of the physician's budget, or simply because the individual is not a good fit in the office, but the individual also happens to be opposed to providing care to LGBTQ patients, does the physician open him/herself up to risk of a complaint to OCR? If so, physicians will be forced to substantially increase their documentation related to hiring and other decision-making related to human resources, adding administrative burden to already overworked practices. These considerations must not be overlooked by regulators, as OCR's enforcement mechanisms include the power to terminate federal funding for the practice or health care program implicated.

Adding to a practice's administrative burden is the Proposal's requirement that physicians submit both an assurance and certification of compliance requirements to OCR. Despite its reasoning in the preamble that HHS is "concerned that there is a lack of knowledge" about federal health care conscience and associated anti-discrimination laws, it remains unclear why OCR would require physicians to make two separate attestations of compliance to the same requirements, particularly given the administration's emphasis on reducing administrative burden in virtually every other space in health care. At the very least, OCR should (1) streamline the certification and assurance requirements with those already required on the HHS portal; and (2) expand the current exemptions from such requirements to include physicians participating not only in Medicare Part B, but also in Medicare Part C and Medicaid, as was the case in the 2008 regulation implementing various conscience laws. We reiterate, however, that we believe the overall compliance attestation requirements are unnecessary. If HHS' concern is about lack of awareness of the conscience laws, the AMA stands ready to assist with the agency's educational efforts in place of increased administrative requirements.

The Proposed Rule also seems to set up a conflict between conscience rights and federal, state, and local anti-discrimination laws, as well as policies adopted by employers and other entities and ethical codes of conduct for physicians and other health professionals. These laws, policies, and ethical codes are designed to protect individuals and patients against discrimination on the basis of race, gender, gender

identity, sexual orientation, disability, immigration status, religion, and national origin. It is unclear under the Proposed Rule how these important anti-discrimination laws, policies, and ethical codes will apply in the context of the expanded conscience rights proposed by OCR. The Proposed Rule also fails to account for those providers that have strongly held moral beliefs that motivate them to treat and provide health care to patients, especially abortion, end-of-life care, and transition-related care. For example, the Church Amendment affirmatively protects health care professionals who support or participate in abortion or sterilization services yet there is no acknowledgement of it in the Proposal.

Moreover, the Proposed Rule appears to conflict with, and in fact contradict, OCR's own mission, which states that "The mission of the Office for Civil Rights is to improve the health and well-being of people across the nation; to ensure that people have equal access to and the opportunity to participate in and receive services from HHS programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law" (emphasis added). In the past, HHS and OCR have played an important role in protecting patient access to care, reducing and eliminating health disparities, and fighting discrimination. There is still much more work to be done in these areas given disparities in racial and gender health outcomes and high rates of discrimination in health care experienced by LGBTQ patients. The Proposed Rule is a step in the wrong direction and will harm patients.

Likewise, the Proposed Rule does not address how conscience rights of individuals and institutions apply when emergency health situations arise. For example, the federal Emergency Medical Treatment and Labor Act (EMTALA) requires hospitals that have a Medicare provider agreement and an emergency room or department to provide an appropriate medical screening to any patient requesting treatment to determine whether an emergency medical condition exists, and to either stabilize the condition or transfer the patient if medically indicated to another facility. Every hospital, including those that are religiously affiliated, is required to comply with EMTALA. By failing to address EMTALA, the Proposed Rule might be interpreted to mean that federal refusal laws are not limited by state or federal legal requirements related to emergency care. This could result in danger to patients' health, particularly in emergencies involving miscarriage management or abortion, or for transgender patients recovering from transition surgery who might have complications, such as infections.

We are also concerned that the Proposed Rule could interfere with numerous existing state laws that protect women's access to comprehensive reproductive health care and other services. For example, the Proposed Rule specifically targets state laws that require many health insurance plans to cover abortion care (e.g., California, New York, and Oregon). OCR overturns previous guidance that was issued by the Obama administration providing that employers sponsoring health insurance plans for their employees were not health care entities with conscience rights; OCR argues that the previous guidance misinterpreted federal law, and, as discussed previously, proposes to add plan sponsors to the definition of health care entities. Likewise, the Proposed Rule could conflict with, and undermine, state laws related to contraceptive coverage. In addition, the Proposed Rule requires entities to certify in writing that they will comply with applicable Federal health care conscience and associated anti-discrimination laws. Under the broad language of the rule, hospitals, insurers, and pharmacies could claim they are being discriminated against if states attempt to enforce laws that require insurance plans that cover other prescription drugs to cover birth control, ensure rape victims get timely access to and information about emergency contraception, ensure that pharmacies provide timely access to birth control, and ensure that

hospital mergers and sales do not deprive patients of needed reproductive health services and other health care services.

In conclusion, the AMA believes that, as currently drafted, the Proposed Rule could seriously undermine patients' access to necessary health services and information, negatively impact federally-funded biomedical research activities, and create confusion and uncertainty among physicians, other health care professionals, and health care institutions about their legal and ethical obligations to treat patients. Given our concerns, we urge HHS to withdraw this proposed rule. If HHS does decide to move forward with a final rule, it should, at the very least, reconcile the rule with existing laws and modify the provisions we have identified to ensure that physicians and other health providers understand their legal rights and obligations.

Sincerely,

James L. Madara, MD

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EXHIBIT 42



March 27, 2018

Alex Azar Secretary Department of Health and Human Services Hubert H. Humphrey Building Room 509F 200 Independence Avenue, SW. Washington, DC 20201

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Re: RIN 0945-ZA03

Dear Secretary Azar:

On behalf of more than 37,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the draft rule relating to protecting conscience rights in health care, as it affects our practice of emergency medicine and the patients we serve.

