Exhibit 41

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March 27, 2018

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Submitted electronically via http://www.regulations.gov

RE: Comments of the California Medical Association: Department of Health and Human Services, Office for Civil Rights RIN 0945-ZA03

Dear Secretary Azar:

On behalf of more than 43,000 physician members and medical students of the California Medical Association (CMA), we appreciate the opportunity to provide comments on the Department of Health and Human Services' (the "Department") proposed rule ("Proposed Rule") on Protecting Statutory Conscience Rights in Health Care.[1] Through a comprehensive program of legislative, legal, regulatory, economic and social advocacy, CMA promotes the science and art of medicine, the care and well-being of patients, the protection of the public health, and the betterment of the medical profession.

CMA supports the comments of the American Medical Association on the Conscience Protections Proposed Rule and offer further comments that address issues that are of particular concern to California physicians. While CMA is a strong advocate for the conscience rights of physicians, we do not believe this Proposed Rule accomplishes its purported aims. We are concerned that the implementation of this Proposed Rule may lead to discrimination that is prohibited under both federal and California law, adversely impact patient access to comprehensive care, and inappropriately insert politics into the patient-physician relationship. Moreover, current federal and California law provide extensive protections for the conscience rights of health care providers, and the supplemental administrative burdens imposed by this rule do not add any meaningful benefit.

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 would inappropriately use OCR's limited resources to encourage discrimination in health care and undermine the ability of states to enforce their own conscience and anti-discrimination

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[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* Proposed Rule].

provisions. For these reasons, CMA urges the Department to withdraw the Proposed Rule in its entirety.

1. The Proposed Rule Expands the Scope of Existing Conscience Protections to Negatively Affect Access to Care.

CMA is concerned with the overly broad application of existing conscience protection laws and the expansion of the definitions in the Proposed Rule. The language of the Proposed Rule would 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 dictate a patient's access to care. 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 "any program or activity with an articulable connection to a procedure, health care service, health program, or research activity."[2] In fact, merely "making arrangements for the procedure," no matter how tangential, would be included in the reach of the Proposed Rule.[3] This means individuals not "assisting in the performance" of a procedure within the ordinary meaning of the term, such as the office scheduler, the technician charged with cleaning surgical instruments, and other medical office and hospital employees, can now assert a new right to refuse care based on their religious and moral convictions. Such an interpretation is potentially disruptive to the normal operations of a medical office or other health care facility and impede the provision of necessary care to patients.

Similarly, the Proposed Rule's definition of "referral" goes beyond any understanding of the term, allowing refusals to provide any information, "by any method, pertaining to a health care service, activity, or procedures[.]" This include information "related to availability, location, training, information resources, private or public funding or financing, or directions" that could help an individual to get the health care service they need.[4] Such an expansive definition could prevent patients from getting information about the availability of comprehensive health care options in their state. CMA believes that these overly broad definitions will result in denial of care and miscommunication to patients without meaningfully advancing physicians' rights of conscience.

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.

[2] Proposed Rule, 83 Fed. Reg. at 3923.
[3] *Id.*
[4] *Id.* at 3924.

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, impeding patients' access to needed health care services and information.

2. **CMA Opposes Discrimination in the Provision of Health Care and Supports Patient Access to Comprehensive Health Care.**

CMA is concerned that the Proposed Rule undermines anti-discrimination protections, particularly with regard to reproductive health, sexual orientation, and gender identity. Since 2012, the Office for Civil Rights has interpreted Section 1557 of the Affordable Care Act's[5] sex discrimination prohibition to extend to claims of discrimination based on gender identity or sex stereotypes and accepted such complaints for investigation. Section 1557's protections assist populations that have been most vulnerable to discrimination, including lesbian, gay, bisexual, and transgender individuals, and help provide those populations equal access to health care and health coverage. Such individuals experience discrimination in obtaining health care which lead to lack of preventative care or delayed care.[6] Section 1557 seeks to address factors that impact access to care for certain populations but does not force physicians to violate their medical judgment. Rather, covered entities, including insurers, must "apply the same neutral, nondiscriminatory criteria [used] for other conditions when the coverage determination is related to gender transition."[7]

California law explicitly prohibits discrimination based on sex, sexual orientation, or gender identity,[8] among other factors. California law provides that persons holding licenses under the provisions of the Business & Professions Code, such as physicians, are subject to disciplinary action for refusing, in whole or in part, or aiding or inciting another licensee to refuse to perform the licensed services to an "applicant" (patient) because of any characteristics under the Unruh Civil Rights Act, that is, the applicant's race, color, sex, religion, ancestry, disability, marital

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[5] 45 C.F.R. §§92.2, 92.206, 92.207.
[6] LAMBDA LEGAL, WHEN HEALTH CARE ISN'T CARING: LAMBDA LEGAL'S SURVEY ON DISCRIMINATION AGAINST LGBT PEOPLE AND PEOPLE LIVING WITH HIV (2010). *Forum: How Discrimination Damages Health Care in LGBTQ Communities*, NPR (March, 21, 2018), https://www.npr.org/sections/health-shots/2018/03/21/594030154/forum-how-discrimination-damages-health-in-lgbtq-communities
[7] Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31435 (proposed May 18, 2016) (to be codified at 45 C.F.R. pt. 92).
[8] *See generally*, CAL. CIV. CODE §51 (The Unruh Civil Rights Act) ("All persons within the jurisdiction of this state are free and equal, and no matter what their sex, race, color, religion, ancestry, national origin, disability, medical condition, genetic information, marital status, sexual orientation, citizenship, primary language, or immigration status are entitled to the full and equal accommodations, advantages, facilities, privileges, or services in all business establishments of every kind whatsoever."_

status, national origin, medical condition, sexual orientation, or genetic information.[9] The California Supreme Court has held that physicians' religious freedom and free speech rights do not exempt physicians from complying with the Unruh Act's prohibition against discrimination based on a person's sexual orientation.[10]

California law also prohibits discrimination by any person under any program that receives any financial assistance from the state.[11] Additionally, the California Insurance Gender Nondiscrimination Act (IGNA) prohibits a health plan and insurer from "refusing to enter into, cancel or decline to renew or reinstate a contract because of race, color, national origin, ancestry, religion, sex, marital status, sexual orientation, or age."[12] Sex includes both gender identity and gender expression.[13] The Proposed Rule lays the groundwork to preempt California laws that have been put into place to ensure that patients in the state have access to comprehensive health care. In addition, the Proposed Rule may also conflict with policies of agencies that accredit health care institutions. For example, the Joint Commission, which accredits and certifies nearly 21,000 facilities in the U.S., has required since 2011 that the nondiscrimination policy of every accredited facility protect transgender patients.[14] The Proposed Rule would conflict with existing state laws and accreditation requirements, creating legal confusion for California physicians.

3. CMA Supports Conscience Protections that Promote the Rights of Providers without Negatively Impacting Patient Care.

CMA policy has always sought to balance the rights of patients to access needed health care with the rights of physicians to exercise their conscience. Conscientious refusals occur most commonly in the field of reproductive medicine, and in many areas of the country patients face challenges in accessing reproductive healthcare.[15] Though CMA advocates for access to abortion

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[9] CAL. BUS. & PROF. CODE §125.6
[10] *North Coast Women's Care Medical Group, Inc. v. San Diego County Superior Court* (Benitez) 189 P.3d 959 (Cal. 2008).
[11] CAL. GOV. CODE §11135.
[12] CAL. HEALTH & SAFETY CODE §1365.5; CAL. INS. CODE §10140. *See also,* Dep't. of Managed Health Care, Gender Nondiscrimination Requirements, Letter No. 12-K (April 9, 2013), *available at* http://www.dmhc.ca.gov/Portals/0/LawsAndRegulations/DirectorsLettersAndOpinions/dl12k.pdf; CAL. CODE REGS. tit 10, § 2561.2.
[13] CAL. HEALTH & SAFETY CODE §1365.59(e).
[14] Joint Commission Standards RI.01.01.01, EP29.
[15] *See, e.g.* (2017), NAT'L WOMEN'S LAW CTR., REFUSALS TO PROVIDE HEALTH CARE THREATEN THE HEALTH AND LIVES OF PATIENTS NATIONWIDE (2017), *available at* https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/08/Refusal-to-Provide-Care.pdf; CATHERINE WEISS ET AL., AM. CIVIL LIBERTIES UNION, RELIGIOUS REFUSALS AND REPRODUCTIVE RIGHTS (2002), *available at* https://www.aclu.org/report/religious-refusals-and-reproductive-rights-report; JULIA KAYE ET AL., AM. CIVIL LIBERTIES UNION HEALTH CARE DENIED (2016), *available at* https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf; KIRA SHEPHERD ET AL., PUB. RIGHTS PRIVATE CONSCIENCE PROJECT, BEARING FAITH THE LIMITS OF CATHOLIC HEALTH CARE FOR WOMEN OF COLOR, 1 (2018), *available at* https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

under accepted ethical medical standards, CMA policy provides that no physician should be required to act against their moral principles. Similarly, while CMA supports the training of all OB/GYN residents and appropriate other residents in primary care specialties in the basic skills of performing abortions, CMA also supports the concept of choice for residents in training, allowing each resident to choose whether or not to participate in elective abortions. CMA has prioritized the physician-patient relationship, and seeks to ensure that health care systems do not interfere with physician-patient communications on reproductive health care, and that access to reproductive health care services is preserved. These principles properly preserve the conscience rights of physicians and their role in providing patient care.

American Medical Association (AMA) policy also recognizes that "at times the expectation that physicians will put patients [sic] needs and preferences first may be in tension with the need to sustain moral integrity and continuity across both personal and professional life."[16] However, it recognizes that this freedom is not unlimited: "[p]hysicians 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."[17] Physicians must consider the harm to patients from refusing to provide treatment and whether the patient will be able to access needed treatment from another physician. The AMA also recognizes that physicians must clearly communicate to the patient which services a physician will or will not provide before entering into a physician-patient relationship, as well as inform patients about all relevant options for treatment, even those to which the physician has conscientious objections.[18]

The Committee on Ethics of American College of Obstetricians and Gynecologists (AGOG) has adopted a number of recommendations that "maximize respect for health care professionals' conscience without compromising the health and well-being of the women they serve."[19] Similar to the AMA opinion, the ACOG opinion recommends that physicians give patients accurate and unbiased information, as well as clearly communicate any moral objections they may have. The ACOG opinion further recognizes that physicians have a duty to refer their patients to other providers for services they cannot provide due to reasons of conscience, and to provide such services in an emergency situation where a referral is impossible. ACOG concludes: "Lawmakers should advance policies that balance protection of providers' consciences with the critical goal of ensuring timely, effective, evidence-based and safe access to all women seeking

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[16] American Medical Association, Policy E-1.1.7, "Physician Exercise of Conscience." *Code of Medical Ethics.* Adopted 2016.
[17] *Id.*
[18] *Id.*
[19] American College of Obstetricians and Gynecologists (ACOG*), The Limits of Conscientious Refusal in Reproductive Medicine*, ACOG Committee on Ethics Opinion Number 385, 5. Adopted November 2007. Reaffirmed 2016).

reproductive services."[20] The Proposed Rule falls short of this aim and the principles of CMA and AMA policies by expansively interpreting existing protections without properly balancing the needs of patients and physicians.

4. Current Federal and State Law Protect the Rights of Physicians and Patients

Existing federal and state laws protect the rights of physicians by allowing states to take nuanced positions on the protecting the conscience rights of health care workers, particularly with regard to abortion, sterilization, and aid-in-dying. Section 88.3 of the rule incorporates the extensive existing law protecting the conscience rights of health care providers and institutions, including, among others, the Church Amendments,[21] the Coats-Snowe Amendment[22] and the Weldon Amendment.[23] In addition, the Affordable Care Act includes health care provider conscience protections within the health insurance exchange system. The law provides that "no qualified health plan offered through an exchange may discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions."[24] Regulations implementing the Act further provide that existing laws protecting religious freedom and belief, including provider conscience laws, the Religious Freedom Restoration Act, the ACA's provisions regarding abortion services, and the ACA's preventive health services regulations, continue to apply.[25]

The Proposed Rule's provisions are not only redundant but will have a chilling effect on the enforcement of and passage of state laws that protect access to health care. The preamble of the Proposed Rule discusses at length state laws that the Department finds objectionable, including California's Department of Managed Health Care's requirement that health insurers must cover abortion services.[26] As mentioned in the Proposed Rule, California law requires most health

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[20] *Id.*
[21] The Church Amendments, 42 U.S.C. § 300a-7 (2018).
[22] Public Health Service Act, 42 U.S.C. § 238n (2018).
[23] The Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009).
[24] 42 U.S.C. §18023 (2018).
[25] 45 C.F.R. §92.2(b)(2).
[26] *See* Proposed Rule, *supra* note 1, at 3888-89. The health insurers filed a complaint, and OCR found there was no violation of the Weldon Amendment. Letter from OCR Director to Complainants (June 21, 2016), *available at* http://www.adfmedia.org/files/ CDMHCInvestigationClosureLetter.pdf.

plans to cover abortion services,[27] as well as all FDA-approved methods of contraception without cost-sharing.[28]

California law already properly balances the rights of physicians and their patients. California has extensive protections for health care providers that do not want to participate in abortion for moral, ethical, or religious reasons, while protecting women who need emergency care.[29] While religiously affiliated hospitals can also exercise their rights under this provision, they must post a notice of their refusal policy so that patients are properly informed about the care they will receive.[30] California law protects the rights of physicians to "decline to comply with an individual health care instruction of health care decision for reasons of conscience"[31] Additionally, California law allows a religious employer to request an exemption from generally applicable requirements for contraceptive coverage in health plans.[32] Increasing the number of federal rules in this area is both unnecessary and will create confusion for providers and their patients.

CMA has sought to ensure that physicians' rights are protected even in an evolving health care landscape. For example, the End of Life Option Act, passed in 2015, permits individuals suffering from a terminal disease to request life-ending medication under certain circumstances.[33] This bill contains extensive provisions ensuring that health care providers with conscientious objections are not subject to any professional sanctions or legal liability for refusing to participate in actions related to the Act's activities.[34] Adding a confusing and unnecessary layer of federal regulations may prevent states from successfully passing and implementing their own conscience protections. The Proposed Rule would impede the ability of states to craft nuanced solutions, such as those found in the End of Life Option Act, that protect the rights of providers in accordance with states' own values.

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[27] See, e.g., Letter from Michelle Rouillard, Director, Dep't of Managed Health Care, to Mark Morgan, Cal. President, Anthem Blue Cross (Aug. 22, 2014), *available at* https://www.dmhc.ca.gov/portals/0/082214letters/abc082214.pdf. *See also* Cal. Dep't of Health Care Servs., Letter to all Medi-Cal Managed Care Health Plans, All Plan Letter No. 15-020: Abortion Services (Sept. 30, 2015), http://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2015/APL15- 020.pdf; Cal. Dep't of Health Care Srvs., Medi-Cal Medical Services Provider Manual Ch. Abortions at p. 1.
[28] CAL. WELF. AND INST. CODE §14132; CAL. INS. CODE §10123.196; CAL HEALTH AND SAFETY CODE § 1367.25.
[29] CAL. HEALTH & SAFETY CODE §123420.
[30] *Id.*
[31] CAL. PROBATE CODE §4734.
[32] CAL. HEALTH & SAFETY CODE §1367.25
[33] Cal. S.B. 128, Stats. 2016, ch. 1.
[34] CAL. HEALTH AND SAFETY CODE §§ 443.14-443.15.

5. CMA Opposes Unnecessary Administrative Burdens on Physicians

Finally, sections 88.4 through 88.6 of the Proposed Rule impose significant new requirements on physicians, who already face an increasing number of administrative burdens due to federal law and various existing federal program requirements. Under the Proposed Rule, physicians must submit certifications and assurance, post lengthy required notices on their website and in conspicuous physical locations, maintain detailed records, and generally ensure compliance with the new rule.[35] The Department conducts an analysis of the estimated burdens for the Proposed Rule[36] in which it looks at the implementation costs for providers. The estimate includes time for providers to familiarize themselves with the Rule and the cost to hire an attorney to review it; at least four hours of staff time to review the assurance and certification language and underlying laws; four hours of staff time to review policies and procedures and the cost of hiring an attorney to assist in the review; and the costs of printing the notice in any paper documents. These costs are burdensome enough in themselves; this analysis fails to fully consider, moreover, the significant time and resources it takes to continuously implement and enforce such a Proposed Rule, and the numerous other administrative and regulatory burdens physicians already face and the degree to which each additional burden detracts from a physician's clinical practice.[37] Excessive administrative tasks imposed on physicians divert time and focus from providing actual care to patients and improving quality, and may prevent patients from receiving timely and appropriate care. CMA opposes adding additional burdens to physicians that do nothing to improve the quality of patient care and create yet more regulatory hurdles for the practice of medicine.