While we believe that enforcement of existing federal conscience protections for health care providers is important, we strongly object to this proposed rule and do not believe it should be finalized. As written, it does not reflect nor allow for our moral and legal duty as emergency physicians to treat everyone who comes through our doors. Both by law¹ and by oath, emergency physicians care for all patients seeking emergency medical treatment. 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 ability to pay, is unethical².

ACEP has specific comments on multiple sections of the proposed rule, which are found below.

Application of Proposals in Emergency Situations

As emergency physicians, we are surprised and concerned that the proposed rule does not in any way address how conscience rights of individuals and institutions interact

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¹ 42 U.S. Code § 1395dd - Examination and treatment for emergency medical conditions and women in labor

² ACEP Code of Ethics for Emergency Physicians; Approved Jan 2017; https://www.acep.org/clinical---practice-management/code-of-ethics-for-emergency-physicians

with the mandated provision of emergency services. The Emergency Medical Treatment and Labor Act (EMTALA) requires clinicians to screen and stabilize patients who come to the emergency department. Such patients have every right to expect the best possible care and to receive the most appropriate treatment and information about their condition.

Patients with life-threatening injuries or illnesses may not have time to wait to be referred to another physician or other healthcare professional to treat them if the present provider has a moral or religious objection. Likewise, emergency departments operate on tight budgets and do not have the staffing capacity to be able to have additional personnel on hand 24 hours a day, 7 days a week to respond to different types of emergency situations that might arise involving patients with different backgrounds, sexual orientations, gender identities, or religious or cultural beliefs. The proposed rule seems to demand that, in order to meet EMTALA requirements, an emergency department 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. Emergency departments serve as the safety-net in many communities, providing a place where those who are most vulnerable and those in need of the most immediate attention can receive care. By not addressing the rights and needs of patients undergoing an emergency, the legal obligations of emergency physicians, and the budget and staffing constraints that emergency departments face, this rule has the potential of undermining the critical role that emergency departments play across the country.

Definition of Referrals

Under the proposed rule, health care providers could refuse not only to perform any given health care service, but also to provide patients access to information about or referrals for such services. The Department of Health and Human Services (HHS) defines a referral broadly in the rule as "the provision of any information... by any method... pertaining to a service, activity, or procedure, including related to availability, location, training, information resources, private or public funding or financing, or direction that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity, or procedure, when the entity or health care entity making the referral sincerely understands that particular health care service, activity, or procedure to be a purpose or possible outcome of the referral."

Such a broad definition of referral as referenced under the proposed rule's prohibition could create unintended consequences, such as preventing patients from getting appropriate care now or even in the future. For example, this definition would allow a primary care physician with a moral or religious objection to abortion to deny referring a pregnant woman (who may not have any immediate intentions or desire for an abortion) to a particular obstetrician-gynecologist out of fear that the woman could eventually receive an abortion from that obstetrician-gynecologist, whether at some point in the future of this pregnancy or even for a future pregnancy.

Another situation where this definition could lead to an undesirable outcome for a patient is when a provider has an objection to a patient's end-of-life wishes expressed in an advance directive. Emergency physicians often treat patients with advanced illness, and ACEP strongly believes that providers should respect the wishes of dying patients including those expressed in advance directives. Most States today allow for a conscience objection and the right to refuse to comply with a patient's advance directive, but they all impose

an obligation to inform such patients and, more importantly, to make some level of effort to transfer the patient to another provider or facility that will comply with the patient's wishes. However, under this proposed rule, providers with a religious or moral objection to their patients' end-of-life or advanced care wishes would have no obligation to either treat these patients in accordance with their wishes or refer them to another provider who would. Unfortunately, it is unclear how such State laws would interact with or be impacted by the federal enforcement aspects of this proposed rule, were it to be finalized. What is clear however, is that if this proposed rule is finalized, the patient's wishes could be ignored and the patient ultimately loses.

In all, the proposed rule's far-reaching definition of referral will likely cause confusion about when a referral may or may not be appropriate, thereby increasing the chances that patients do not receive accurate or timely information that may be critical to their overall health and wellbeing. The proposed rule therefore threatens to fundamentally undermine the relationship between providers and patients, who will have no way of knowing which services, information, or referrals they may have been denied, or potentially whether they were even denied medically appropriate and necessary services to begin with. Additionally, given that many insurance plans such as HMOs require referrals before coverage of specialty services, the proposed rule could place patients at financial risk based on the refusal of their primary care physician to provide a referral.

The definition of referral is representative of one of the major, unacceptable flaws in the rule: it does not focus on the needs of patients or our responsibility as providers to treat them. The rule does not mention the rights of patients even once or seek comment on how patients can still be treated if providers have a moral and religious objection to their treatment. It seems to imply that these providers have no responsibility to their patients to make sure they receive the best possible care when they are unable to provide it themselves, and there is no process or guidance in place for these providers to still try to serve their patients. The lack of attention to protecting and serving patients is one of the major reasons we believe that the rule should be withdrawn.

Requirement to Submit Written Assurances and Certifications of Compliance

HHS would require certain recipients of federal funding (including hospitals that provide care to patients under Medicare Part A) to submit annual written assurances and certifications of compliance with the federal health care conscience and associated anti-discrimination laws as a condition of the terms of acceptance of the federal financial assistance or other federal funding from HHS. There are several exceptions from the proposed requirements for written assurance and certification of compliance, including physicians, physician offices, and other health care practitioners participating in Part B of the Medicare program. However, "excepted" providers could become subject to the written certification requirement if they receive HHS funds under a separate agency or program, such as a clinical trial.