As discussed above and in the Proposed Rule, federal and state laws already protect health care provider conscience rights.[38] These long-standing provisions of federal law provide sufficient protection to physicians seeking to exercise their conscience rights. Instead of guaranteeing additional protection, this Proposed Rule would negatively impact patient access to care, sanction discrimination in health care settings, and impose increased administrative burdens on physicians, including paperwork requirements and significant staff time with no demonstrable benefit to the provision of health care.

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[35] Proposed Rule, *supra* note 1, at 3928-30.
[36] *Id.* at 3912-15.
[37] *See, e.g* Jessica Davis, *JAMA: EHRs fail to reduce administrative billing costs,* HEALTHCARE IT NEWS (Feb. 21, 2018), http://www.healthcareitnews.com/news/jama-ehrs-fail-reduce-administrative-billing-costs; Alexi A. Wright and Ingrid T. Katz. *Beyond Burnout – Redesigning Care to Restore Meaning and Sanity for Physicians*, 378 NEW ENG. J. OF MEDICINE 308 (Jan. 2018), http://www.nejm.org/doi/full/10.1056/NEJMp1716845
[38] The Church Amendments, 42 U.S.C. §§300a-7 *et seq.* (2018); Public Health Service Act, 42 U.S.C. §236(n)); and the Weldon Amendment (Consolidated Appropriations Act, 2012, Pub.L. No. 112-74, 125 Stat. 786).

Conclusion

Thank you for your consideration. If you have questions, please contact me at jrubenstein@cmanet.org or (916) 551-2554.

Sincerely,

Jessica Rubenstein
Associate Director
Center for Health Policy
California Medical Association

Exhibit 42

California Pan-Ethnic Health Network

Advancing health justice and equity for 25 years

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March 27, 2018

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: RIN 945-ZA03
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

By Electronic Submission

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, Proposed Rule (RIN 0945-ZA03 and Docket No. HHS-OCR-2018-002

To whom it may concern:

I am writing on behalf of the California Pan-Ethnic Health Network (CPEHN) in response to the request for public comment on the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26.[1] CPEHN's mission is to improve access to health care and eliminate health disparities by advocating for public policies and sufficient resources to address the health needs of communities of color.

The proposed rule puts Californians at great risk: The rule as proposed introduces broad and poorly defined language to the existing law that already provides ample protections to health care workers that refuse to participate in a health care service to which they have a moral objection. This could result in medical care that fails to comply with established medical practice guidelines, negating long-standing principles of informed consent, undermining the ability of health facilities to provide care in an orderly and efficient manner. As written, the law could allow anyone such as providers, behavioral therapists, pharmacists, hospitals, insurers or other health care entities to be misled into believing that they may refuse on religious grounds to administer an HIV test to a gay or bisexual man or to provide mental health counseling to a transgender woman who may be at risk of self-harm. We know that this type of unjust denial of care has occurred, such as a California physician's denial of donor insemination to a lesbian couple, even though the doctor routinely provided the same service to

[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].

heterosexual couples. [2]

The proposed rule prioritizes the rights of health care providers over the rights of individuals: The rule puts the needs of the provider above the needs of the patient, failing even to clarify exceptions for emergency care. Under the new rule, providers would not even be required to notify the patient that they are exercising their religious or moral exemption. The language if adopted, would allow any licensed health professional to refuse treatment or referral for vulnerable clients even if it could provide the duty of care. In the event of a harmful consequence (e.g. suicide, self-injury, or harm to others) the provider could claim no responsibility by invoking their rights, thereby rendering the entire anti-discrimination clause enforceable.

Existing law already provides ample protection for health care providers who want to exercise their personal beliefs: Existing refusal of care laws (such as for abortion and sterilization services) are already being used across the country to deny patients the care they need.[3] The proposed rule attempts to expand on these laws in numerous ways that are directly contrary to the stated purpose of the existing laws including in instances where there no scientific evidence that care should be denied. For example, certain religiously-affiliated hospitals and individual clinicians have refused to provide rape victims with emergency contraception to prevent pregnancy[4] based on the belief that it can cause an abortion, even though there is no scientific evidence that this is the case.

The new rule will result in greater health disparities: The regulations fail to account for the significant burden that will be imposed on patients, a burden that will fall disproportionately and most harshly on women, people of color, people living with disabilities, and Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ) individuals. These communities already experience severe health disparities and discrimination. In California for example, Latinos and African Americans have twice the prevalence of type 2 diabetes and are twice as likely to die from the disease. These types of health disparities are often compounded for people of color who hold multiple intersectional identities (ie. women, individuals living with disabilities, LGBTQ, people living in rural communities). For example, LGBTQ and HIV-affected people of color are more likely to require medical attention as a result of hate violence when compared to other survivors. In California, African-American women are more likely to die in childbirth and less likely to access critical post-partem care. Rather than encouraging health care providers to find additional justifications for the denial of critical health care services, HHS should focus on its mission of eliminating barriers to care for those who need it the most.

The proposed rule is unwarranted and will make it impossible for OCR to do its job of ensuring patients are protected from discrimination: The proposed rule is a giant step backwards in preventing discrimination in health care settings. By issuing the proposed rule

[2] Hardaway, Lisa, *Settlement Reached in Case of Lambda Legal Lesbian Client Denied Infertility Treatment by Christian Fundamentalist Doctors,* Lambda Legal, September 29, 2009, accessed at https://www.lambdalegal.org/news/ca_20090929_settlement-reached.
[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/; Uttley, L., et al, *Miscarriage of Medicine,* MergerWatch and the ACLU (2013), https://www.aclu.org/report/miscarriage-medicine.
[4] Erdely, Sabrina, *Doctors' beliefs can hinder patient care*, SELF magazine, June 22, 2007, accessed at http://www.nbcnews.com/id/19190916/print/1/displaymode/1098/

along with the newly created "Conscience and Religious Freedom Division," the Department seeks to 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. As stated in the NPRM itself, between 2008 and November 2016, the Office for Civil Rights received 10 complaints alleging violations of federal religious refusal laws; OCR received an additional 34 similar complaints between November 2016 and January 2018. By comparison, during a similar time period from fall 2016 to fall 2017, OCR received more than 30,000 complaints alleging either civil rights or HIPAA violations. These numbers demonstrate that rulemaking to enhance enforcement authority over religious refusal laws is not warranted.

The proposed rule tramples on states' and local governments' efforts to protect patients' health and safety, including their nondiscrimination laws: The proposed rule will have a chilling effect on the enforcement and passage of state laws that protect access to health care and prevent discrimination against individuals seeking medical care. 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.

For all these reasons, we urge the administration to put patients first, and withdraw the proposed regulations.

Sincerely,

Caroline B. Sanders, MPP
Director Policy Analysis, CPEHN

Exhibit 43

March 27, 2018

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945–ZA03
Hubert H. Humphrey Building
200 Independence Avenue SW
Room 509F
Washington, DC 20201

RE: RIN 0945–ZA03

To Whom It May Concern:

The California Primary Care Association (CPCA) represents over 1,300 not-for-profit community clinics and health centers (CCHCs) in California that provide comprehensive, high quality health care services to low-income, uninsured, and underserved Californians. CPCA member health centers provide nearly 20 million patient encounters to over 6.2 million patients each year. CCHC patients are primarily low income, often speak a primary language other than English, come from diverse cultural and ethnic backgrounds, and often have a limited choice of providers due to language, culture, geographic, or income barriers. The potential impact of this regulation will fall heavily on those patients who already face enormous barriers to getting the care they need, making access even harder for vulnerable groups such as those seeking end-of-life care, persons affected by HIV/AIDS, women, persons of color, and lesbian, gay, bisexual, and transgender individuals.

I. The Proposed Rule is Contrary to the Mission of CCHCs

CPCA strongly believes that employers, including health centers, should maintain the right to hire individuals who are able to meet the requirements of their job description, including the provision of the full spectrum of care needed by CCHC patients. Health centers must - by mission and design - conduct their business in a way that meets the health needs of their specific underserved communities. Any efforts by providers or other health care personnel to limit the information and access that patients are entitled to receive, even when the CCHC may not provide those services itself, is incompatible with the mission and function of the organization. As primary care providers who care for patients and communities, we must maintain the ability of our health centers to employ individuals who further our mission of providing comprehensive primary and preventive care and furthering important public health goals.

Nearly all CPCA member health centers have a consumer-majority board of directors that must have the discretion to build a facility and company culture that reflects the core values and meets the health needs of their communities. Forcing health centers to employ practitioners regardless of their aversion to clear, evidence-based public health priorities, such as vaccinations, contraceptives, mental health treatment, and other services covered under this rule, contradicts the spirit and the efficacy of the community health center program.

II. The Proposed Rule Undermines Patient Safety and Medical Standards of Care

The language of this rule is broad and ambiguous enough that medical staff may interpret the regulation to indicate that they can not only refuse, but decline to tell the patient where he would be able to obtain lifesaving services or even inform patients of their treatment options. This puts the health of the patient, and potentially that of others, at risk. Further, the proposed rule threatens informed consent, a necessary principle of patient-centered decision-making. Informed consent relies on disclosure of medically accurate information by providers so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether. This right relies on two factors: access to relevant and medically-accurate information about treatment choices and alternatives, and provider guidance based on generally accepted standards of practice. Both factors make trust between patients and health care professionals a critical component of quality of care. However, this proposed rule suggests that a medical provider or staff could refuse to offer information, if that information might be used to obtain a service to which the refuser objects, allowing staff to impose their own religious beliefs on their patients by withholding vital information about treatment options. Such an attenuated relationship to informed consent could result in withholding information that would violate medical standards of care.

III. The Office of Civil Rights Should Prevent Discrimination

CPCA appreciates and strongly supports the Office of Civil Rights' (OCR) efforts to prevent discrimination. Always, health centers and our employees act without regard to race, religion, ethnicity, gender identity, or sexual orientation. However, this proposed rule, will in fact discriminate and deny care to disadvantaged and vulnerable populations. We fear this proposed rule could actually individuals to discriminate against those seeking essential care. **For these reasons, CPCA stands firmly against this proposed rule.**

Thank you for the opportunity to comment.

Sincerely,

Andie Patterson
Director of Government Affairs
California Primary Care Association

Exhibit 44

CALLEN-LORDE

March 27, 2018

Attention: Conscience NPRM

U.S. Department of Health and Human Services
Office for Civil Rights
RIN 0945-ZA03
Hubert H. Humphrey Building, Room 209F
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Azar:

On behalf of Callen-Lorde Community Health Center, we submit these comments to the federal Department of Health and Human Services ("Department") and its Office for Civil Rights ("OCR") in **strong opposition to the proposed regulation entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority**."[1]

Callen-Lorde is a growing federally qualified health center (FQHC) with three locations in New York City and a mission to serve lesbian, gay, bisexual and transgender communities and people living with HIV in addition to its geographic service areas. As a community-based health center, Callen-Lorde is open to all regardless of ability to pay. Callen-Lorde provides primary care, dental care, behavioral health care, care coordination and case management, as well as health education services, and its current primary care patient base nearly 18,000 people, approximately 25 percent of whom are patients of transgender or gender non-binary experience and 20% of whom are people living with HIV.

The regulations as proposed would introduce broad and poorly defined language to the existing law that already provides ample protection for the ability of health care providers to refuse to participate in a health care service to which they have moral or religious objections. While the proposed regulations purport to provide clarity and guidance in implementing existing federal religious exemptions, in reality they are vague and confusing. The proposed rule creates the potential for exposing patients to medical care that fails to comply with established medical practice guidelines, negating long-standing principles of informed consent, and undermines the ability of health facilities to provide care in an orderly and efficient manner.

Most important, the regulations fail to account for the significant burden that will be imposed on patients, a burden that will fall disproportionately and most harshly on women, people of color, people living with disabilities, and Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ) individuals. These communities already experience severe health disparities and discrimination, conditions that will be exacerbated by the proposed rule, possibly ending in in poorer health outcomes. By issuing the proposed rule along with the newly created "Conscience and Religious Freedom Division," the Department seeks to 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

[1] U.S. Dept. of Health and Human Serv., Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880-3931 (Jan. 26, 2018) (hereinafter "proposed rule").

the care they need. For these reasons, the National Health Law Program calls on the Department and OCR to withdraw the proposed rule in its entirety.

I. Under the guise of civil rights, the proposed rule seeks to deny medically necessary care

Civil rights laws and Constitutional guarantees, such as due process and equal protection, are designed to ensure full participation in civil society. The proposed rule, while cloaked in the language of non-discrimination, is designed to deny care and exclude disadvantaged and vulnerable populations. The adverse consequences of health care refusals and other forms of discrimination are well documented. As the Department stated in its proposed rulemaking for § 1557,

> "[e]qual access for all individuals without discrimination is essential to achieving" the ACA's aim to expand access to health care and health coverage for all, as "discrimination in the health care context can often...exacerbate existing health disparities in underserved communities."[2]

The Department and OCR have an important role to play in ensuring equal health opportunity and ending discriminatory practices that contribute to health disparities. Yet, this proposed rule represents a dramatic, harmful, and unwarranted departure from OCR's historic and key mission. The proposed rule appropriates language from civil rights statutes and regulations that were designed to improve access to health care and applies that language to deny medically necessary care.

The federal government argues that robust religious refusals, as implemented by this proposed rule, will facilitate open and honest conversations between patients and physicians.[3] As an outcome of this rule, the government believes that patients, particularly those who are "minorities", including those who identify as people of faith, will face fewer obstacles in accessing care.[4] The proposed rule will not achieve these outcomes. Instead, the proposed rule will increase barriers to care, harm patients by allowing health care professionals to ignore established medical guidelines, and undermine open communication between providers and patients. The harm caused by this proposed rule will fall hardest on those most in need of care.

II. The expansion of religious refusals under the proposed rule will disproportionately harm communities who already lack access to care

Women, individuals living with disabilities, LGBTQ persons, people living in rural communities, and people of color face severe health and health care disparities, and these disparities are compounded for individuals who hold these multiple identities. For example, among adult women, 15.2 percent of those who identified as lesbian or gay reported being unable to obtain medical care in the last year due to cost, as compared to 9.6 percent of straight individuals.[5] Women of color experience health

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[2] Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172, 54,194 (Sept. 8, 2015) (codified at 45 C.F.R. pt. 2).
[3] 83 Fed. Reg. 3917.
[4] *Id.*
[5] Brian P. Ward et al., *Sexual Orientation and Health Among U.S. Adults: National Health Interview Survey*, NAT'L CTR. FOR HEALTH STATISTICS, 2013 9 (2014), https://www.cdc.gov/nchs/data/nhsr/nhsr077.pdf.

care disparities such as high rates of cervical cancer and are disproportionately impacted by HIV.[6] Meanwhile, people of color in rural America are more likely to live in an area with a shortage of health professionals, with 83% of majority-Black counties and 81% of majority-Latino/a counties designated by the federal Health Resources and Services Administration (HRSA) as Health Professional Shortage Areas (HPSAs).

The expansion of refusals as proposed under this rule will exacerbate these disparities and undermine the ability of these individuals to access comprehensive and unbiased health care, including sexual and reproductive health information and services. Any efforts by providers or other health care personnel to limit the information and access that patients are entitled to receive, even when the organization may not provide those services itself, is incompatible with true consumer choice and individual decision making.

As a federally-qualified healthcare facility that was born out of the Stonewall era, Callen-Lorde knows firsthand the impact stigma and discrimination has on the health outcomes of populations who have been historically marginalized in healthcare and society. For the purposes of these comments, we will focus our response on the impact these proposed regulations will have on the LGBTQ community and LGBTQ health equity.

a. The proposed rule would harm LGBTQ Communities who continue to face rampant discrimination and health disparities

The proposed rule will compound the barriers to care that LGBTQ individuals face, particularly the effects of ongoing and pervasive discrimination by potentially allowing providers to refuse to provide services and information vital to LGBTQ health.

LGBTQ people continue to face discrimination in many areas of their lives, including health care, on the basis of their sexual orientation and gender identity. The Department's Healthy People 2020 initiative recognizes, "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights."[7] LGBTQ people still face discrimination in a wide variety of services affecting access to health care, including reproductive services, adoption and foster care services, child care, homeless shelters, and transportation services – as well as physical and mental health care services.[8] In a recent study published in *Health Affairs*, researchers examined the

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[6] In 2014, Latinas had the highest rates of contracting cervical cancer and Black women had the highest death rates. *Cervical Cancer Rates By Rates and Ethnicity*, CTRS. FOR DISEASE CONTROL & PREVENTION, (Jun. 19, 2017), https://www.cdc.gov/cancer/cervical/statistics/race.htm.;At the end of 2014, of the total number of women diagnosed with HIV, 60 percent were Black. *HIV Among Women,* CTRS. FOR DISEASE CONTROL & PREVENTION, Nov. 17, 2017, https://www.cdc.gov/hiv/group/gender/women/index.html.
[7] *Healthy People 2020, Lesbian, Gay, Bisexual, and Transgender Health*, U.S. DEPT. HEALTH & HUMAN SERV., https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health, (last accessed on Mar. 8, 2018).
[8] HUMAN RIGHTS WATCH, *All We want is Equality: Religious Exemptions and Discrimination against LGBT People in the United States*, (Feb. 2018), https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people.