ACEP finds the lack of clarity around this requirement extremely concerning, as we believe that it will pose a significant burden on health care professionals including emergency physicians.

First, the rule does not account for all the possible circumstances or arrangements that would potentially force "excepted" physicians to file certifications. For example, some emergency physicians who are participating in Medicare Part B also have joined an accountable care organization (ACO) led by a hospital where they see patients. In many cases, the ACO has entered into a contract with the Centers for Medicare

& Medicaid Services (CMS) to be part of the Medicare Shared Savings Program or a Center for Medicare & Medicaid Innovation (CMMI) ACO model. Since the ACO includes both physicians and a hospital and therefore receives payments from both Parts A and B of Medicare, it is unclear whether emergency physicians who are part of the ACO would lose their exemption status. Numerous other alternative payment models besides ACO models are operated by CMS and involve participation from both hospitals and physicians. HHS should clarify whether physicians who are part of these models would still be exempted from the certification requirement.

Second, it is unclear whether clinicians who treat Medicaid patients are exempt from the requirement. In the rule, HHS includes Medicaid in the list of examples for why some exemptions may be appropriate³, but does not actually list reimbursement from the program as one of the exceptions. Some of our members may see only patients with Medicaid, so this lack of clarity is of great concern to them.

Third, ACEP is concerned about the cost-burden that this proposal will have on the hospitals, free-standing emergency departments, and emergency physicians who are subject to the requirement. CMS estimates that the assurance and certification requirement alone could cost health care entities nearly \$1,000 initially and \$900 annually thereafter to sign documents, review policies and procedures, and update policies and procedures and conduct training. This substantial cost is on top of the cost of posting a notice, which is estimated to be \$140 per entity. Since emergency physicians by law must provide services to patients regardless of their insurance status, their total reimbursement, if any, rarely covers the full cost of providing the services. By adding more burdensome government mandates that emergency departments must cover out of their own constrained budgets, the proposed rule could potentially jeopardize the financial viability of the emergency care safety net. While we believe the proposed rule should be withdrawn because it is so problematic, in the event the rule is finalized, ACEP requests that at minimum emergency departments, and the physicians and other health care providers that furnish care within them, be exempt from the written assurances and certifications of compliance requirement.

Notice Requirement

The proposed rule requires all health entities to post a notice on their websites and in locations in their organizations where public notices are typically posted. This notice advises people about their rights and the entity's obligation to abide by federal health care conscience and associated anti-discrimination laws. The notice also provides information about how to file a complaint with the Office of Civil Rights within HHS. The rule requires entities to use a prescribed notice, found in "Appendix A" of the rule, but seeks comment on whether to permit entities to draft their own notices.

ACEP objects to this posting requirement. Beyond our concerns with the burden of having to adhere to another government-imposed mandate as discussed above, we also are troubled by the fact that the notice in no way addresses the needs of patients or our responsibilities as providers to treat them. It does not provide any information about the fundamental rights of patients to receive the most accurate information and best available treatment options for their conditions. We therefore have grave concerns about posting the notice as currently drafted.

³ On pages 73- 74 of the proposed rule, HHS states "Furthermore, the Department believes that, due primarily to their generally smaller size, several of the excepted categories of recipients of Federal financial assistance or other Federal funds from the Department are less likely to encounter the types of issues sought to be addressed in this regulation. For example, State Medicaid programs are already responsible for ensuring the compliance of their sub-recipients as part of ensuring that the State Medicaid program is operated consistently with applicable nondiscrimination provisions."

It is also unclear whose exact responsibility it is to post the notice(s). Most emergency physicians are employed by a group independent from the hospital that houses the emergency department where they see patients. Therefore, would the hospital's posted notice be sufficient, or would the group that the hospital's emergency physicians are employed by need to also take on this responsibility as a separate entity, with a separate, additional posting in the emergency department?

If so, posting this notice in the emergency department could potentially be considered a violation of EMTALA. EMTALA requires providers to screen and stabilize patients who come to the emergency department. Therefore, notices that could potentially dissuade patients from receiving care that is mandated by Federal law cannot be posted publicly in the emergency department. Since the notice proposed in this rule explicitly states that providers have the right to decline treatment for patients based on their conscience, religious beliefs, or moral convictions, some patients may become concerned that they would not be treated appropriately and decide to leave before they treated— a violation of EMTALA.

In light of the above concerns, ACEP urges the Department to withdraw the proposed rule. We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at idavis@acep.org.

Sincerely,

Paul D. Kivela, MD, MBA, FACEP

ACEP President

EXHIBIT 43



March 23, 2018

VIA ELECTRONIC SUBMISSION

Secretary Alex Azar
U.S. Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Attention: Comments on RIN 0945-ZA03 – Proposed Rule Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Secretary Azar,

The National Institute for Reproductive Health (NIRH) believes a health care provider's personal beliefs should never determine the care a patient receives. That is why we strongly oppose the Department of Health and Human Services' (the "Department") proposed rule ("Proposed Rule"), which seeks to permit discrimination in all aspects of health care.¹

The Proposed Rule seeks to unlawfully expand refusals to provide care by attempting to allow individuals and health care entities who receive federal funding to refuse to provide *any* part of a health service or program. In addition, the Proposed Rule unlawfully attempts to create new refusals seemingly out of thin air. Such expansions exceed the Department's authority; violate the Constitution; undermine the ability of states to protect their citizens; undermine critical HHS programs like Title X; interfere with the provider-patient relationship; and threaten the health and well-being of people across the country and around the world.