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intersection of gender identity, sexual orientation, race, and economic factors in health care access.[9] They concluded that discrimination as well as insensitivity or disrespect on the part of health care providers were key barriers to health care access and that increasing efforts to provide culturally sensitive services would help close the gaps in health care access.[10]

b. Discrimination against the transgender community

Discrimination based on gender identity, gender expression, gender transition, transgender status, or sex-based stereotypes is necessarily a form of sex discrimination.[11] Numerous federal courts have found that federal sex discrimination statutes reach these forms of gender-based discrimination.[12] In 2012, the Equal Employment Opportunity Commission (EEOC) likewise held that "intentional discrimination against a transgender individual because that person is transgender is, by definition, discrimination based on sex and such discrimination therefore violates Title VII."[13]

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[9] Ning Hsieh and Matt Ruther, HEALTH AFFAIRS, *Despite Increased Insurance Coverage, Nonwhite Sexual Minorities Still Experience Disparities In Access To Care* (Oct. 2017) 1786–1794.
[10] *Id.*
[11] *See, e.g., EEOC v. R.G. & G.R. Harris Funeral Homes*, No. 16-2424 (6th Cir. Mar. 7, 2018); *Whitaker v. Kenosha Unified Sch. Dist.*, 858 F.3d 1034 (7th Cir. 2017) (Title IX and Equal Protection Clause); Doddsv. U.S. Dep't of Educ., 845 F.3d 217 (6th Cir. 2016) (Title IX and Equal Protection Clause); *Barnes v. City of Cincinnati*, 401 F.3d 729 (6th Cir. 2005) (Title VII of the 1964 Civil Rights Act); Smith v. City of Salem, 378 F.3d 566 (6th Cir. 2004) (Title VII); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213 (1st Cir. 2000) (Equal Credit Opportunity Act); *A.H. ex rel. Handling v. Minersville Area School District*, 3:17-CV-391, 2017 WL 5632662 (M.D. Pa. Nov. 22, 2017) (Title IX and Equal Protection Clause); *Stone v. Trump*, ---F.Supp.3d ---, No. 17–2459 (D. Md. Nov. 21, 2017) (Equal Protection Clause); Doe v. Trump, ---F.Supp.3d ---, 2017 WL 4873042 (D.D.C. Oct. 30, 2017) (Equal Protection Clause); *Prescott v. Rady Children's Hospital-San Diego*, ---F.Supp.3d ---, 2017 WL 4310756 (S.D. Cal. Sept. 27, 2017) (Section 1557); *E.E.O.C. v. Rent-a-Center East, Inc.*, ---F.Supp.3d ---, 2017 WL 4021130 (C.D. Ill. Sept. 8, 2017) (Title VII); *Brown v. Dept. of Health and Hum. Serv.*, No. 8:16DCV569, 2017 WL 2414567 (D. Neb. June 2, 2017) (Equal Protection Clause); *Smith v. Avanti*, 249 F.Supp.3d 1194 (D. Colo. 2017) (Fair Housing Act); *Students & Parents for Privacy v. U.S. Dep't of Educ.*, No. 16-cv-4945, 2016 WL 6134121 (N.D. Ill. Oct. 18, 2016) (Title IX); *Mickens v. Gen. Elec. Co.* No. 16-603, 2016 WL 7015665 (W.D. Ky. Nov. 29, 2016) (Title VII); *Fabian v. Hosp. of Cent. Conn.*, 172 F.Supp.3d 509 (D. Conn. 2016) (Title VII); *Cruz v. Zucker*, 195 F.Supp.3d 554 (S.D.N.Y. Jul. 5, 2016) (Section 1557); *Doe v. State of Ariz.*, No. CV-15-02399-PHX-DGC, 2016 WL 1089743 (D. Ariz. Mar. 21, 2016) (Title VII); *Dawson v. H&H Elec., Inc.*, No. 4:14CV00583 SWW, 2015 WL 5437101 (E.D. Ark. Sept. 15, 2015) (Title VII); *U.S. v. S.E. Okla. State Univ.*, No. CIV–15–324–C, 2015 WL 4606079 (W.D. Okla. 2015) (Title VII); *Rumble v. Fairview Health Serv.*, No. 14–cv–2037, 2015 WL 1197415 (D. Minn. Mar. 16, 2015) (Section 1557); *Finkle v. Howard Cty.*, 12 F.Supp.3d 780 (D. Md. 2014) (Title VII); *Schroer v. Billington*, 577 F. Supp. 2d 293 (D.D.C. 2008) (Title VII); *Lopez v. River Oaks Imaging & Diagnostic Grp.*, Inc., 542 F.Supp.2d 653 (S.D. Tex. 2008) (Title VII); *Mitchell v. Axcan Scandipharm,* Inc., No. Civ.A. 05-243, 2006 WL 456173 (W.D. Pa. 2006) (Title VII); *Tronettiv. Healthnet Lakeshore Hosp.*, No. 03–CV–0375E, 2003 WL 22757935 (W.D.N.Y. Sept. 26, 2003) (Title VII).
[12] *See, e.g., Smith v. City of Salem*, 378 F.3d 566, 572-75 (6th Cir. 2004); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213, 215-16 (1st Cir. 2000) (Equal Credit Opportunity Act); *Schwenk v. Hartford*, 204 F.3d 1187 (9th Cir. 2000) (Gender Motivated Violence Act). *See also* Statement of Interest of the United States at 14, *Jamal v. Saks*, No. 4:14-cv-02782 (S.D. Tex. Jan. 26, 2015).
[13] *Macy v. Holder*, E.E.O.C. App. No. 0120120821, 2012 WL 1435995, *12 (Apr. 20, 2012).

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Twenty-nine percent of transgender individuals were refused to be seen by a health care provider on the basis of their perceived or actual gender identity and 29 percent experienced unwanted physical contact from a health care provider.[14] Additionally, the 2015 U.S. Transgender Survey found that 23 percent respondents did not see a provider for needed health care because of fears of mistreatment or discrimination.[15]

Data obtained by Center for American Progress (CAP) under a FOIA request indicates the Department's enforcement was effective in resolving issues of anti-LGBTQ discrimination. CAP received information on closed complaints of discrimination based on sexual orientation, sexual orientation-related sex stereotyping, and gender identity that were filed with the Department under Section 1557 of the ACA from 2012 through 2016.

- "In approximately 30% of these claims, patients alleged denial of care or insurance coverage simply because of their gender identity – not related to gender transition."
- "Approximately 20% of the claims were for misgendering or other derogatory language."
- "Patients denied care due to their gender identity or transgender status included a transgender woman denied a mammogram and a transgender man refused a screening for a urinary tract infection."[16]

As proposed, the rule could allow religiously affiliated hospitals to not only refuse to provide transition related treatment for transgender people, but to also deny surgeons who otherwise have admitting privileges to provide transition related surgery in the hospital. Transition-related care is not only medically necessary, but for many transgender people it is lifesaving.

Callen-Lorde's very existence is a response to provider and systemic discrimination in healthcare as experienced by LGBTQ individuals and communities. So profound was the need for non-judgmental, quality primary care for LGBTQ populations, that we created our own center. Now, nearly 50 years later – when so many human and civil rights advances having been made – LGB and TGNB people still are being mistreated by providers. Sadly, Callen-Lorde's capacity to serve its communities is consistently being stretched. We firmly believe that the care we provide should be the norm and that true liberation will only come when the LGBTQ community and our families can adequately access culturally competent and comprehensive health care in all forms.

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[14] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR. FOR AMERICAN PROGRESS, (Jan. 18, 2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/?link_id=2&can_id=d90c309ac9b5a0fa50d294d0b1cdf0b2&source=email-rx-for-discrimination&email_referrer=&email_subject=rx-for-discrimination.

[15] NAT'L CTR. FOR TRANSGENDER EQUALITY, *The Report of the 2015 U.S. Transgender Survey* 5 (2016), *available at* https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf [hereinafter *2015 U.S. Transgender Survey*].

[16] Sharita Gruberg & Frank J. Bewkes, Center for American Progress, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial* (March 7, 2018), *available at* https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/.

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In the weeks leading up to the deadline for these comments, Callen-Lorde administered a short on-line survey to its patients, staff and community members. The survey confirmed what we know already: **LGB and TBNB individuals still face discrimination in health care and are denied care as a result.** We surveyed 58 individuals ranging in age from 22- 83 years old and more than 20 percent of respondents indicated that they either may have – or were – denied care by a provider because of the provider's religious or moral objections.

A select few of the written testimonies pulled from the survey are included in these comments.

Testimonies of Transgender Discrimination

Kyle, 22-year-old transgender man and Callen-Lorde staff person stated: ***"I have had psychiatrists refuse to see me because they are uncomfortable with my gender identity and transition. I also had a primary care provider who delayed referral to transition specialists for the same reason. It was very distressing to have my transition delayed and feel like my provider isn't there to help me progress. The psychiatrist denying care makes me worried about mental health professionals more generally and have to be very careful when seeking mental health services. As a person of transgender experience, if I saw signs up in health practices notifying patients of their ability to discriminate if they choose, I would be very hesitant to return. I would feel like I had no protection and a chance of not receiving adequate healthcare."***

Aaron, a, 29 transgender man and patient of Callen-Lorde stated: ***"Where I grew up I could not find a provider to prescribe me hormones and during high school I was sent for a psych ER visit for suicidal ideation. One of the clinicians refused to see me and none of the hospital staff knew what transgender was. This was in 2005 in rural New Jersey. I did not receive treatment for my gender dysphoria and depression for many years because there were no providers who would work with me."***

Anonymous, 25 gender non-conforming person, stated: ***"Doctors would either completely avoid my gender or would tell me they didn't "understand it" and to go find a place that does. I was scared by that and never followed up on a different doctor until much later. Freedom of Speech doesn't mean freedom to oppress or discriminate."***

c. Discrimination Based Upon Sexual Orientation

Many LGBTQ people lack insurance and providers are not competent in health care issues and obstacles that the LGBTQ community experiences.[17] LGBTQ people still face discrimination. According to one survey, 8 percent of lesbian, gay, bisexual, and queer individuals had an experience within the year prior to the survey where a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation and 7 percent experienced unwanted physical contact and violence from a health care provider.[18]

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[17] Medical schools often do not provide instruction about LGBTQ health concerns that are not related to HIV/AIDS. Jen Kates et al., *Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender Individuals in the U.S*, KAISER FAMILY FOUND.12 (2017), http://files.kff.org/attachment/Issue-Brief-Health-and-Access-to-Care-and-Coverage-for-LGBT-Individuals-in-the-US.
[18] Mirza, *supra* note 34.

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Fear of discrimination causes many LGB people to avoid seeking health care, and, when they do seek care, LGB people are frequently not treated with the respect that all patients deserve. The study "When Health Care Isn't Caring" found that 56 percent of LGB people reported experiencing discrimination from health care providers – including refusals of care, harsh language, or even physical abuse – because of their sexual orientation.[19] Almost ten percent of LGB respondents reported that they had been denied necessary health care expressly because of their sexual orientation.[20] Delay and avoidance of care due to fear of discrimination compound the significant health disparities that affect the lesbian, gay, and bisexual population. These disparities include:

- LGB individuals are more likely than heterosexuals to rate their health as poor, have more chronic conditions, and have higher prevalence and earlier onset of disabilities.[21]
- Lesbian and bisexual women report poorer overall physical health than heterosexual women.[22]
- Gay and bisexual men report more cancer diagnoses and lower survival rates, higher rates of cardiovascular disease and risk factors, as well as higher total numbers of acute and chronic health conditions.[23]
- Gay and bisexual men and other men who have sex with men (MSM) accounted for more than half (56 percent) of all people living with HIV in the United States, and more than two-thirds (70 percent) of new HIV infections.[24]
- Bisexual people face significant health disparities, including increased risk of mental health issues and some types of cancer.[25]

Testimonies of Sexual Orientation Discrimination

> Anonymous, 25-year-old cisgender female, stated ***"Doctor refused to give me an IUD because I am unmarried. I told her I wasn't trying to prevent a pregnancy because I'm a lesbian, but that I wanted the IUD to control painful periods. She told me she couldn't see me as a patient anymore. Luckily I found another provider relatively easily, but it was very upsetting to hear that my doctor refused to see me because of my sexuality."***

This discrimination affects not only the mental health and physical health of LGBTQ people, but that of their families as well. One pediatrician in Alabama reported that "we often see kids who haven't seen a pediatrician in 5, 6, 7 years, because of fear of being judged, on the part of either their

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[19] LAMBDA LEGAL, *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination Against LGBT People and People with HIV* 5 (2010), *available at* .http://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf.
[20] *Id.*
[21] David J. Lick, Laura E. Durso & Kerri L. Johnson, *Minority Stress and Physical Health Among Sexual Minorities*, 8 PERS. ON PSYCHOL. SCI. 521 (2013), *available at* http://williamsinstitute.law.ucla.edu/research/health-and-hiv-aids/minority-stress-and-physical-health-among-sexual-minorities/.
[22] *Id.*
[23] *Id.*
[24] CTRS FOR DISEASE CONTROL & PREVENTION, *CDC Fact Sheet: HIV Among Gay and Bisexual Men* 1(Feb. 2017), https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/cdc-msm-508.pdf.
[25] HUMAN RIGHTS CAMPAIGN ET AL., *Health Disparities Among Bisexual People* (2015) *available at* http://hrc-assets.s3-website-us-east-1.amazonaws.com//files/assets/resources/HRC-BiHealthBrief.pdf.

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immediate family or them [identifying as LGBTQ]".[26] It is therefore crucial that LGBTQ individuals who have found unbiased and affirming providers, be allowed to remain with them. If turned away by a health care provider, 17 percent of all LGBTQ people, and 31 percent of LGBTQ people living outside of a metropolitan area, reported that it would be "very difficult" or "not possible" to find the same quality of service at a different community health center or clinic.[27]

The proposed rule allowing providers to deny needed care would reverse recent gains in combatting discrimination and health care disparities for LGBT persons. Refusals also implicate standards of care that are vital to LGBTQ health. Medical professionals are expected to provide LGBTQ individuals with the same quality of care as they would anyone else. The American Medical Association recommends that providers use culturally appropriate language and have basic familiarity and competency with LGBTQ issues as they pertain to any health services provided.[28] The World Professional Association for Transgender Health guidelines provide that gender-affirming interventions, when sought by transgender individuals, are medically necessary and part of the standard of care.[29] The American College of Obstetricians and Gynecologists warns that failure to provide gender-affirming treatment can lead to serious health consequences for transgender individuals.[30] LGBTQ individuals already experience significant health disparities, and denying medically necessary care on the basis of sexual orientation or gender identity exacerbates these disparities.

In addition, LGBTQ individuals face disparities in medical conditions that may implicate the need for reproductive health services. For example, lesbian and bisexual women report heightened risk for and diagnosis of some cancers and higher rates of cardiovascular disease.[31] The LGBTQ community is significantly at risk for sexual violence.[32] Eighteen percent of lesbian, gay, bisexual students have reported being forced to have sex.[33] Transgender women, particularly women of color, face high rates of HIV.[34]

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[26] HUMAN RIGHTS WATCH, *supra* note 28.
[27] Mirza, *supra* note 34.
[28] *Community Standards of Practice for the Provision of Quality Health Care Services to Lesbian, Gay, Bisexual, and Transgender Clients*, GAY LESBIAN BISEXUAL & TRANSGENDER HEALTH ACCESS PROJECT, http://www.glbthealth.org/CommunityStandardsofPractice.htm (last visited Jan. 26, 2018, 12:59 PM); *Creating an LGBTQ-friendly Practice*, A.M.A., https://www.ama-assn.org/delivering-care/creating-lgbtq-friendly-practice#Meet a Standard of Practice (last visited Jan. 26, 2018, 12:56 PM).
[29] *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People*, WORLD PROF. ASS'N FOR TRANSGENDER HEALTH (2011), https://s3.amazonaws.com/amo_hub_content/Association140/files/Standards%20of%20Care%20V7%20-%202011%20WPATH%20(2)(1).pdf.
[30] *Committee Opinion 512: Health Care for Transgender Individuals*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (Dec. 2011), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-for-Transgender-Individuals.
[31] Kates, *supra* note 37, at 4.
[32] Forty-six percent of bisexual women have been raped and 47 percent of transgender people are sexually assaulted at some point in their lifetime. This rate is particularly higher for transgender people of color. Kates, *supra* note 37, at 8.; *2015 U.S. Transgender Survey*, *supra* note 35, at 5.
[33] *Health Risks Among Sexual Minority Youth*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/healthyyouth/disparities/smy.htm (last updated May 24, 2017).
[34] More than 1 in 4 transgender women are HIV positive. Kates, *supra* note 37, at 6.