By issuing the Proposed Rule and creating a new division within the Office of Civil Rights ("OCR") – the new "Conscience and Religious Freedom Division" – the Department seeks to inappropriately use OCR's limited resources in order to affirmatively allow institutions, insurance companies, and almost anyone involved in patient care to use their personal beliefs to deny people the care they need. For these reasons the National Institute for Reproductive Health calls on the Department and OCR to withdraw the Proposed Rule in its entirety.

¹ Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (proposed Jan. 26, 2018) (to be codified at 45 C.F.R. pt. 88) [hereinafter Rule].



The Proposed Rule Unlawfully Exceeds the Department's Authority by Impermissibly Expanding Religious Refusals to Provide Care

The Proposed Rule attempts to expand the reach not only of existing harmful refusal of care laws but also to create new refusals of care where none were intended.

a. The Proposed Rule Seeks to Allow the Refusal of any Health Service Based on Personal Belief

The Proposed Rule will exacerbate health inequities by expanding the ability to refuse critical services, including abortion and transition-related care. Specifically, the Department and OCR are attempting to require a broad swath of entities to allow individuals to refuse "any lawful health service or activity based on religious beliefs or moral convictions (emphasis added)."² Read in conjunction with the rest of the Proposed Rule, it is clear this is intended to allow any entity involved in a patient's care—from a hospital board of directors to the receptionist that schedules procedures—to use their personal beliefs to determine a patient's access to care.

b. The Proposed Rule Unlawfully Expands Already Harmful Abortion/Sterilization Refusal of Care Laws

Already existing refusal of care laws are used across the country to deny patients the care they need.³ The Proposed Rule attempts to expand these laws in numerous ways that are directly contrary to the stated purpose of the existing laws. For example, one provision of the Church Amendments allows individuals who work for or with entities receiving grants or contracts for biomedical or behavioral research entities to refuse to participate in "any lawful health services or research activity" based on religious beliefs or moral convictions specifically related to the service or research activity to which they object.⁴ But the Proposed Rule attempts to broaden this provision to allow individuals to refuse to perform aspects of their jobs based on a mere reference to a religious or moral belief regardless of whether it relates to the specific biomedical or behavioral service or research activity they are working on.⁵ Such an attempted expansion goes beyond what the statute enacted by Congress allows. Furthermore, the Proposed Rule would expansively apply other provisions of the Church Amendments to, among other things,

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² See id. at 12.

³ See, e.g., Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide, NAT'L WOMEN'S L. CTR. (2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/; Catherine Weiss, et al., Religious Refusals and Reproductive Rights, AM. CIVIL LIBERTIES UNION (2002), https://www.aclu.org/report/religious-refusals-and-reproductive-rights-report; Julia Kaye, et al., Health Care Denied, AM. CIVIL LIBERTIES UNION 1 (2016),

https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf; Kira Shepherd, et al., Bearing Faith The Limits of Catholic Health Care for Women of Color, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

⁴ The Church Amendments, 42 U.S.C. § 300a-7 (2018).

⁵ See Rule supra note 1, at 185.



individuals working under global health programs funded by the Department thereby allowing global health providers and entities to refuse individuals the care they need contrary to the very purpose of such programs.

Similarly, the Proposed Rule defines common phrases and words used throughout existing refusals of care laws and civil rights laws in ways that stretch their intended meaning beyond recognition. For example, the definition of "assist in the performance" greatly expands the types of services that can be refused to include merely "making arrangements for the procedure" no matter how tangential. This means individuals not "assisting in the performance" of a procedure within the ordinary meaning of the term, such as the hospital room scheduler, the technician charged with cleaning surgical instruments, and other hospital employees, can now assert a new right to refuse. The Proposed Rule's definition of "referral" similarly goes beyond any understanding of the term, allowing refusals to provide any information, including location or funding, that could help an individual to get the care they need.

Furthermore, the Proposed Rule's new and unwarranted expanded definitions often exceed, or are not in accordance with, existing definitions contained within the statutes the Proposed Rule seeks to enforce. Specifically, under the Coats and Weldon Amendments "health care entity" is defined to encompass a limited and specific range of individuals and entities involved in the delivery of health care. The Proposed Rule attempts to combine separate definitions of "health care entity" found in different statutes and applicable in different circumstances into one broad term. Such an attempt to expand the meaning of a statutory term Congress already took the time to define not only fosters confusion, but goes directly against congressional intent. By expressly defining the term "health care entity" Congress implicitly rejected the inclusion of the other terms the Department now attempts to insert. 10

When these impermissibly broad definitions are combined with the expansive interpretations of the underlying statutes, they work together to further expand refusals of care to allow more individuals and entities to refuse to provide access to health care. For example, one way the Weldon Amendment is expanded under the Proposed Rule is through the definition of "discrimination." In particular, the Proposed Rule defines "discrimination" against a health care entity broadly to include a number of activities, including denying a grant or employment as well as an unspecified catch-all phrase "any activity reasonably regarded as discrimination." In

⁶ *Id.* at 180.

⁷ *Id.* at 183.

⁸ The Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009); Public Health Service Act, 42 U.S.C. § 238n (2018).

⁹ See Rule supra note 1, at 182.