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Refusals to treat individuals according to medical standards of care put patients' health at risk, particularly for women and LGBTQ individuals. Expanding religious refusals will further put needed care, including reproductive health care, out of reach for many. Given the broadly-written and unclear language of the proposed rule, if implemented, some providers may misuse this rule to deny services to LGBTQ individuals on the basis of perceived or actual sexual orientation and gender identity. Allowing providers to flout established medical guidelines and deny medically accurate, evidence-based care impairs the ability of patients to make a health decision that expresses their self-determination.

Finally, the proposed rule threatens to turn back the clock to the darkest days of the AIDS pandemic when same-sex partners were routinely denied hospital visitation and health care providers scorned sick and dying patients.

III. The proposed rule undermines longstanding ethical and legal principles of informed consent

The proposed rule threatens informed consent, a necessary principle of patient-centered decision-making. Informed consent relies on disclosure of medically accurate information by providers so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.[35] This right relies on two factors: access to relevant and medically-accurate information about treatment choices and alternatives, and provider guidance based on generally accepted standards of practice. Both factors make trust between patients and health care professionals a critical component of quality of care.

The proposed rule purports to improve communication between patients and providers, but instead, will deter open, honest conversations that are vital to ensuring that a patient is able to be in control of their medical circumstances. For example, the proposed rule suggests that someone could refuse to offer information, if that information might be used to obtain a service to which the refuser objects. Such an attenuated relationship to informed consent could result in withholding information far beyond the scope of the underlying statutes, and would violate medical standards of care.

In recent decades, the U.S. medical community has primarily looked to informed consent as key to assuring patient autonomy in making decisions.[36] Informed consent is intended to help balance the unequal balance of power between health providers and patients and ensure patient-centered decision-making. Moreover, consent is not a yes or no question but rather is dependent upon the patient's understanding of the procedure that is to be conducted and the full range of treatment options for a patient's medical condition. Without informed consent, patients will be unable to make medical decisions that are grounded in agency, their beliefs and preferences, and that meet their personal needs. This is particularly problematic as many communities, including women of color and women living with disabilities, have disproportionately experienced abuse and trauma at the hands of providers and institutions.[37] In order to ensure that patient decisions are based on free will, informed

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[35] TOM BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (4th ed. 1994); CHARLES LIDZ ET AL., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY (1984).
[36] BEAUCHAMP & CHILDRESS, *supra* note 58; Robert Zussman, *Sociological perspectives on medical ethics and decision-making*, 23 ANN. REV. SOC. 171-89 (1997).
[37] Gutierrez, E. R. *Fertile Matters: The Politics of Mexican Origin Women's* Reproduction, 35-54 (2008) (discussing coercive sterilization of Mexican-origin women in Los Angeles); Jane Lawrence, *The Indian*

consent must be upheld in the patient-provider relationship. The proposed rule threatens this principle and may very well force individuals into harmful medical circumstances.

According to the American Medical Association: "The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice."[38]The American Nursing Association similarly requires that patient autonomy and self-determination are core ethical tenets of nursing. "Patients have the moral and legal right to determine what will be done with their own persons; to be given accurate, complete and understandable information in a manner that facilitates an informed judgment; to be assisted with weighing the benefits, burdens and available options in their treatment."[39] Similarly, pharmacists are called to respect the autonomy and dignity of each patient.[40]

Various state and federal laws require that health care professionals inform and counsel patients on specific issues such as preventing the spread of HIV/AIDS, non-directional information on family planning and abortion options, and emergency contraception to prevent pregnancy from rape.[41] In *Brownfield v. Daniel Freeman Marina Hospital*, a California court addressed the importance of patients' access to information in regard to emergency contraception. The court found that:

> "The duty to disclose such information arises from the fact that an adult of sound mind has 'the right, in the exercise of control over [her] own body, to determine whether or not to submit to lawful medical treatment.' Meaningful exercise of this right is possible only to the extent that patients are provided with adequate information upon which to base an intelligent decision with regard to the option available."[42]

Health Service and the Sterilization of Native American Women, 24 AM. INDIAN Q. 400, 411-12 (2000) (referencing one 1974 study indicating that Indian Health Services would have coercively sterilized approximately 25,000 Native American Women by 1975); Alexandra Minna Stern, *Sterilized in the Name of Public Health*, 95 AM. J. PUB. H. 1128, 1134 (July 2005) (discussing African-American women forced to choose between sterilization and medical care or welfare benefits and Mexican women forcibly sterilized). *See also Buck v. Bell*, 274 U.S. 200, 207 (1927) (upholding state statute permitting compulsory sterilization of "feeble-minded" persons); Vanessa Volz, *A Matter of Choice: Women With Disabilities, Sterilization, and Reproductive Autonomy in the Twenty-First Century*, 27 WOMEN RTS. L. REP. 203 (2006) (discussing sterilization reform statutes that permit sterilization with judicial authorization).

[38] *The AMA Code of Medical Ethics' Opinions on Informing Patients: Opinion 9.09 – Informed Consent*, 14 AM. MED. J. ETHICS 555-56 (2012), http://journalofethics.ama-assn.org/2012/07/coet1-1207.html.

[39] *Code of ethics for nurses with interpretive statements, Provision 1.4 The right to self-determination*, AM. NURSES ASS'N (2001), https://www.truthaboutnursing.org/research/codes/code_of_ethics_for_nurses_US.html.

[40] *Code of Ethics for Pharmacists*, AM. PHARMACISTS ASS'N (1994).

[41] *See, e.g.*, *State HIV Laws*, CTR. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/hiv/policies/law/states/index.html (last visited Nov. 13, 2017, 1:22PM); *Emergency Contraception*, GUTTMACHER INST. (Oct. 1, 2017), https://www.guttmacher.org/state-policy/explore/emergency-contraception.

[42] *Brownfield v. Daniel Freeman Marina Hospital*, 256 Cal. Rptr. 240 (Ct. App. 1989).

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In addition, the proposed rule does not provide any protections for health care professionals who want to provide, counsel, or refer for health care services that are implicated in this rule, for example, reproductive health or gender affirming care. Due to the rule's aggressive enforcement mechanisms and its vague and confusing language, providers may fear to give care or information. The inability of providers to give comprehensive, medically accurate information and options that will help patients make the best health decisions violates medical principles such as, beneficence, no maleficence, respect for autonomy, and justice. In particular, the principle of beneficence "requires that treatment and care do more good than harm; that the benefits outweigh the risks, and that the greater good for the patient is upheld."[43] In addition, the proposed rule undermines principles of quality care. Health care should be safe, effective, patient-centered, timely, efficient, and equitable.[44] Specifically, the provision of the care should not vary due to the personal characteristics of patients and should ensure that patient values guide all clinical decisions.[45] The expansion of religious refusals as envisioned in the proposed rule may compel providers to furnish care and information that harms the health, well-being, and goals of patients.

In particular, the principles of informed consent, respect for autonomy, and beneficence are important when individuals are seeking end of life care. These patients should be the center of health care decision-making and should be fully informed about their treatment options. Their advance directives should be honored, regardless of the physician's personal objections. Under the proposed rule, providers who object to various procedures could impose their own religious beliefs on their patients by withholding vital information about treatment options— including options such as voluntarily stopping eating and drinking, palliative sedation or medical aid in dying. These refusals would violate these abovementioned principles by ignoring patient needs, their desires, and autonomy and self-determination at a critical time in their lives. Patients should not be forced to bear the brunt of their provider's religious or moral beliefs regardless of the circumstances.

IV. The regulations fail to consider the impact of refusals on persons living with substance use disorders (SUD)

The over breadth of this proposed rule could be devastating to people with Substance Use Disorder (SUD). Rather than promoting the evidence-based standard of care, the rule could allow anyone from practitioners to insurers to refuse to provide, or even recommend, Medication Assisted Treatment (MAT) and other evidence-based interventions due simply to a personal objection.

The opioid epidemic continues to claim too many lives. According to the Centers for Disease Control and Prevention (CDC), over 63,000 people in the U.S. died from drug overdose in 2016.[46] The latest

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[43] Amy G. Bryant & Jonas J. Schwartz, *Why Crisis Pregnancy Centers Are Legal but Unethical*, 20 AM. MED. ASS'N J. ETHICS 269, 272 (2018).
[44] INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 3 (Mar. 2001), *available at* http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf.
[45] *Id.*
[46] Holly Hedegaard M.D., et al. *Drug Overdose Deaths in the United States, 1999-2016*, NAT'L CTR. FOR HEALTH STATISTICS1-8 (2017).

numbers show a 2017 increase in emergency department overdose admissions of 30% across the country, and up to 70% in some areas of the Midwest.[47]

The clear, evidence-based treatment standard for opioid use disorder (OUD) is medication-assisted treatment (MAT).[48] Buprenorphine, methadone, and naltrexone are the three FDA-approved drugs for treating patients with opioid use disorder. MAT is so valuable to treatment of addiction that the World Health Organization considers buprenorphine and methadone "Essential Medications."[49] Buprenorphine and methadone are, in fact, opioids. However, while they operate on the same receptors in the brain as other opioids, they do not produce the euphoric effect of other opioids but simply keep the user from experiencing withdrawal symptoms. They also keep patients from seeking opioids on the black market, where risk of death from accidental overdose increases. Patients on MAT are less likely to engage in dangerous or risky behaviors because their physical cravings are met by the medication, increasing their safety and the safety of their communities.[50] Naloxone is another medication key to saving the lives of people experiencing an opioid overdose. This medication reverses the effects of an opioid and can completely stop an overdose in its tracks.[51] Information about and access to these medications are crucial factors in keeping patients suffering from SUD from losing their jobs, losing their families, and losing their lives.

However, stigma associated with drug use stands in the way of saving lives.[52] America's prevailing cultural consciousness, after decades of treating the disease of addiction as largely a criminal justice and not a public health issue, generally perceives drug use as a moral failing and drug users as less deserving of care. For example, a needle exchange program designed to protect injection drug users from contracting blood borne illnesses such as HIV, Hepatitis C, and bacterial endocarditis was shut down in October 2017 by the Lawrence County, Indiana County Commission due to their moral objection to drug use, despite overwhelming evidence that these programs are effective at reducing

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[47] *Vital Signs*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vitalsigns/opioid-overdoses/.
[48] U.S. DEP'T HEALTH & HUM. SERV., PUB NO. (SMA)12-4214, MEDICATION-ASSISTED TREATMENT FOR OPIOID ADDICTION IN OPIOID TREATMENT PROGRAMS (2012), https://store.samhsa.gov/shin/content/SMA12-4214/SMA12-4214.pdf; National Institute on Drug Abuse, *Effective Treatments for Opioid Addiction*, https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction.
[49] World Health Organization, 19th WHO Model List of Essential Medicines (April 2015), http://www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf
[50] OPEN SOC'Y INST., BARRIERS TO ACCESS: MEDICATION-ASSISTED TREATMENT AND INJECTION-DRIVEN HIV EPIDEMICS 1 (2009), https://www.opensocietyfoundations.org [https://perma.cc/YF94-88AP].
[51] *See* James M. Chamberlain & Bruce L. Klein, *A Comprehensive Review of Naloxone for the Emergency Physician*, 12 AM. J. EMERGENCY MED. 650 (1994).
[52] Ellen M. Weber, *Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance*, 13 J. HEALTH CARE L. & POL'Y 49, 56 (2010); German Lopez, *There's a highly successful treatment for opioid addiction. But stigma is holding it back.*, VOX, Nov. 15, 2017, https://www.vox.com/science-and-health/2017/7/20/15937896/medication-assisted-treatment-methadone-buprenorphine-naltrexone.

harm and do not increase drug use.[53] One commissioner even quoted the Bible as he voted to shut it down. Use of naloxone to reverse overdose has been decried as "enabling these people" to go on to overdose again.[54]

In this frame of mind, only total abstinence is seen as successful treatment for SUD, usually as a result of a 12-step or faith-based program. MAT is considered by many to be simply "substituting one drug for another drug."[55] This belief is so common that even the former Secretary of the Department is on the record as opposing MAT because he didn't believe it would "move the dial," since people on medication would be not "completely cured."[56] The scientific consensus is that SUD is a chronic disease, and yet many recoil from the idea of treating SUD with medication like any other illness such as diabetes or heart disease.[57] The White House's own opioid commission found that "negative attitudes regarding MAT appeared to be related to negative judgments about drug users in general and heroin users in particular."[58]

People with SUD already suffer due to stigma and have a difficult time finding appropriate care. For example, it can be difficult to find access to local methadone clinics in rural areas.[59] Other roadblocks, such as artificial caps on the number of patients to whom doctors can prescribe buprenorphine, further prevent people with SUD from receiving appropriate care.[60] Only one-third of treatment programs across the country provide MAT, even though treatment with MAT can cut overdose mortality rates in half and is considered the gold standard of care. [61] The current Secretary of the Department has noted that expanding access to MAT is necessary to save lives and that it will be

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[53] German Lopez, *An Indiana county just halted a lifesaving needle exchange program, citing the Bible*, VOX, Oct. 20, 2017, https://www.vox.com/policy-and-politics/2017/10/20/16507902/indiana-lawrence-county-needle-exchange.

[54] Tim Craig & Nicole Lewis, *As opioid overdoses exact a higher price, communities ponder who should be saved*, WASH. POST, Jul. 15, 2017, https://www.washingtonpost.com/world/as-opioid-overdoses-exact-a-higher-price-communities-ponder-who-should-be-saved/2017/07/15/1ea91890-67f3-11e7-8eb5-cbccc2e7bfbf_story.html?utm_term=.4184c42f806c.

[55] Lopez, *supra* note 75.

[56] Eric Eyre, *Trump officials seek opioid solutions in WV*, CHARLESTON GAZETTE-MAIL, May 9, 2017, https://www.wvgazettemail.com/news/health/trump-officials-seek-opioid-solutions-in-wv/article_52c417d8-16a5-59d5-8928-13ab073bc02b.html.

[57] Nora D. Volkow et al., *Medication-Assisted Therapies — Tackling the Opioid-Overdose Epidemic*, 370 NEW ENG. J. MED. 2063, http://www.nejm.org/doi/full/10.1056/NEJMp1402780.

[58] Report of the President's Commission on Combating Drug Addiction and the Opioid Crisis, Nov. 1, 2017, https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf

[59] Christine Vestal, *In Opioid Epidemic, Prejudice Persists Against Methadone*, STATELINE, Nov. 11, 2016, http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/11/11/in-opioid-epidemic-prejudice-persists-against-methadone

[60] 42 C.F.R. §8.610.

[61] Matthais Pierce, et al., *Impact of Treatment for Opioid Dependence on Fatal Drug-Related Poisoning: A National Cohort Study in England*, 111:2 ADDICTION 298 (Nov. 2015); Luis Sordo, et al., Mortality Risk During and After Opioid Substitution Treatment: Systematic Review and Meta-Analysis of Cohort Studies, BMJ (2017), http://www.bmj.com/content/357/bmj.j1550.; Alex Azar, Secretary, U.S. Dep't of Health & Hum. Serv., Plenary Address to National Governors Association, (Feb. 24, 2018), https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/plenary-addres-to-national-governors-association.html.

"impossible" to quell the opioid epidemic without increasing the number of providers offering the evidence-based standard of care.[62] This rule, which allows misinformation and personal feelings to get in the way of science and lifesaving treatment, will not help achieve the goals of the administration; it will instead trigger countless numbers of deaths.

V. The proposed rule permits health care professionals to opt out of providing medical care that the public expects by allowing them to disregard evidence-based standards of care

Medical practice guidelines and standards of care establish the boundaries of medical care that patients can expect to receive and that providers should be expected to deliver. The health services impacted by refusals are often related to reproductive and sexual health, which are implicated in a wide range of common health treatment and prevention strategies. Information, counseling, referral and provisions 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. Many of these conditions disproportionately affect women of color.[63] The expansion of these refusals as outlined in the proposed rule will put women, particularly women of color, who experience these medical conditions at greater risk for harm.

Moreover, a 2007 survey of physicians working at religiously-affiliated hospitals found that nearly one in five (19 percent) experienced a clinical conflict with the religiously-based policies of the hospital.[64] While some of these physicians might refer their patients to another provider who could provide the necessary care, one 2007 survey found that as many as one-third of patients (nearly 100 million people) may be receiving care from physicians who do not believe they have any obligations to refer their patients to other providers.[65]

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[62] Azar, *supra* note 84.