¹⁰ The doctrine of expression unius est exclusion alterius (the expression of one thing implies the exclusion of others) as applied to statutory interpretation creates a presumption that when a statute designates certain persons, things, or manners of operation, all omissions should be understood as exclusions.

¹¹ See Rule supra note 1, at 180.

¹² *Id*.



a Proposed Rule that seeks to protect those who want to discriminate, this broad definition is nonsensical and inappropriate. Further such a vague and inappropriate definition provides no functional guidance to entities on how to comply with the applicable requirements, thereby fostering confusion.

The Proposed Rule Carries Severe Consequences for Patients and will Exacerbate Already Existing Inequities

a. Refusals of Care Make it Difficult for Many Individuals to Access the Care They Need

Across the country refusals of care based on personal beliefs have been invoked in countless ways to deny patients the care they need. ¹³ One woman experiencing pregnancy complications rushed to the only hospital in her community, a religiously affiliated facility, where she was denied the miscarriage management she needed because the hospital objected to this care. ¹⁴ Another woman experiencing pregnancy loss was denied care for ten days at a religiously affiliated hospital outside Chicago, Illinois. ¹⁵ In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy. ¹⁶ Another patient in Arkansas endured a number of dangerous pregnancy complications and could not risk becoming pregnant again. She requested a sterilization procedure at the time of her Cesarean delivery, but her Catholic hospital provider refused to give her the procedure. ¹⁷ Another woman was sent home by a religiously affiliated hospital with two Tylenol after her water broke at 18 weeks of pregnancy. Although she returned to the hospital twice in the following days, the hospital did not give her full information about her condition and treatment options. ¹⁸

¹⁴ See Kira Shepherd, et al., Bearing Faith The Limits of Catholic Health Care for Women of Color, Pub. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 6 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

¹³ See, e.g., supra note 3.

¹⁵ See Julia Kaye, et al., *Health Care* Denied, Am. CIVIL LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

¹⁶ See Kira Shepherd, et al., Bearing Faith The Limits of Catholic Health Care for Women of Color, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 29 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

¹⁷ See The Patient Should Come First: Refusals to Provide Reproductive Health Care, NAT'L WOMEN'S L. CTR. (2017), https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/05/Refusals-FS.pdf; Sandhya Somashekhar, A Pregnant Woman Wanted her Tubes Tied. Her Catholic Hospital Said No., WASH. POST (Sept. 13, 2015), <a href="https://www.washingtonpost.com/national/a-pregnant-woman-wanted-her-tubes-tied-her-catholic-hospital-said-no/2015/09/13/bd2038ca-57ef-11e5-8bb1-b488d231bba2_story.html?utm_term=.8c022b364b75.

¹⁸ See Kira Shepherd, et al., Bearing Faith The Limits of Catholic Health Care for Women of Color, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 27 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.



b. Refusals of Care are Especially Dangerous for Those Already Facing Barriers to Care

Refusals of care based on personal beliefs already make it difficult for many individuals to access health care and have real consequences for those denied the care they need because of a provider or hospital's religious beliefs. When women and families are uninsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services or travel to another location, refusals bar access to necessary care. ¹⁹ This is especially true for immigrant patients who often lack access to transportation and may have to travel great distances to get the care they need. ²⁰ In rural areas there may be no other sources of health and life preserving medical care. ²¹ In developing countries where many health systems are weak, health care options and supplies are often unavailable. ²² When these individuals encounter refusals of care, they may have nowhere else to go.

This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals. For example, new research shows that women of color in many states disproportionately receive their care at Catholic hospitals. In nineteen states, women of color are more likely than white women to give birth in Catholic hospitals. ²³ These hospitals as well as many Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provides guidance on a wide range of hospital matters, including reproductive health care and can keep providers from offering the standard of care. ²⁴ Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals, and as a result, women were delayed care or transferred to other facilities at great risk to their health. ²⁵ The reach of this type of

¹⁹ In 2016, an estimated 11 percent of women between the ages of 19 to 64 were uninsured. Single mothers, women of color, and low-income women are more likely to be uninsured. Women's Health Insurance Coverage, KAISER FAMILY FOUND. 1, 3 (Oct. 31, 2017), http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage.
²⁰ Athena Tapales et al., The Sexual and Reproductive Health of Foreign-Born Women in the United States, CONTRACEPTION 8, 16 (2018), http://www.contraceptionjournal.org/article/S0010-7824(18)30065-9/pdf; Nat'l Latina Inst. For Reproductive Health & Ctr. For Reproductive Rights, https://www.nuestra.org/pdf/NT-spread.pdf.
http://www.nuestrotexas.org/pdf/NT-spread.pdf

²¹ Since 2010, eighty-three rural hospitals have closed. *See Rural Hospital Closures: January 2010 – Present*, THE CECIL G. SHEPS CTR FOR HEALTH SERVS. RES. (2018), http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.

²² See Nurith Aizenman, Health Care Costs Push a Staggering Number of People into Extreme Poverty, NPR (Dec. 14, 2017), https://www.npr.org/sections/goatsandsoda/2017/12/14/569893722/health-care-costs-push-a-staggering-number-of-people-into-extreme-poverty; Tracking Universal Health Coverage: 2017 Global Monitoring Report, WORLD HEALTH ORG. & THE WORLD BANK (2017),

http://documents.worldbank.org/curated/en/640121513095868125/pdf/122029-WP-REVISED-PUBLIC.pdf.

²³ See Kira Shepherd, et al., Bearing Faith The Limits of Catholic Health Care for Women of Color, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 12 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

²⁴ See id. at 10-13.

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²⁵ Lori R. Freedman, When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals, Am. J. PUB. HEALTH (2008), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.



religious refusal of care is growing with the proliferation of both the types of entities using religious beliefs to discriminate and the number of religiously affiliated entities that provide health care and related services.²⁶

In addition, in many of the countries where the Department implements global AIDS programs, many of the patients served already face numerous barriers to care, including a broad and harmful refusal provision contained within the statute governing such programs.²⁷

c. In Proposing this Rule, the Agency has Abandoned its Legal Obligations to Adequately Account for Harm to Patients

By expanding refusals of care the Proposed Rule will exacerbate the barriers to health care services patients need. It is evident that the harm caused by this Proposed Rule will fall hardest on those most in need of care by allowing individuals and health care entities to use their personal beliefs to dictate patient care. The Department should remember, under Executive Order 13563, an agency may only propose regulations where it has made a reasoned determination that the benefits justify the costs and where the regulations are tailored "to impose the least burden on society." The Proposed Rule plainly fails on both counts. Although the Proposed Rule attempts to quantify the costs of compliance, it completely fails to address the costs and burdens to patients who may be denied care and who then may incur and experience even greater social and medical costs. ²⁹

Moreover, the Establishment Clause of the First Amendment requires the government to adequately account for just these sorts of consequences when considering whether to grant religious exemptions and, in fact, bars granting an exemption when it would detrimentally affect any third party. Because the Proposed Rule would cause substantial harm, including to patients, it would violate the Establishment Clause. It

²⁶ See, e.g., Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care, AM. CIVIL LIBERTIES UNION & MERGER WATCH (2013), https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf.

²⁷ See The Mexico City Policy: An Explainer, KAISER FAMILY FOUND. (June 1, 2017), https://www.kff.org/global-health-policy/fact-sheet/mexico-city-policy-explainer/.

²⁸ Improving Regulation and Regulatory Review, Executive Order 13563 (Jan. 18, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review.

²⁹ See Rule supra note 1, at 94-177.

³⁰ U.S. Const. amend. I; *Cutter v. Wilkinson*. 554 U.S. 709, 720, 722 (2005) (to comply with the Establishment Clause, courts "must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries" and must ensure that the accommodation is "measured so that it does not override other significant interests") (citing *Estate of Thornton v. Caldor*, 472 U.S. 703, 710 (1985)); *see also Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).

³¹ Respecting religious exercise may not "unduly restrict other persons such as employees, in protecting their own.

³¹ Respecting religious exercise may not "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling." *See Burwell v. Hobby Lobby*, 134 S. Ct. at 2787. When considering



The Proposed Rule Will Undermine Critical Federal Health Programs, including Title X

The Proposed Rule would seemingly allow health care entities to receive grants and contracts under HHS-funded programs or other federal health programs, such as Title X, the only domestic family planning program, while refusing to provide key services required by those programs.³² For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling³³ and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.³⁴ Under the Proposed Rule, the Department would seemingly allow entities to apply for and receive federal funds while exempting them from the core legal and programmatic duties upon which such funds are generally conditioned.³⁵ The Proposed Rule creates uncertainty about whether Title X grantees may ensure that the subrecipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. Such actions are particularly concerning in the context of federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for low-income populations.³⁶ When it comes to Title X, the Proposed Rule would not only sanction conduct at odds with pre-existing legal requirements, but could also undermine the program's fundamental objectives. Every year millions of low-income, including under-insured, and uninsured individuals, rely on Title X clinics to access services they otherwise might not be able to afford.³⁷

The Proposed Rule Will Carry Severe Consequences for Providers and Undermine the Provider-Patient Relationship

Existing refusals of care based on personal beliefs already undermine open communication between providers and patients, interfere with providers' ability to provide care according to medical standards, and ignore the reality that many providers want to provide comprehensive care. Hospital systems across the country use religious beliefs to prevent their employees from

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whether the birth control coverage requirement was the least restrictive means in Hobby Lobby, the Court considered that the accommodation offered by the government ensured that affected employees "have precisely the same access to all FDA-approved contraceptives as employees of companies whose owners have no religious objections to providing coverage." *See id.* at 2759. In other words, the effect of the accommodation on women would be "precisely zero." *Id.* at 2760.

³² See Rule supra note 1, at 180-181, 183. See also Title X Family Planning, U.S. DEP'T OF HEALTH & HUMAN SERVS. (2018), https://www.hhs.gov/opa/title-x-family-planning/index.html; Title X an Introduction to the Nation's Family Planning Program, NAT'L FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOC. (2017) (hereinafter NFPRHA), https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf.

³³ See, e.g., Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).

³⁴ See What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).

³⁵ See, e.g., Rule supra note 1, at 180-185.

³⁶ See NFPRHA supra note 34.

³⁷ See id.



treating patients regardless of the professional, ethical, or moral convictions of these providers.³⁸ The Proposed Rule would exacerbate these problems by emboldening health care entities and institutions, including foreign and international organizations, to bind the hands of providers and attempt to limit the types of care they can provide.