[63] For example, Black women are three times more likely to be diagnosed with lupus than white women. Latinas and Asian, Native American, and Alaskan Native women also are likely to be diagnosed with lupus. Office on Women's Health, *Lupus and women*, U.S. DEP'T HEALTH & HUM. SERV. (May 25, 2017), https://www.womenshealth.gov/lupus/lupus-and-women. Black and Latina women are more likely to experience higher rates of diabetes than their white peers. Office of Minority Health, *Diabetes and African Americans*, U.S. DEP'T OF HEALTH & HUM. SERV. (Jul. 13, 2016), https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=18; Office of Minority Health, *Diabetes and Hispanic Americans*, U.S. DEP'T OF HEALTH & HUM. SERV. (May 11, 2016), https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=63. Filipino adults are more likely to be obese in comparison to the overall Asian population in the United States. Office of Minority Health, *Obesity and Asian Americans*, U.S. DEP'T OF HEALTH & HUM. SERV. (Aug. 25, 2017), https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=55. Native American and Alaskan Native women are more likely to be diagnosed with liver and kidney/renal pelvis cancer in comparison to non-Hispanic white women. Office of Minority Health, *Cancer and American Indians/Alaska Natives*, U.S. DEP'T OF HEALTH & HUM. SERV. (Nov. 3, 2016), https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=31.

[64] Debra B. Stulberg M.D. M.A., et al., *Religious Hospitals and Primary Care Physicians: Conflicts over Policies for Patient Care*, J. GEN. INTERN. MED. 725-30 (2010) *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2881970/.

[65] Farr A. Curlin M.D., et al., *Religion, Conscience, and Controversial Clinical Practices*, NEW ENG. J. MED. 593–600 (2007) *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2867473/.

a. Sexually transmitted infections (STIs)

Religious refusals also impact access to sexual health care more broadly. Contraceptives and access to preventative treatment for sexually transmitted infections are a critical aspect of health care. The CDC estimates that 20 million new sexually transmitted infections occur each year. Chlamydia remains the most commonly reported infectious disease in the U.S., while HIV/AIDS remains the most life threatening. Women, especially young women, and Black women, are hit hardest by Chlamydia—with rates of Chlamydia 5.6 times higher for Black than for white Americans.[66] Consistent use of condoms results in an 80 percent reduction of HIV transmission, and the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the World Health Organization all recommend the condom use be promoted by providers.[67]

b. HIV Health

For HIV, in addition to consistent condom use, pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) are an important part of prevention for those at high risk for contracting HIV. The American College of Obstetricians and Gynecologists recommends that PrEP be considered for individuals at high risk of contracting HIV.[68] Under the proposed rule, an insurance company could refuse to cover PrEP or PEP because of a religious belief. Refusals to promote and facilitate condom use because of religious beliefs and refusals to prescribe PrEP or PEP because of a patient's perceived or actual sexual orientation, gender identity, or perceived or actual sexual behaviors is in violation of the standards of care and harms patients already at risk for experiencing health disparities. Both PrEP and PEP have been shown to be highly effective in preventing HIV infection. Denying access to this treatment would adversely impact vulnerable, highest risk populations including gay and bisexual men.

VI. The regulations are overly broad, vague, and will cause confusion in the health care delivery system

[66] *Sexually Transmitted Disease Surveillance 2016*, CTR. FOR DISEASE CONTROL & PREVENTION (Sept. 2017), https://www.cdc.gov/std/stats16/CDC_2016_STDS_Report-for508WebSep21_2017_1644.pdf.
[67] American Academy of Pediatrics Committee on Adolescence, *Condom Use by Adolescents*, 132 PEDIATRICS (Nov. 2013), http://pediatrics.aappublications.org/content/132/5/973; American Academy of Pediatrics, American College of Obstetricians and Gynecologists, March of Dimes Birth Defects Foundation. Guidelines for perinatal care. 6th ed. Elk Grove Village, IL; Washington, DC: American Academy of Pediatrics; American College of Obstetricians and Gynecologists; 2007; American College of Obstetricians and Gynecologists. Barrier methods of contraception. Brochure (available at http://www.acog.org/publications/patient_education/bp022.cfm). Washington, DC: American College of Obstetricians and Gynecologists; 2008 July; World Health Organization, UNAIDS, UNFPA, *Position statement on condoms and HIV prevention*, UNICEF (2009), https://www.unicef.org/aids/files/2009_position_paper_condoms_en.pdf.
[68] ACOG *Committee Opinion 595: Preexposure Prophylaxis for the Prevention of Human Immunodeficiency Virus*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (May 2014), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Preexposure-Prophylaxis-for-the-Prevention-of-Human-Immunodeficiency-Virus.

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The regulations dangerously expand the application of the underlying statutes by offering an extremely broad definition who can refuse and what they can refuse to do. Under the proposed rule, any one engaged in the health care system could refuse services or care. The proposed rule defines workforce to include "volunteers, trainees or other members or agents of a covered entity, broadly defined when the conduct of the person is under the control of such entity."[69] Under this definition, could any member of the health care workforce refuse to serve a patient in any way – could a nurse assistant refuse to serve lunch to a transgender patient, could a billing specialist refuse to help a patient who had sought contraceptive counseling?

a. Discrimination

The failure to define the term "discrimination" will cause confusion for providers, and as employers, expose them to liability. Title VII already requires that employers accommodate employees' religious beliefs to the extent there is no undue hardship on the employer.[70] The regulations make no reference to Title VII or current EEOC guidance, which prohibits discrimination against an employee based on that employee's race, color, religion, sex, and national origin.[71] The proposed rule should be read to ensure that the long-standing balance set in Title VII between the right of individuals to enjoy reasonable accommodation of their religious beliefs and the right of employers to conduct their businesses without undue interference is to be maintained.

By failing to define "discrimination," supervisors in health care settings will be unable to proceed in the orderly delivery of health care services, putting women's health at risk. The proposed rule impermissibly muddies the interpretation of Title VII and current EEOC guidance. If implemented, health care entities may be forced to choose between complying with a fundamentally misguided proposed rule and long-standing interpretation of Title VII.

Finally, the proposed rule's lack of clarity regarding what constitutes discrimination, may undermine non-discrimination laws. Because of the potential harm to individuals if religious refusals were allowed, courts have long rejected arguments that religiously affiliated organizations can opt out of anti-discrimination requirements.[72] Instead, courts have held that the government has a compelling interest in ending discrimination and that anti-discrimination statutes are the least restrictive means of doing so. Indeed, the majority opinion in *Burwell v. Hobby Lobby Stores, Inc.* makes it clear that the decision should not be used as a "shield" to escape legal sanction for discrimination in hiring on the

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[69] 83 Fed. Reg. 3894.
[70] 42 U.S.C. § 2000e-2.; *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.
[71] *Id.*
[72] See e.g., *Bob Jones Univ. v. United States*, 461 U.S. 574 (1983) (holding that the government's interest in eliminating racial discrimination in education outweighed any burdens on religious beliefs imposed by Treasury Department regulations); *Newman v. Piggie Park Enters., Inc.*, 390 U.S. 400 (1968) (holding that a restaurant owner could not refuse to comply with the Civil Rights Act of 1964 and not serve African-American customers based on his religious beliefs); *Dole v. Shenandoah Baptist Church*, 899 F.2d 1389, 1392 (4th Cir. 1990) (holding a religious school could not compensate women less than men based on the belief that "the Bible clearly teaches that the husband is the head of the house, head of the wife, head of the family"); *Hamilton v. Southland Christian Sch., Inc.*, 680 F.3d 1316 (11th Cir. 2012) (reversing summary judgment for religious school that claimed a religious right to fire teacher for becoming pregnant outside of marriage).

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basis of race, because such prohibitions further a "compelling interest in providing an equal opportunity to participate in the workforce without regard to race," and are narrowly tailored to meet that "critical goal."[73] The uncertainty regarding how the proposed rule will interact with non-discrimination laws is extremely concerning.

Conclusion

Callen-Lorde Community Health Center opposes the proposed rule as it expands religious refusals to the detriment of patients' health and well-being. We are concerned that these regulations, if implemented, will interfere in the patient-provider relationship by undermining informed consent. The proposed rule will allow anyone in the health care setting to refuse health care that is evidence-based and informed by the highest standards of medical care. The outcome of this regulation will harm communities who already lack access to care and endure discrimination.

Thank you for your attention to our comments. If you have any questions, please reach out to the following:

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[73] *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, slip op. at 46 (2014).

Exhibit 45

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www.americanprogress.org

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building
200 Independence Avenue, S.W. Room 509F
Washington, D.C. 20201

March 27, 2018

RE: Public Comment in Response to the Proposed Regulation, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03

Dear Secretary Azar,

The Center for American Progress ("Center") is committed to ensuring that all individuals have access to quality, affordable health care and believes that 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 that 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 patient-provider relationship; distort essential protections for religious freedom to justify discrimination; 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 reprioritize 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 Center calls on the Department and OCR to withdraw the Proposed Rule in its entirety.

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

[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 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 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] For example, a receptionist may refuse to schedule an abortion for a patient, citing moral objections, or an ambulance driver may refuse to drive a woman experiencing severe pregnancy complications to a hospital, citing a religious objection to participating in procedures that may end the pregnancy.[6]

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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.

[6] *See Trump Administration Proposes Sweeping Rule to Permit Personal Beliefs to Dictate Health Care*, NAT'L WOMEN'S L. CTR. (2018), https://nwlc.org/resources/trump-administration-proposes-sweeping-rule-to-permit-personal-beliefs-to-dictate-health-care/.

Such an attempted expansion goes beyond what the statute enacted by Congress allows.[7] Furthermore, the Proposed Rule would expansively apply other provisions of the Church Amendments to, among other things, 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.

In addition, even though longstanding legal interpretation applies section (d) of the Church Amendments singularly to participation in abortion and sterilization procedures, the Proposed Rule does not make this limitation clear. This ambiguity can encourage an overly broad interpretation of the statute that empowers a provider to refuse to provide *any* health care service or information for a religious or moral reason, potentially including not just sterilization and abortion procedures, but treatments that have an incidental effect on fertility, including Pre-Exposure Prophylaxis services, infertility care, treatments related to gender dysphoria, and HIV treatment. Some providers may try to claim even broader refusal abilities, as our recent analysis of complaints to HHS showed that transgender patients are most often discriminated against simply for being who they are.[8] Any rule, if it is to advance, must make the limitation of this statute clear.

If religious or moral exemptions related to sterilization are misinterpreted to include treatments that simply have an incidental effect on fertility—as the vague and sweeping language of this rule encourages—it can lead to refusals that go beyond what federal law allows and allow individuals and institutions to refuse a dangerously broad range of medically-needed treatments. For example, the Proposed Rule would allow a medical provider to refuse to treat an HIV positive transgender patient or to provide emergency care simply because the patient is transgender.[9]

Another example of the Proposed Rule's overly broad expansion of section (d) is the preamble's statement that the exemption applies to the Unaccompanied Alien Children ("UAC") program because the program contracts out health care for unaccompanied minors in the Department's custody. The rule's preamble indicates an intent for this to be far-reaching and permit any grantee or contractor caring for an unaccompanied minor to deny access to any form of care the grantee or contractor objects to.[10] For example, if an unaccompanied minor in the Department's custody is sexually assaulted, they are entitled to access emergency contraception and, although the Department does not fund abortion services for unaccompanied minors outside of very limited circumstances, unaccompanied minors in the UAC program still have a legal right to these health services. The Department's classification of the UAC program as a health service

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[7] The Church Amendments, 42 U.S.C. § 300(c)(2)(B)(2018).
[8] *See* Sharita Gruberg & Frank J. Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial*, CTR. FOR AM. PROGRESS (2018), https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/.
[9] *See TLC condemns illegal HHS rule granting 'license to discriminate'*, TRANSGENDER LAW CTR. (2018), https://transgenderlawcenter.org/archives/14188
[10] *See* Sharita Gruberg, et al., *How Overly Broad Religious Exemptions Are Putting Children at Risk of Sexual Abuse*, CTR. FOR AM. PROGRESS (2016), https://www.americanprogress.org/issues/immigration/news/2016/05/12/137356/how-overly-broad-religious-exemptions-are-putting-children-at-risk-of-sexual-abuse/.

program in the rule's preamble reveals the Department's intent to permit grantees and contractors to block access to these health services for unaccompanied minors in the Department's custody.

The Proposed Rule also 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.[11] 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.[12]

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.[13] In addition to the statutory definitions of health care entities under the Coats and Weldon Amendments, the Proposed Rule would expand those definitions to include: health care personnel; applicants or participants for training or study in the health professions; laboratories; entities engaging in biomedical or behavioral research; plan sponsors, issuers, or third-party administrators; and components of State and local governments.[14] 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.[15]

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 and to fundamentally block access to health care. For example, one way the Weldon Amendment is expanded under the Proposed Rule is through the definition of "discrimination."[16] 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

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[11] *Id.* at 180.
[12] *Id.* at 183.
[13] 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).
[14] *See* Rule *supra* note 1, at 182.
[15] 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.
[16] *See* Rule *supra* note 1, at 180.

discrimination."[17] In 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.[18] 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.[19] Another woman experiencing pregnancy loss was denied care for ten days at a religiously affiliated hospital outside Chicago, Illinois.[20] In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy.[21] 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.[22] 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, as her condition grew more severe, the hospital did not give her full information about her condition and treatment options.[23]

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

Refusals of care based on personal beliefs have a disproportionate impact on those who already face barriers to care. This is especially true for immigrant patients who often lack access to

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[17] *Id.*
[18] *See, e.g.*, *supra* note 3.
[19] *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.
[20] *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.
[21] *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.
[22] *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), 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.
[23] *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.

transportation and may have to travel great distances to get the care they need.[24] In rural areas, there may be no other sources of health and life preserving medical care.[25] This problem is exacerbated by anti-choice state laws, which force women in rural areas to drive longer distances multiple times or lose hours of pay because of a lack of options for abortion care where they live. Many rural clinics that do offer reproductive healthcare services do not provide abortion services: In Washington State, a 1998 study found that of 31 clinics in rural areas of the state, only one offered abortion services.[26]

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.[27] These hospitals as well as many Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs), which provide guidance on a wide range of hospital matters, including reproductive health care, and can keep providers from offering the standard of care.[28] 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.[29] The reach of this type of 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.[30]

In developing countries where many health systems are weak, health care options and supplies are often unavailable.[31] 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,

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[24] 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, *Nuestra Voz, Nuestra Salud, Nuestro Texas: the Fight for Women's Reproductive Health in the Rio Grande Valley* 1, 7 (2013), http://www.nuestrotexas.org/pdf/NT-spread.pdf.

[25] 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/.

[26] *See* Kathleen Reeves, *A Pioneering Effort to Increase Rural Women's Access to Safe Abortion in Iowa*, REWIRE (Apr. 23, 2010), https://rewire.news/article/2010/08/23/ppiowas-pioneering-efforts-ensure-rural-access/.

[27] *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.

[28] *See id.* at 10-13.

[29] 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/.

[30] *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.

[31] *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.

including a broad and harmful refusal provision contained within the statute governing such programs.[32]

For lesbian, gay, bisexual, transgender and queer (LGBTQ) patients, obtaining access to quality, culturally competent care already poses significant challenges. We recently found that 8 percent of lesbian, gay, bisexual and queer (LGBQ) survey respondents and 29 percent of transgender respondents reported a doctor or other health care provider refusing to see them because of their actual or perceived sexual orientation or gender identity.[33] This type of discrimination has a tangible impact on LGBTQ people's health: 8 percent of LGBQ respondents and 22 percent of transgender respondents reported avoiding or postponing needed medical care in the past year due to disrespect or discrimination from health care staff, delaying medically necessary care and treatment.[34] Discrimination also negatively impacts LGBTQ patients' relationship with their doctors: LGBTQ people who reported experiencing some form of anti-LGBTQ discrimination in the past year were nearly three times as likely to avoid doctor's offices out of fear of discrimination. The proposed regulation threatens to make health care even more inaccessible for LGBTQ patients by removing recourse and encouraging further discrimination from providers or hospitals.

When LGBTQ patients are turned away or refused treatment, it is much harder—and sometimes simply not possible—to find a viable alternative. In a recent study we conducted, one in five LGBTQ people, including 31 percent of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away. That rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41 percent reporting that it would be very difficult or impossible to find an alternative provider.[35] For these patients, being turned away by a medical provider is not just an inconvenience; it often means being denied care entirely and having no viable alternative options.

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

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[32] *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/.
[33] See Shabab Ahmed et al., *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR. FOR AM. PROGRESS (2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.
[34] *See id.*
[35] *See id.*

society."[36] 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.[37]

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.[38] Because the Proposed Rule would cause substantial harm, including to patients, it would violate the Establishment Clause.[39]

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.[40] For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling[41] and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.[42] 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.[43] 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

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[36] 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.

[37] *See* Rule *supra* note 1, at 94-177.

[38] 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).

[39] 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 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.

[40] *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.

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

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

[43] *See, e.g.*, Rule *supra* note 1, at 180-185.

federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for low-income populations.[44] When it comes to Title X, the Proposed Rule would not only sanction conduct at odds with pre-existing legal requirements and violate Section 1557 of the Affordable Care Act (ACA), but could also undermine Title X's fundamental objectives. Every year, millions of low-income, under-insured, and uninsured individuals rely on Title X clinics to access services they otherwise might not be able to afford.[45] Of the four million clients who Title X clinics serve, almost two-thirds have family incomes at or below the federal poverty level, for whom Title X clinics provide no-cost services, and over half are women of color.[46]

The Proposed Rule Will Carry Severe Consequences for Providers and Undermine the Patient-Provider 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 treating patients regardless of the professional, ethical, religious, or moral convictions of these providers.[47] 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. Indeed, the Proposed Rule ignores that many providers' religious and moral convictions compel them to prioritize their patients' health and that such broad exemptions for institutions may create a burden on the beliefs of providers in addition to the beliefs of patients.

The Proposed Rule threatens informed consent, a necessary principle intended to help balance the power dynamics between health providers and patients and ensure patient-centered decision-making.[48] 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.[49] Various associations of medical and advocacy groups, such as the American College of Physicians, have released statements outlining concerns that laws and regulations concerning medicine are not "supported by evidence-based guidelines and/or [are] not individualized to the needs of the specific patient."[50] By allowing providers, including hospital and health care

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[44] *See* NFPRHA *supra* note 34.
[45] *See id.*
[46] *Title X Family Planning Annual Report: 2016 National Summary*, DEP'T OF HEALTH AND HUMAN SERVS. (2017), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf.
[47] *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.
[48] *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).
[49] *See id.*
[50] *See* Donna Barry, et al., *Changing the Conversation on Abortion Restrictions*, CTR. FOR AMERICAN PROGRESS (2015), https://www.americanprogress.org/issues/women/reports/2015/09/30/121940/changing-the-conversation-on-abortion-restrictions/.

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.[51]

These conversations are already fraught with undue requirements, especially in regard to abortion care. Physicians in several states across the country are required to mandate waiting periods and counseling, discuss fetal development and pain, and advise on the risks of abortion, most of which have been debunked by medical research.[52] The Proposed Rule further intrudes on the patient-provider relationship when it comes to abortion care by allowing personal religious beliefs to interfere with the provision of comprehensive information to the patient.

The Proposed Rule also undermines adherence to evidence-based clinical practice guidelines and established standards of care by allowing providers to ignore existing guidelines and standards, particularly those for reproductive and sexual health. Clinical practice guidelines and standards of care establish the accepted course of care for specific conditions. For example, the standard of care for treating individuals with a range of common medical conditions such as heart disease, diabetes, epilepsy, lupus, obesity, and some cancers includes counseling, referral, and provision of contraceptives and, in some cases, abortion services.[53] 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 without clinical justification and deny recommended 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.[54] No health 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.[55] Instead, the Proposed Rule appropriates

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[51] *See* Rule *supra* note 1, at 150-151.
[52] See *Counseling and Waiting Periods for Abortion*, GUTTMACHER INST. (2018), https://www.guttmacher.org/state-policy/explore/counseling-and-waiting-periods-abortion.
[53] *See* Susan Berke Fogel, *Health Care Refusals: Undermining Quality Care for Women*, NAT'L HEALTH LAW PGRM. (2012), http://www.healthlaw.org/issues/reproductive-health/health-care-refusals/health-care-refusals-undermining-care-for-women#.Wrku35Pwbfa.
[54] *See* The Church Amendments, 42 U.S.C. § 300a-7(c) (2018).
[55] *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

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.[56] Recipients of HHS federal financial assistance are required to complete and file an "Assurance of Compliance with Non-Discrimination Laws and Regulations", in which they agree to comply with non-discrimination provisions in a number of laws, including Section 1557 of the ACA.[57] The requirements will significantly burden 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.[58] If finalized, however, the Proposed Rule will represent a radical departure from the Department's mission to combat discrimination, protect patient access to 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.[59] 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 fact that hospitals

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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.").

[56] *See* Rule *supra* note 1, at 203-214.

[57] *See Assurance of Compliance*, DEP'T OF HEALTH AND HUMAN SERVS. OFFICE FOR CIVIL RIGHTS, https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf (retrieved Mar. 27, 2018).

[58] 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.

[59] *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/hiv/index.html; *National Origin Discrimination*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/index.html; *Health Disparities*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/health-disparities/index.html.

serving predominantly people of color tend to be teaching or not-for-profit hospitals and have higher rates of risk-adjusted mortality.[60] 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.[61] Further, the disparity in maternal mortality is growing rather than decreasing,[62] which in part may be due to the reality that women of color have long been the subject of discrimination in health care. For example, women's pain is routinely undertreated and often dismissed.[63] 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.[64] Similarly, lesbian, gay, bisexual and transgender patients disproportionately experience higher rates of chronic conditions as well as earlier onset of disabilities in comparison to cisgender and heterosexual individuals but simultaneously face significant barriers to accessing health care, including cultural stigma, cost-related issues, and gaps in coverage.[65]

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.[66]

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,[67] the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[68] With respect to religion, Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when

[60] *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.
[61] *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.
[62] *See id.*
[63] *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).
[64] *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).
[65] *See* Jennifer Kates, et al., *Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender (LGBT) Individuals in the US*. KAISER FAMILY FOUND. (2017), https://www.kff.org/disparities-policy/issue-brief/health-and-access-to-care-and-coverage-for-lesbian-gay-bisexual-and-transgender-individuals-in-the-u-s/.
[66] *See supra* note 46.
[67] 42 U.S.C. § 2000e-2 (1964).
[68] *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.

requested, unless the accommodation would impose an "undue hardship" on an employer.[69] 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.[70]

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 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.[71] 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 department to provide to anyone who comes to the emergency department an appropriate medical screening to determine whether an emergency medical condition exists, necessary stabilizing treatment, and appropriate transfer of the individual to another hospital if either the person requests the transfer or the hospital does not have the capability or capacity to provide the necessary stabilizing treatment.[72] Under EMTALA, every Medicare hospital is required to comply – even those that are religiously affiliated.[73] 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.

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[69] *See id.*
[70] 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.
[71] *See* Rule *supra* note 1, at 180-181.
[72] 42 U.S.C. § 1395dd(a)-(c).
[73] 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).

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

The Proposed Rule will have a chilling effect on the enforcement and passage of state laws that protect access to health care and prevent discrimination against individuals seeking medical care. By granting broad exemptions for providers, hospitals, insurance companies, and support staff to refuse care to patients based on religious or moral beliefs, the Proposed Rule creates conflicts with hundreds of state and local health care nondiscrimination laws. It is therefore disingenuous for the Department to claim that the Proposed Rule "does not impose substantial direct effects on States," "does not alter or have any substantial direct effects on the relationship between the Federal government and the States," and "does not implicate" federalism concerns under Executive Order 13132. In addition, 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.[74] Moreover, the Proposed Rule invites states to further expand refusals of care laws by making clear that this expansive rule is a floor, and not a ceiling, for religious exemption laws.[75]

The Department's Rushed Rulemaking Process Failed to Follow Required Procedures

The Department rushed to publish this rule without first publishing any notice regarding it in its Unified Regulatory Agenda, as is normally required but in this case was not enforced. The failure to follow proper procedure reflects an inadequate consideration of the Proposed Rule's impact on patients' health.

The timing of the Proposed Rule also illustrates a lack of sufficient consideration. The Proposed Rule was published just two months after the close of a public comment period for a Request for Information closely related to this rule. The 12,000-plus public comments were not all posted until mid-December, a month before this Proposed Rule was released. Nearly all of the comments submitted at that time related to the subjects covered by the Proposed Rule—namely, the refusal of care by federally funded health care institutions or their employees on the basis of personal beliefs. This short period of time calls into question the comprehensiveness of the review of the Request for Information (RFI) and whether the Proposed Rule was developed in an arbitrary and capricious manner. Many faith-based organizations submitted comments for the RFI articulating a strong objection to the idea that faith-based organizations face any barriers to engaging with HHS and calling for a commitment by HHS to ensure equal access to healthcare for all. These organizations have been left to wonder if, despite claiming an interest in protecting religious and moral objections, the process has accounted for their feedback at all.[76]

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[74] *See, e.g.*, Rule, *Supra* note 1, at 3888-89.
[75] *See id.*
[76] See *Rabbi Jonah Dov Pesner 'to' Center for Faith-Based and Neighborhood Partnerships*, Nov. 21, 2017, RELIGIOUS ACTION CTR. FOR REFORM JUDAISM, https://rac.org/sites/default/files/HHS%20RFI%20Comment%20November%2021%202017.pdf; *The Coalition Against Religious Discrimination 'to' Center for Faith-Based and Neighborhood Partnerships*, Nov. 24, 2017, COALITION AGAINST RELIGIOUS DISCRIMINATION, https://transequality.org/sites/default/files/docs/2017-11-24%20-%20CARD%20Response%20to%20HHS%20RFI%20FINAL.PDF.

Conclusion

The Proposed Rule will allow health care providers, hospitals, insurance companies and support staff to cite personal religious and moral objections in order to dictate patient care by unlawfully expanding already harmful refusals of care. The Proposed Rule is arbitrary, capricious and discriminatory, violates multiple federal statutes and the Constitution, is burdensome to states, contradicts the positions of a wide array of religious groups who support balancing religious liberty with other critical freedoms, ignores congressional intent, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons, the Center calls on the Department to withdraw the Proposed Rule in its entirety.

Sincerely,

Shilpa Phadke
Vice President, Women's Initiative
Center for American Progress

Exhibit 46

March 27, 2018

VIA ELECTRONIC TRANSMISSION

Office for Civil Rights (OCR), Office of the Secretary, HHS
ATTN: Roger Severino
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Re: Conscience NPRM, RIN 0945-ZA03

Dear Mr. Severino,

The Center for Health and Gender Equity (CHANGE) is pleased to submit to the Department of Health and Human Services (Department) the following comments on the Protecting Statutory Conscience Rights in Health Care NPRM (Proposed Rule) published on January 26, 2018, at 83 Fed. Reg. 3880. We do not address the entirety of the rule, but instead, we limit the scope of these comments to the expansion of the Church Amendments to global health, the expansion of definitions, the direct conflict with the Non-Discrimination in Delivery of Service provision, the effect on patients, providers, and systems, and violations of medical ethics, standards, and international human rights.

As an organization committed to gender equity and the empowerment of women and girls throughout the world, we strongly support efforts to prevent discrimination against individuals receiving health care services and oppose policies permitting entities to deny individuals services due to religious or moral objection. Refusal policies allowing entities to withhold services or information on the basis of religious or moral objection disregard accepted ethical standards for medical care, undermine individuals' autonomy to make informed decisions, and affect the delivery of quality health care throughout the world. Religious refusal clauses undermine program goals and adversely impact the very people the programs intend to benefit while disregarding the government's contractual requirements to prevent discrimination.

1. **Expansion to Global Health**

We strongly oppose the expansion of the applicability of part 88 to global health programs. As proposed, the Department's interpretation of entities would apply to global health programs through the Church Amendments which includes any program or service "funded in whole or in part under a program administered by the...Secretary of Health and Human Services."[1] As noted in the proposed rule[2], the

[1] 42 U.S.C. §300a-7(d)(1973).
[2] Protecting Statutory Conscience Rights in Health Care, 83 Fed. Reg. 3880, 3880 (proposed Jan. 26, 2018) (to be codified at 45 C.F.R. pt. 88).

Department of State and USAID administer these programs and already have Helms Amendment[3] restrictions placed upon them. The Helms Amendment states any organization receiving U.S. government funding is not required "to endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection."[4] By expanding the Church Amendments and by extension the proposed certification and notice requirements of part 88, the Department would be exerting effort and resources on redundancy while privileging the individual rights of those "performing or assisting in the performance of a program"[5] over those of individual patients.

2. Non-Discrimination in Service Delivery Provision

We strongly oppose the Proposed Rule as it directly conflicts with the principle of non-discrimination in the delivery of services, and the related provision in Department contracts. This provision states a person cannot be discriminated against in the administration of a Department program or service based on "non-merit factors such as race, color, national origin, religion, sex, gender identity, sexual orientation, or disability (physical or mental)."[6] Through the implementation of the proposed rule, the Department would be allowing discrimination based on each of these factors. Each person who participates in or receives benefits from the Department services, or programs deserves to be free from discrimination by their health care provider.

The proposed rule will do more to hinder patient's access to care than to protect health care providers, employees, students, or volunteers. By allowing employees and providers to refuse to deliver services, patients lose access not only to services and information they depend on, but also to their autonomy to make their own health care decisions based on a complete understanding of their options. By giving more weight to religious entitlements than individual autonomy, the Department is encouraging discrimination.

3. Expansion of Definitions

Assist in the Performance

We strongly oppose the expanded definition of "assist in the performance." In the proposed rule, the Department seeks to expand the definition of "assist in the performance" to include all person with an "articulable connection" to the performance of the procedure, service, or program "so long as the individual involved is a part of the workforce of a Department-funded entity."[7] By expanding this definition, the focus is turned to those administering the program rather than the providers and patients who will know what is best for their individual situation. Anyone remotely connected to a program could disrupt access to care for patients although they are not actually providing the service or information.

[3] 22 U.S.C. §7631(d).
[4] *Id.*
[5] *Supra* note 1.
[6] Non-Discrimination in Service Delivery, 48 C.F.R. §352.237-74 (2015).
[7] Protecting Statutory Conscience Rights in Health Care, *supra* note 2, at 3892.

Entity
We suggest a clarification with the new definition of "entity" in the proposed rule. The definition does not speak to the applicability to foreign governments and the United Nations as recipients of Department funds. This definition should plainly communicate that foreign governments and the United Nations and related bodies are explicitly exempt from religious refusal provisions as well as the certification and notice requirements in respect for their individual sovereignty.[8]

4. Religious Refusals Affect Surrounding Persons and Systems

The Proposed Rule would further limit the access to care for patients around the world. Many patients who would be refused care by one provider would not be able to access the care they seek elsewhere due to the limited amount of local providers, expenses to travel to a provider, and the time required to seek out alternatives. Patient health suffers when they cannot access safe and appropriate care.

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[9], 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.

In addition to limiting the patient's ability to access care, the Proposed Rule would overburden providers and facilities who are willing to provide patients the care they require. This additional workload for some providers would affect the efficiency of the resources they have access to by misusing their resources to accommodate providers unwilling to provide comprehensive and non-discriminatory care.

5. Violation of Medical Ethics and Standards

Medical ethics guidelines require providers to prioritize patient care over conscience claims. Current guidelines by the International Federation of Gynecology and Obstetrics (FIGO) state that a doctor objecting to abortion based on conscience "has an obligation to refer the woman to a colleague who is not in principle opposed to termination." The current World Health Organization (WHO) safe abortion

[8] *Murray v. The Schooner Charming Betsy*, 6 U.S. 64, 118 (1804) ("an act of Congress ought never to be construed to violate the law of nations if any other possible construction remains, and consequently can never be construed to violate neutral rights, or to affect neutral commerce, further than is warranted by the law of nations as understood in this country.")
[9] 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.

guidance further stipulates that the referral must be to someone in the same or another easily accessible health care facility. If a referral is not possible, the objecting provider is obligated to provide safe abortion to save the woman's life and to prevent risks to her health. Any woman who presents with complications due to abortion must receive treatment with urgency and respect, as with any other emergency case. [10]

Health care providers or institutions that claim personal or religious beliefs to justify refusal of services undermine the objectives of their profession, which is to provide healthcare to all those who need it. Furthermore, providers represent a monopoly, because they offer a sought-after, specialized, and finite service. Patients are the weaker party in this situation and providers prioritizing their own consciences over the needs and rights of those they are supposed to serve shifts even more power into their hands. The more marginalized the person seeking services, the more likely they will face difficulty overcoming the power imbalance to demand and access the services they need.

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.[11] Individuals seeking reproductive health care, regardless of their reasons for needing these services, should be treated with dignity and respect.

6. **Violation of International Human Rights Standards**

International human rights standards, to date, do not require states to guarantee a right to "conscientious objection" for health care providers. On the contrary, human rights treaty monitoring bodies have called for limitations on the exercise of conscience claims, when states allow for such claims, in order to ensure that providers do not hinder access to services and thus infringe on the rights of others. They call out states' insufficient regulation of the use of "conscientious objection," and in most cases, direct states to take steps to guarantee access to services. They also affirm clearly that claims of "conscientious objection" must never be exercised by institutions.[12]

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[10] Brooke R. Johnson Jr et al., "Conscientious Objection to Provision of Legal Abortion Care," *International Journal of Gynecology and Obstetrics* 123 (2013): S60–62; Department of Reproductive Health and Research, "Safe Abortion: Technical and Policy Guidance for Health Systems" (World Health Organization, 2012), http://www.who.int/reproductivehealth/publications/unsafe_abortion/9789241548434/en/.