The Proposed Rule threatens informed consent, a necessary principle of patient-centered decision-making intended to help balance the power dynamics between health providers and patients and ensure patient-centered decision-making.³⁹ Informed consent requires providers disclose relevant and medically accurate information about treatment choices and alternatives so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.⁴⁰ By allowing providers, including hospital and health care institutions, to refuse to provide patients with information, the Proposed Rule makes it impossible for patients to have full information regarding treatment options. While the Department claims the Proposed Rule improves communication between patients and providers, in truth it will deter open, honest conversations that are vital to ensuring that a patient can control their medical circumstances.⁴¹

The Proposed Rule also disregards standards of care established by the medical community by allowing providers to opt out of providing medical care. Medical practice guidelines and standards of care establish the boundaries of medical services that patients can expect to receive and that providers should be expected to deliver. Yet, the Proposed Rule seeks to allow providers and institutions to ignore the standards of care, particularly surrounding reproductive and sexual health. Information, counseling, referral and provision of contraceptive and abortion services are part of the standard of care for a range of common medical conditions including heart disease, diabetes, epilepsy, lupus, obesity, and cancer. ⁴² Individuals seeking reproductive health care, regardless of their reasons for needing these services, should be treated with dignity and respect. Allowing providers to flout established medical guidelines and deny medically accurate,

⁴² For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care. Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant. Am. Diabetes Ass'n, Standards of Medical Care in Diabetes-2017, 40 Diabetes Care § 114-15, S117 (2017), available at

http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement 1.DC1/DC 40 S1 final.pdf. The American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics guidelines state that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually suggested regardless of fetal age or potential for survival. AM. ACAD. OF PEDIATRICS & AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES FOR PERINATAL CARE 232 (7th ed. 2012).

³⁸ See Julia Kaye, et al., *Health Care Denied*, Am. CIVIL LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

³⁹ See Tom Beauchamp & James Childress, Principles of Biomedical Ethics (4th ed. 1994); Charles Lidz et Al., Informed consent: A study of decisionmaking in psychiatry (1984).

⁴⁰ See id.

⁴¹ See Rule supra note 1, at 150-151.



evidence-based care to patients harms them and impairs their ability to make the health care decision that is right for them.

In addition, the Proposed Rule ignores the many providers with deeply held moral convictions that affirmatively motivate them to provide patients with health care, including abortion, transition-related care, and end-of-life care. Moreover, the Proposed Rule fails to acknowledge the Church Amendments' protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce. An ohealth care professional should face discrimination from their employer because they treated or provided information to a patient seeking an abortion.

The Department is Abdicating its Responsibility to Patients

The Proposed Rule exceeds OCR's authority by abandoning OCR's mission to address health disparities and discrimination that harms patients. ⁴⁴ Instead, the Proposed Rule appropriates language from civil rights statutes and regulations that were intended to improve access to health care and applies that language to situations for which it was not intended. By taking the language of civil rights laws and regulations out of context, the Proposed Rule creates a regulatory scheme that is not only nonsensical but is affirmatively harmful. For example, the notice and certification of compliance and assurance requirements simply do not make sense when applied to the laws the Proposed Rule seeks to enforce. ⁴⁵ They will place a significant and burdensome requirement on health care providers and impose unique challenges for those working in other countries by taking resources away from patient care without adding any benefit.

The Department, including OCR, has an important role to play in ensuring equal opportunity to access health care and ending discriminatory practices that contribute to poor health outcomes and health disparities. ⁴⁶ If finalized, however, the Proposed Rule will represent a radical departure from the Department's mission to combat discrimination, protect patient access to care,

⁴³ See The Church Amendments, 42 U.S.C. § 300a-7(c) (2018).

⁴⁴ OCR's Mission and Vision, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/ocr/about-us/leadership/mission-and-vision/index.html ("The mission of the Office for Civil Rights is to improve the health and well-being of people across the nation; to ensure that people have equal access to and the opportunity to participate in and receive services from HHS programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").

⁴⁵ See Rule supra note 1, at 203-214.

⁴⁶ As one of its first official acts in 1967, the Office of Equal Health Opportunity undertook the massive effort of inspecting 3,000 hospitals to ensure they were complying with Title VI's prohibition against discrimination on the basis of race, color, or national origin. 42. U.S.C. § 2000d (1964). After this auspicious start, the Office of Equal Health Opportunity which would eventually become OCR would go on to ensure that health programs and activities it regulated complied with key anti-discrimination laws including Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 (1973), Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 (1972), the Age Discrimination Act of 1976, 42 U.S.C. § 6101 (1976), and Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116 (2010), among others. Through robust enforcement of these laws, OCR has worked to reduce discrimination in health care.



and eliminate health disparities. Through robust enforcement of civil rights laws, OCR has worked to reduce discrimination in health care by ending overtly discriminatory practices such as race segregation in health care facilities, segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things. 47

Nevertheless, there is still work to be done, and the Proposed Rule seeks to divert limited resources away from ending discrimination. De facto segregation, for example, continues to contribute to poorer health outcomes for Black people. According to one study, over half of the racial disparity in survival for heart attack patients can be attributed to the lower performance of hospitals that serve predominantly people of color. And these disparities do not occur in isolation. Black women, for example, are three to four times more likely than white women to die during or after childbirth. Further, the disparity in maternal mortality is growing rather than decreasing, which in part may be due to the reality that women have long been the subject of discrimination in health care and the resulting health disparities. For example, women's pain is routinely undertreated and often dismissed. And due to gender biases and disparities in research, doctors often offer women less aggressive treatment, or even no treatment, for conditions such as heart disease. Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care. Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a doctor or other health care

⁵¹ See, e.g., Diane E. Hoffmann & Anita J. Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29:1 J. OF L., MED., & ETHICS 13, 13-27 (2001).

⁴⁷ See, e.g., Serving People with Disabilities in the Most Integrated Setting: Community Living and Olmstead, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/community-living-and-olmstead/index.html; Protecting the Civil Rights and Health Information Privacy Rights of People Living with HIV/AIDS, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/hit/index.html; National Origin Discrimination, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/health-disparities/index.html.