[11] *See* 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.

[12] "Human Rights Standards," The Storehouse for Abortion Law and Policy (Ipas, n.d.), http://www.ipas.org/en/The-Storehouse-for-Abortion-Law-and-Policy/Conscientious-objection/Human-rights-standards.aspx.

The European human rights systems have repeatedly stated that if domestic law allows health care providers to refuse to provide legal reproductive health services on grounds of conscience, states must ensure that they do not hinder access to care and must put mechanisms in place to guarantee access to lawful services. Two bodies of the European human rights system have each heard three cases related to the exercise of "conscientious objection" and neither has recognized it as right in the case of health care.[13]

7. **Alternative Action**

Current legislation and the authority given to the Department of Health and Human Services are already adequate to support and protect both conscience rights and patients from discrimination. Extending the Church Amendments would be a misuse of resources and time.

We appreciate the opportunity to provide comments on the proposed rule, and we look forward to continuing to work together to ensure health and safety for individuals throughout the world.

Thank you,

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[13] Center for Reproductive Rights, "Conscientious Objection and Reproductive Rights - International Human Rights Standards" (Center for Reproductive Rights, July 2013), https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/_Conscientious_FS_Intro_English_FINAL.pdf.

Exhibit 47

Office of Public Policy

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Provider Conscience Regulation.

Comments by the Center for Inquiry Office of Public Policy.

The proposed Provider Conscience Regulation purports to provide rules designed to help enforce three federal statutes, namely the Church Amendments (42 U.S.C. § 300a-7), Public Health Service (PHS) Act §245 (42 U.S.C. § 238n), and the Weldon Amendment (Consolidated Appropriations Act, 2008, Pub. L. No. 110-161, § 508(d), 121 Stat. 1844, 2209) (hereinafter "the statutes"). Collectively, in material part, the statutes provide that certain health care workers and entities cannot be discriminated against if they refuse to engage in, provide, pay for, or provide coverage of, certain activities or procedures, in particular abortion or sterilization.

The Center for Inquiry /Office of Public Policy strongly recommends that the Secretary of Health and Human Services (HHS) not implement the proposed Provider Conscience Regulation as a final rule for the following reasons:

1. There is no evidence that the regulation is needed. The proposed regulation cites no factual support for its supposition that health care professionals are at risk of being subject to illegal discrimination or that persons are discouraged from entering the health care professions because of concern about discrimination;

2. The regulation's rationale is based on a thorough misunderstanding of employment discrimination law as applied to workers outside the health care professions. The regulation provides far greater rights to health care workers than are enjoyed by workers in other professions, while improperly discounting the rights of patients;
3. The extension of the original statutes to require written assurances of non-discrimination goes beyond the original intent of the legislation, and unnecessarily burdens health care providers and institutions;
4. The proposed regulations will have a serious adverse impact on family well-being, contrary to the assertions on p. 29 of the proposed regulation;
5. The absence of a specific, scientifically supported definition of "abortion" and/or "sterilization" will cause confusion and could result in contraception, misunderstood by some as a form of abortion, being included as a service to which some health care workers will object.

Each of these points will be discussed in detail below.

1. No Factual Support for the Regulation

Federal regulations must be rational and based on careful consideration of all relevant factors. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.,* 463 U.S. 29 (1983). An essential component of the agency's requisite reasoned analysis is the development of an administrative record that provides clear support for the agency's position that the proposed regulation is necessary. *Id.* In this regard, the proposed regulation is severely deficient.

HHS cites no evidence that any of the existing statutes are routinely violated or ignored. In fact, the proposed regulation fails to cite one instance of a confirmed violation of any of the statutes. The sole justification for the proposed regulation is the agency's speculation that there "appears to be an attitude towards the health care professions that health care professionals and institutions should be required to provide or assist in the provision of medicine or procedures to which they object, or else risk being subjected to discrimination" (proposed regulation, p. 9). However, appearances are not facts. Appearances cannot legally provide a justification for federal regulation.

Significantly, the one reference that HHS cites to support its speculation about an appearance of discrimination is a report (specifically, an ethics committee opinion) of the American College of Obstetrics and Gynecology (ACOG) that HHS interprets as posing a potential conflict with the statutes. However, the ACOG has issued a statement denying that its policy presents any conflict with the statutes. In fact, the committee opinion is a reasoned discussion of the meaning of conscience

in a professional context. *See ACOG Committee Opinion.* Number 385. November 2007, p.1. www.acog.org/from_home/publications/ethics/co385.pdf). It proposes four criteria for determining the limits of conscientious refusal and makes seven recommendations that would ensure that a patient's welfare is a provider's primary concern, while advising providers on acceptable ways to refuse. Thus, the ACOG's report provides absolutely no justification for the proposed regulation.

At a minimum, to justify the proposed regulation, HHS must provide details about actual cases of statutory violations and describe how its proposed regulations would eliminate or reduce such misconduct. In the absence of such a factual record, the proposed regulation is "arbitrary and capricious," and, therefore, a violation of the Administrative Procedure Act, 5 U.S. § 706. See *Motor Vehicles Mfrs. Ass'n*, 463 U.S. at 43 (agency action arbitrary and capricious if there is no rational connection between the facts found and the choice made.)

2. **Inconsistency with Federal Employment Discrimination Law**

The proposed regulation states that one of the principal reasons it is supposedly needed is that there is a perception that health care professionals lack the same "rights of conscience and self-determination" that extend to others (proposed regulation, p. 10). This rationale is seriously flawed, and cannot provide a justification for the proposed regulation. There is no evidence of such a misperception. Furthermore, the proposed regulation would provide *greater* rights to health care workers than other workers currently enjoy under federal law. Effectively, the proposed regulation would create two classes of employees: those inside and those outside the health care professions, with the former having the special privilege of being able to refuse to provide a service regardless of the adverse effect of the refusal on the needs of their employer or the public.

Title VII of the Civil Rights Act of 1964, 42 U.S. §§ 2000e-2000e-15, is the principal federal statute providing protection to workers against discrimination. Title VII includes an explicit prohibition of discrimination based on religion, and this prohibition has been interpreted to require employers to accommodate an employee's religious beliefs, including a belief that providing a certain service, such as working on the Sabbath, is immoral.

However, Title VII carefully balances the rights of employees against the employer's needs and the needs of the public. Employers are required to excuse an employee from providing service *only* if excusing the employee results in no significant cost or adverse effects. *See Trans World Airlines v. Hardison*, 432 U.S. 63, 80-81 (1977). Accordingly, almost every court applying Title VII has concluded that the obligation to refrain from discriminating against an employee does not require an employer to allow an employee to categorically refuse to perform the essential functions of a job on the basis of religion if such a refusal has significant consequences for others. *See, e.g., Shelton v. University of Med. and Dentistry of New Jersey*, 223 F.3d 220 (3d Cir. 2000) (employer could discharge a nurse who refused to assist in treating a patient who required an emergency caesarian section, which would have terminated the pregnancy).

In sharp contrast to the balancing that takes place under Title VII, the proposed regulation contains no discussion of any limitations of the need to accommodate an employee's religious beliefs. It provides a blank check to employees who want to invoke religion any time they choose to decline to provide a service. This inconsistency with Title VII will cause confusion and uncertainty among health care institutions and patients and will lead to conflicting legal results.

The problems caused by the proposed regulation's failure to balance the rights of health care workers against the needs of patients is exacerbated by the proposed regulation's excessively broad definition of covered individuals. Any individual who "assists in the performance" of a health care activity or service can refuse to provide such assistance on grounds of conscience. This regulation could cause chaos in the delivery of services. As HHS candidly admits, the proposed regulation would include not only operating room nurses who might have religious objections to a procedure, but also "an employee whose task it is to clean the instruments used in a particular procedure" (proposed regulation, p. 14). But since the regulation applies both inside and outside the operating room, the regulation would also "protect" a secretary who refuses to schedule an urgent procedure and also refuses to refer the patient to another health care provider, a dietician who refuses to prepare a meal for a patient undergoing an "immoral" procedure, a hospital warehouse worker who refuses to unload a truck delivering "immoral" medical supplies, or even the truck driver herself were she employed by a health care entity. The harm to patients could be unimaginable, even though the health care entity they thought would help them is funded in part by their own tax dollars.

3. Requirement for Written Assurances

The proposed regulation requires written certification by recipients of federal funds that they will comply with the statutes. This requirement was not part of any of the three original statutes and goes beyond their original intent. The reason for this requirement given by HHS is that it worries that "the public and many health care providers are largely uninformed of the protections afforded to individuals and institutions under these provisions" (proposed regulation, p. 9). But HHS does not supply any figures or even any anecdotal evidence that there is a lack of information about these protections or that this lack of information has caused harm. The written requirement seems like a remedy for a nonexistent problem.

The requirement to provide written assurances of compliance in order to receive federal funds is also excessively burdensome. The Department's claim that "the future benefits will exceed the costs of complying with the regulation" (proposed regulation, p. 23)

is doubtful in view of the table on the following page, where almost 590,000 health care "entities" are listed as affected by the regulation. Even if one could accept HHS's estimate of the costs as $44.5 million per year, experience demonstrates that the expenses of compliance with federal regulations always increase as paperwork inundates administrators. Thus the services provided by federally funded health care providers will lose at least $44.5 million a year, affecting, among other things, the care given to about 17 million women a year who use federally funded services for family planning.

4. Impact on family well-being

The claim that the regulations will not have an impact on family well-being (proposed regulation, p. 29) is belied by logic as well as experience. If a woman cannot obtain emergency contraception because a pharmacist mistakenly believes that it causes abortion, she may have either an unwanted child or have to undergo an expensive abortion. No one could deny that such an event would have an adverse impact on family well-being. The Guttmacher Institute reports that 60 percent of women who seek abortions already have one or more children, so family well-being is uppermost in their minds (Guttmacher Institute. 2008. *Facts on Induced Abortion in the United States*. www.guttmacher.org/pubs/fb_induced_abortion.html). The ACOG, in the committee opinion referenced above, cites cases of provider refusal that clearly affected families adversely.

The Department cannot claim that this Provider Conscience Regulation will not have an impact on family well-being, especially when it is crafted to privilege the religious beliefs of health care workers over the welfare of patients.

5. Definition of abortion and sterilization

The draft of this regulation issued in July was severely criticized by many who value the separation of church and state as well as those who promote women's welfare because it included a controversial and scientifically unsupported definition of abortion. That definition has been removed from the proposed regulation; indeed, the regulation contains no definition of abortion. However, the absence of any definition is not necessarily an improvement.

As indicated, "abortion or sterilization" are now undefined. By leaving these terms undefined, HHS has deliberately left open the possibility of wide and mistaken definitions of abortion. Pharmacists who refuse to dispense emergency contraception on the grounds that it is an abortifacient misunderstand the facts about its operation.

Emergency contraception prevents fertilization, not implantation of a fertilized ovum. But such scientific facts are easily misunderstood and distorted. Because the regulation speaks only of "abortion," there is room for personal interpretations of the word based on religious and ideological beliefs.

Thus a secretary or receptionist in a health clinic, who entertains factually unsupportable but "sincere" religious beliefs about the effects of contraception, can refuse to make an appointment for a woman or a man seeking help with effective contraception on the grounds that he/she objects to abortion. This is outrageous in the United States, where 73% of voters support policies making contraception available to all, including those who depend on federally funded health care providers.

Conclusion

HHS should not implement the proposed regulation. There is no factual record demonstrating a need for the regulation; the regulation is based entirely on conjecture; it is inconsistent with other federal laws and regulations; it exceeds the scope of the authorizing statutes; it imposes unjustified burdens on health care providers; it contains ill-advised definitions or no definitions at all where they are needed; and it will have a serious adverse impact on patient care and on reproductive rights.

A health care provider's first priority must be the welfare of the patient, and accommodation of his/her own personal beliefs must not come at the expense of patient care. After all, the health care worker voluntarily chose her/his profession, and the obligations that derive from offering health care services. Without any justification, this regulation reverses that priority, elevating a health care worker's personal feelings over patient need. As a result, the proposed regulation attaches burdens on health care to the distribution of federal funds designed to promote health care. No more glaring example of an irrational regulation can be imagined.

Respectfully Submitted September 25, 2008

Contact: Toni Van Pelt

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Exhibit 48

March 27, 2018

Via Electronic Submission: *Regulations.gov*

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Public Comment in Response to the Proposed Regulation, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03

The Center for Medicare Advocacy (Center) is pleased to provide comments in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26. The Center, founded in 1986, is a national, non-partisan law organization that works to ensure fair access to Medicare and quality health care. At the Center, we provide education and advocacy on behalf of older people and people with disabilities to help secure fair access to necessary health care. We draw upon our direct experience with thousands of individuals to help educate policy makers about how their decisions affect the lives of real people. Additionally, we provide legal representation to ensure that people receive the health care benefits for which they are eligible, and the quality health care they need.

General Comments

As we stated in our comments to the Department of Health and Human Services Strategic Plan FY 2018-2022, HHS must undertake activities to identify and address health disparities with the ultimate goal of eliminating them. In activities spanning the Office for Civil Rights ("OCR"), Office of Minority Health, Office of Women's Health, Administration for Community Living, as well as the Centers for Medicare & Medicaid Services, all of HHS' endeavors must ensure that disparities are not heightened but are prevented. We once again encourage you to implement your programs in a way that addresses cultural competency, race, ethnicity, language, immigration status, age, disability, sex, gender identity and sexual orientation. The programs HHS administers must be unbiased, based on research, evidence, and medical and health-related

facts, and must be responsive to individual patient and consumer needs and wishes. Services should be offered to all in accordance with their personal beliefs and convictions. The decision to obtain any health service, including reproductive health care, should remain with the individual.

The Department's rushed rulemaking process failed to follow required procedures

The Department rushed to publish this rule without first publishing any notice regarding it in its Unified Regulatory Agenda, as is normally required. The failure to follow proper procedure reflects an inadequate consideration of the rule's impact on patients' health.

We continue to strongly urge all federal agencies to be transparent regarding opportunities for public comment and active in promoting such opportunities, in order to gather broad feedback from stakeholders and the general public.

Specific Comments

The Center believes a health care provider's personal beliefs should not determine the care a patient receives. That is why we strongly oppose the Department's 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. Such expansions exceed the Department's authority; violate the Constitution; undermine the ability of states to protect their citizens; undermine critical HHS programs; 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 – 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 Center calls on the Department and OCR to withdraw the Proposed Rule in its entirety.

Expanding religious refusals can exacerbate the barriers to care that LGBTQ individuals already face.

Every day too many LGBTQ people face discrimination and other barriers to accessing lifesaving care. These barriers are especially pronounced for transgender patients. The proposed regulation ignores the prevalence of discrimination and damage it causes and will undoubtedly lead to increased discrimination and flat-out denials of care for some of the most vulnerable

[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].

members of our community. We all deeply value freedom of religion, but sweeping exemptions that obstruct access to care are a fundamental distortion of that principle.

LGBTQ people, women, and other vulnerable groups around the country already face enormous barriers to getting the care they need.[2] Accessing quality, culturally competent care and overcoming outright discrimination is an even greater challenge for those living in areas with already limited access to health providers. The proposed regulation threatens to make access even harder and for some people nearly impossible.

Patients living in less densely populated areas already face a myriad of barriers to care including less access to health insurance coverage, lower incomes, and lower rates of paid sick leave. This is in addition to the universal costs of transportation, taking time from work, and other incidentals that go along with obtaining care in the first place. For many, the sheer distance to a healthcare facility can be a significant barrier to getting care. For example, more than half of rural women live more than 30 minutes away from a hospital that provides basic obstetric care.[3] Patients seeking more specialized care like that required for fertility treatments, endocrinology, or HIV treatment or prevention are often hours away from the closest facility offering these services. For example, a 2015 survey of nearly 28,000 transgender adults nationwide found that respondents needed to travel much further to seek care for gender dysphoria as for other kinds of care.[4]

This means if these patients are turned away or refused treatment, it is much harder—and sometimes simply not possible—for them to find a viable alternative. In a recent study, nearly one in five LGBTQ people, including 31% of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away. That rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider.[5]

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[2] *See, e.g.*, Institute of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (2011), http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx; Sandy E. James et al., *The Report of the U.S. Transgender Survey* 93–126 (2016), www.ustranssurvey.org/report; Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* (2010), http://www.lambdalegal.org/publications/when-health-care-isnt-caring; Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

[3] American College of Obstetrics and Gynecologists, *Health Disparities in Rural Women* (2014), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Disparities-in-Rural-Women#17.