⁴⁸ See Skinner et al., Mortality after Acute Myocardial Infarction in Hospitals that Disproportionately Treat African-Americans, NAT'L INSTIT. OF HEALTH 1 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1626584/pdf/nihms13060.pdf.

⁴⁹ See Nina Martin, Black Mothers Keep Dying After Giving Birth. Shalon Irving's Story Explains Why, NPR (Dec. 2017), https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irvings-story-explains-why.

⁵⁰ See id.

⁵² See, e.g., Judith H. Lichtman et al., Symptom Recognition and Healthcare Experiences of Young Women with Acute Myocardial Infarction, 10 J. of the Am. Heart Ass'n 1 (2015).

⁵³ See, e.g., When Health Care Isn't Caring, LAMBDA LEGAL 5 (2010),

https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring_1.pdf. A survey examining discrimination against LGBTQ people in health care more than half of respondents reported that they have experienced at least one of the following types of discrimination in care: being refused needed care; health care professionals refusing to touch them or using excessive precautions; health care professionals using harsh or abusive language; being blamed for their health care status; or health care professionals being physically rough or abusive.



provider had refused to see them because of their actual or perceived sexual orientation or gender identity in the year before the survey. 54

OCR must work to address these disparities, yet the Proposed Rule seeks to prioritize the expansion of existing religious refusal laws beyond their statutory requirements and create new religious exemptions where none had previously existed rather than using already limited resources to protect patient access to health care. The Proposed Rule will harm patient care and is antithetical to OCR's mission—to eliminate discriminatory practices that contribute to persistent health inequality. ⁵⁵

The Proposed Rule Conflicts with Other Existing Federal Law

The Proposed Rule generates chaos through its failure to account for existing laws that conflict with the refusals to care it would create.

For example, the Proposed Rule makes no mention of Title VII,⁵⁶ the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.⁵⁷ With respect to religion, Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer.⁵⁸ For decades, Title VII has established the legal framework for religious accommodations in the workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on patients, coworkers, public safety, and other legal obligations. The Proposed Rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both. Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.⁵⁹

Furthermore, the language in the Proposed Rule would seem to put health care entities in the position of being forced to hire people who intend to refuse to perform essential elements of a position even though Title VII would not require such an "accommodation." For example, there is no guidance about whether it is impermissible "discrimination" for a Title X-funded health

⁵⁶ 42 U.S.C. § 2000e-2 (1964).

⁵⁴ See Jaime M. Grant et al., *Injustice at Every Turn: a Report of the National Transgender Discrimination Survey*, NAT'L GAY AND LESBIAN TASK FORCE & NAT'L CTR. FOR TRANSGENDER EQUALITY, http://www.thetaskforce.org/static html/downloads/reports/reports/ntds full.pdf.

⁵⁵ See supra note 46.

⁵⁷ Title VII of the Civil Rights Act of 1964, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.

⁵⁸ See id.

⁵⁹ Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), *available at* https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii religious hhsprovider reg.html.



center not to hire a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests because the applicant refuses to provide non-directive options counseling even though the employer would not be required to do so under Title VII. 60 It is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

In addition, the Proposed Rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person to another facility. 61 Under EMTALA every hospital is required to comply – even those that are religiously affiliated.⁶² Because the Proposed Rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

The Proposed Rule Will Make It Harder for States to Protect their Residents

The Proposed Rule will have a chilling effect on the enforcement of and passage of state laws that protect access to health care and prevent discrimination against individuals seeking medical care. The preamble of the Proposed Rule discusses at length state laws that the Department finds objectionable, such as state laws that require anti-abortion counseling centers to provide information about where reproductive health care services can be obtained or whether facilities have licensed medical staff, as well as state laws that require health insurance plans to cover abortion. 63 Moreover, the Proposed Rule invites states to further expand refusals of care by making clear that this expansive rule is a floor, and not a ceiling, for religious exemption laws. 64

⁶⁰ See Rule supra note 1, at 180-181.

^{61 42} U.S.C. § 1295dd(a)-(c) (2003).

⁶² In order to effectuate the important legislative purpose, institutions claiming a religious or moral objection to treatment must comply with EMTALA, and courts agree. See, e.g., Shelton v. University of Medicine and Dentistry of New Jersey, 223 F.3d 220, 228 (3rd Cir. 2000); In In re Baby K, 16 F.3d 590, 597 (4th Cir. 1994); Nonsen v. Medical Staffing Network, Inc. 2006 WL 1529664 (W.D. Wis.); Grant v. Fairview Hosp., 2004 WL 326694, 93 Fair Empl. Prac. Cas. (BNA) 685 (D. Minn. 2006); Brownfield v. Daniel Freeman Marina Hosp., 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); Barris v. County of Los Angeles, 972 P.2d 966, 972 (Cal. 1999). 63 See, e.g., Rule, Supra note 1, at 3888-89.

⁶⁴ See id.



Conclusion

The Proposed Rule will allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care. The Proposed Rule is discriminatory, violates multiple federal statutes and the Constitution, ignores congressional intent, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons, the National Institute for Reproductive Health calls on the Department to withdraw the Proposed Rule in its entirety. If you have any questions, please do not hesitate to contact Rose MacKenzie at mackenzie@nirhealth.org or 646-520-3519.

Sincerely,

Andrea Miller

President

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India Uuller

& National Institute for Reproductive Health Action Fund