[4] Sandy E. James et al., *The Report of the U.S. Transgender Survey* 99 (2016), www.ustranssurvey.org/report

[5] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

For these patients, being turned away by a medical provider is not just an inconvenience: it often means being denied care entirely with nowhere else to go.

The Proposed carries severe consequences for patients and will exacerbate already existing inequities.

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."[6] 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.[7]

The Proposed Rule lacks safeguards to protect patients from harmful refusals of care.

The proposed regulation includes no limitations to its sweeping exemptions that would protect patients' rights under the law and ensures that they receive medically warranted treatment. The expanded religious exemptions in the proposed regulations also conflict with many patient protections in federal laws like the Affordable Care Act (ACA) and the Emergency Medical Treatment and Active Labor Act. While protections under these laws are subject to religious exemptions provided under federal statute, they are not subject to exemptions whose scope goes beyond federal law—including many of the exemptions expanded in this rule. Additionally, the proposed regulation's approach to religious exemptions—which appears to allow for no limitations even when those exemptions unjustifiably harm patients or employers—conflict with the well-established standard under other federal laws, like Title VII of the Civil Rights Act. Title VII ensures that employers can consider the effect that providing a religious accommodation would have on coworkers, customers, and patients, as well as factors like public safety, public health, and other legal obligations. A standard that appears to allow for none of these considerations, and instead appears to require broad, automatic exemptions, would create confusion and undermine the federal government's ability to properly enforce federal laws.

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[6] 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.

[7] *See* Rule *supra* note 1, at 94-177.

The Proposed Rule attempts to inappropriately broaden religious exemptions in a way that can lead to dangerous denials of medically necessary treatments.

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)."[8] 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.

The Proposed Rule tramples on states' and local governments' efforts to protect patients' health and safety, including their nondiscrimination laws.

The Department claims that its unwarranted new interpretations of federal law supersede laws passed by state and local governments to ensure patients' access to health care. By claiming to allow individuals and institutions to refuse care to patients based on the providers' religious or moral beliefs in such a sweeping way, the proposed rule creates conflicts with hundreds of state and local nondiscrimination laws around the country that apply to health care. It therefore is disingenuous for the Department to claim that the proposed rule "does not impose substantial direct effects on States," "does not alter or have any substantial direct effects on the relationship between the Federal government and the States," and "does not implicate" federalism concerns under Executive Order 13132.

The Proposed Rule will carry severe consequences for providers and undermine the provider-patient relationship

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.[9] 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.[10] 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,

[8] *See id.* at 12.

[9] *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).

[10] *See id.*

in truth it will deter open, honest conversations that are vital to ensuring that a patient can control their medical circumstances.[11]

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.[12] 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.

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.[13] If finalized, however, the Proposed Rule will represent a radical departure from the Department's mission to combat discrimination, protect patient access to 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.[14]

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[11] *See* Rule *supra* note 1, at 150-151.

[12] *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.").

[13] 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.

[14] *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/hiv/index.html; *National Origin Discrimination*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/index.html; *Health*

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. A better use of OCR's limited resources would be 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.[15]

In addition, the Proposed Rule fails to address treatment of patients facing emergency health situations. 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.[16] Under EMTALA every hospital is required to comply – even those that are religiously affiliated.[17] 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.

Implement the Affordable Care Act

The Affordable Care Act has done much to reduce disparate access to care in our nation's health care system. We must note that the ACA is the law of the land, and the Administration is legally obligated to implement the law.

Unfortunately, we have watched as the Administration cut the last enrollment period in half; slashed funding for enrollment assistance and advertising; refused to participate in enrollment events; shut down healthcare.gov during critical times; and issued regulations to allow the sale of "junk" plans (such as Association Health Plans and Short-Term, Limited Duration Policies). The repeated attempts to undermine our nation's health care system must end. **All** Americans deserve access to affordable, quality health coverage.

Disparities, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/health-disparities/index.html.

[15] *See supra* note 46.

[16] 42 U.S.C. § 1295dd(a)-(c) (2003).

[17] 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).

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.

We appreciate the opportunity to submit these comments. For additional information, please contact David Lipschutz, Senior Policy Attorney (licensed in CA and CT), at dlipschutz@medicareadvocacy.org, or 202-293-5760.

Exhibit 49

March 27, 2018
U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945–ZA03
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

VIA ELECTRONIC SUBMISSION

Re: Comments on Notice of Proposed Rule on Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (Docket No.: HHS–OCR–2018–0002)

We are writing to express our deep concern and full opposition to the Notice of Proposed Rulemaking ("the proposed rule" or "the NPRM") on Protecting Statutory Conscience Rights in Health Care, published by the Department of Health and Human Services ("HHS") on January 26, 2018. HHS' proposed rule clearly aims to limit access to healthcare services, including reproductive healthcare services, by grossly mischaracterizing and expanding federal healthcare refusal laws at the expense of patient care. We strongly urge HHS to withdraw this NPRM in its entirety.

Since 1992, the Center for Reproductive Rights has used the power of law to advance reproductive rights as fundamental human rights worldwide. Our litigation and advocacy over the past 26 years have expanded access to reproductive healthcare around the nation and the world. We have played a key role in securing legal victories in the United States, Latin America, Sub-Saharan Africa, Asia, and Eastern Europe on issues including access to life-saving obstetrics care, contraception, safe abortion services, and comprehensive sexuality information. We envision a world where every person participates with dignity as an equal member of society, regardless of gender; where every woman is free to decide whether or when to have children and whether or when to get married; where access to quality reproductive healthcare is guaranteed; and where every woman can make these decisions free from coercion or discrimination.

As articulated below, this NPRM should be withdrawn in its entirety because:

- It proposes expanding religious and moral refusal laws without protecting access to care, which historically has harmed women,
- LGBTQ individuals, and marginalized communities;
- It violates the Administrative Procedure Act on multiple grounds, including by severely and repeatedly exceeding the parameters and authority of the federal refusal laws it purports to enforce;
- It harmfully prioritizes healthcare provider objections over patient care; and
- It is unconstitutional.

I. The Misapplication and Misuse of Healthcare Refusal Laws Harms Women and Marginalized Individuals and Violates International Human Rights Law.

A. Where religious and moral refusal laws are implemented without protecting access to healthcare, including reproductive healthcare, women are harmed.

The proposed rule attempts to expand religious and moral refusal laws at the expense of ensuring access to care. In general, religious and moral refusal laws allow an individual to opt out of providing a specific healthcare service on religious or moral grounds. Because religious and moral refusals to healthcare inherently create an impediment to the provision of healthcare, refusals must be balanced with the patient's right to receive a healthcare service or benefit, and should be implemented in a way that ensures the patient's right to care is protected.[1] This principle is protected and advanced by numerous laws, including the Emergency Medical Treatment and Labor Act (EMTALA), international human rights standards,[2] and professional standards set by various medical associations, such as the American College of Obstetricians and Gynecologists and the American Medical Association.[3]

When implemented without balancing, religious and moral refusal laws can be and have been exploited to limit access or deny care, particularly in the field of reproductive healthcare. Refused services include access to safe pregnancy termination, miscarriage management, and contraception, which are all necessary to ensure women's health and wellbeing.

Where healthcare entities prioritize refusals without also ensuring access to care, they risk the health and safety of patients. For example, researchers have documented numerous instances in which the Ethical and Religious Directives ("the Directives") at Catholic hospitals have led hospital administrators to prohibit doctors from treating patients. Rape survivors have been denied access to and information about emergency contraception at hospitals that prioritize religious concerns over patient wellbeing. Likewise, pharmacists with religious objections have denied women emergency contraception,[4] making it impossible for some women to obtain emergency contraception in time to prevent pregnancy.[5]

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[1] The Supreme Court has held in the past that religious exemptions must be balanced against the impact on women's healthcare. In Zubik v. Burwell, the Court ordered the parties to resolve their cases in a way that ensured there would be *no* impact on women's access to seamless contraceptive coverage. Zubik v. Burwell, 136 S. Ct. 1557, 1560 (2016). Similarly, Burwell v. Hobby Lobby rejected the notion that for-profit corporations' religious beliefs must be accommodated regardless of the impact—specifically noting that the new accommodation would have an impact on women that "would be precisely zero." Burwell v. Hobby Lobby, 134 S. Ct. 2751 (2014).

[2] Brief for foreign and international law experts, Lawrence O. Gostin, et al. as Amici Curiae supporting respondents, Zubik v. Burwell, 136 S. Ct. 1557 (2016) (Nos. 14-1418, 14-1453, 14-1505, 15-35, 15-105, 15-119, and 15-191), http://www.scotusblog.com/wp-content/uploads/2016/02/02.17.16_amicus_brief_in_support_of_respondents-_crr.pdf.

[3] The American College of Obstetricians and Gynecologists and the American Medical Association both recognize a duty to refer in order to safeguard patients' rights and access to certain reproductive healthcare. *See, e.g.,* American College of Obstetricians and Gynecologists Committee on Ethics, *Committee Opinion No. 385: The limits of conscientious refusal in reproductive medicine*, 2007, https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Ethics/The-Limits-of-Conscientious-Refusal-in-Reproductive-Medicine ("Physicians and other health care providers have the duty to refer patients in a timely manner to other providers if they do not feel that they can in conscience provide the standard reproductive services that patients request."); American Medical Association, *AMA Code of Medical Ethics Opinion 1.1.7: Physician Exercise of Conscience*, https://www.ama-assn.org/delivering-care/physician-exercise-conscience ("In general, physicians should refer a patient to another physician or institution to provide treatment the physician declines to offer.").

[4] Pharmacists in at least twenty-four states have refused to sell birth control or emergency contraception to women. *See* Gretchen Borchelt, *Pharmacists Can't Be Allowed to Deny Women Emergency Contraception*, U.S. NEWS & WORLD REPORT, Oct. 15, 2012, http://www.usnews.com/opinion/articles/2012/10/15/pharmacists-cant-be-allowed-to-deny-women-emergency-contraception.

[5] *See* Catholics for Choice (formerly Catholics for a Free Choice), *Second Chance Denied: Emergency Contraception in Catholic Hospital Emergency Rooms* (Jan. 2002), http://www.catholicsforchoice.org/wp-content/uploads/2013/12/2002secondchancedenied.pdf.

Similarly, a study of care for ectopic pregnancies concluded that some Catholic hospitals, based on the Directives, were "precluding physicians from providing women with ectopic pregnancies with information about and access to a full range of treatment options [. . .] resulting in practices that delay care and may expose women to unnecessary risks."[6] And in one case of miscarriage mismanagement, a woman named Tamesha Means was sent home twice by a Catholic hospital, even though her water had broken after only 18 weeks of pregnancy and she was in excruciating pain.[7] The hospital justified its denial of care based on a Directive prohibiting pre-viability pregnancy termination. Even when Tamesha returned for the third time, now presenting with an infection, the hospital denied her care until she began to deliver, when the hospital finally tended to her miscarriage.[8]

Mis-implementation of refusal laws may also result in severe sanctions for those who prioritize patient care over religious concerns. In a widely-reported case, a Catholic hospital provided an abortion to a woman whose risk of mortality was "close to 100 percent" if she continued the pregnancy.[9] The hospital administrator, Sister Margaret McBride, was promptly excommunicated,[10] and the diocese stripped the hospital of its Catholic affiliation.[11] The U.S. Conference of Catholic Bishops supported the sanctions and issued a memo confirming that the Directive in question does not permit the direct termination of a pregnancy—even to save a woman's life.[12]

The prioritization and exploitation of refusals over patient care, even in emergency situations, has already resulted in harm to women who are deprived of healthcare, especially reproductive healthcare. The NPRM dangerously continues in this vein by failing to address the impacts on patient care, and may exacerbate the types of harm described above. The NPRM should therefore be withdrawn in its entirety.

B. Religious and moral refusal laws disproportionately affect marginalized individuals, including economically disadvantaged women, rural women, and LGBTQ individuals.

By significantly expanding the reach of federal refusal laws without guaranteeing access to care, the proposed rule threatens harm to all patients, but may particularly increase the risk of

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[6] A.M. Foster et al., *Do Religious Restrictions Influence Ectopic Pregnancy Management? A National Qualitative Study (Abstract)*, 21 WOMEN'S HEALTH ISSUES (Mar.-Apr. 2011), http://www.ncbi.nlm.nih.gov/pubmed/21353977.

[7] ACLU, *Tamesha Means v. United States Conference of Catholic Bishops*, updated June 30, 2015, https://www.aclu.org/cases/tamesha-means-v-united-states-conference-catholic-bishops?redirect=reproductive-freedom-womens-rights/tamesha-means-v-united-states-conference-catholic-bishops.

[8] In another example, a patient who was 19 weeks pregnant presented with a miscarriage. Instead of providing a uterine evacuation, the Catholic hospital transferred her to a tertiary medical center and refused to provide medical care even when she became septic with a 106-degree fever—all because a fetal heartbeat could still be discerned. *See* Lori R. Freedman et al., *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, 98 AM. J. PUB. HEALTH 1774 (2008), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.

[9] Barbara Bradley Hagerty, *Nun Excommunicated for Allowing Abortion*, NPR, May 19, 2010, http://www.npr.org/templates/story/story.php?storyId=126985072.

[10] Id. Ms. McBride has since regained good standing with the Catholic Church. *McBride un-excommunicated*, AMERICA MAGAZINE, Dec. 14, 2011.

[11] Dan Harris, *Bishop Strips Hospital of Catholic Status After Abortion,* ABC NEWS, Dec. 22, 2010, http://abcnews.go.com/Health/abortion-debate-hospital-stripped-catholic-status/story?id=12455295.

[12] U.S. Conference of Catholic Bishops, *The Distinction between Direct Abortion and Legitimate Medical Procedures* (June 23, 2010), http://www.usccb.org/about/doctrine/publications/upload/direct-abortion-statement2010-06-23.pdf.

exploitation and abuse of refusals at the expense of marginalized individuals. While an objecting provider presents an obstacle to any patient, it may impose a particularly challenging burden on marginalized individuals. Economically disadvantaged women, rural women, and LGBTQ individuals already face barriers to care, including limited financial means, language and cultural differences, medical providers' unconscious biases, historic discrimination, and geography.[13] And now a healthcare provider's religiously motivated refusal to provide care may force a patient to choose between foregoing care or taking on the burden of locating and traveling to a non-refusing provider.

An individual who needs to plan a new visit to a non-objecting provider will often need a flexible work schedule and faces added transportation and child care costs. This creates an additional hardship, especially for economically disadvantaged women.[14] In rural areas, the closest non-objecting provider may be located far away. For example, after being denied emergency contraception by her local pharmacist, a woman in Ohio was forced to drive 45 miles to another pharmacy in order to obtain it.[15] Many women in similar situations do not have the means to make these additional trips.[16] The impact of refusals therefore falls heavily on rural women, who are four times more likely to reside in medically underserved areas.[17] Reproductive health services are especially difficult for them to access, since obstetrics/gynecologic services and other medical specialties are even less common in rural settings.[18] The inappropriate expansion of refusals under the NPRM will undoubtedly exacerbate this harm.

LGBTQ individuals also face particularly acute barriers to receiving the healthcare they need, which are compounded by religious and moral refusal laws. Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a doctor or other healthcare provider had refused to see them because of their actual or perceived sexual orientation in the year before the survey.[19] In a recent study, nearly one in five LGBTQ people, including 31% of transgender people, said that it would be very difficult or impossible to get the healthcare they need at another hospital if they were turned away.[20] That rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider.[21] When they are able to access care, many individuals report "that health care professionals have used harsh language towards them, refused to touch them or used excessive precaution, or blamed the individuals for their health

[13] American College of Obstetricians and Gynecologists, *Committee Opinion No. 516: Health Care Systems for Underserved Women* (Jan. 2012), http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-Systems-for-Underserved-Women.
[14] *See, e.g.*, Kaiser Family Foundation, *Women and Health Care: A National Profile* 24 (July 2005), *available at* https://kaiserfamilyfoundation.files.wordpress.com/2013/01/women-and-health-care-a-national-profile-key-findings-from-the-kaiser-women-s-health-survey.pdf.
[15] Gretchen Borchelt, *Pharmacists Can't Be Allowed to Deny Women Emergency Contraception*, U.S. NEWS & WORLD REPORT, Oct. 15, 2012, http://www.usnews.com/opinion/articles/2012/10/15/pharmacists-cant-be-allowed-to-deny-women-emergency-contraception.
[16] Id.
[17] *See* National Women's Law Center, *Fact Sheet: If You Care about Religious Freedom You Should Care about Reproductive Justice!* (2014), https://nwlc.org/resources/if-you-care-about-religious-freedom-you-should-care-about-reproductive-justice/, (citing U.S. Department of Health & Human Services, *Facts about . . . Rural Physicians*, http://www.shepscenter.unc.edu/rural/pubs/finding_brief/phy.html).
[18] Id.
[19] *See* Jaime M. Grant et al., *Injustice at Every Turn: a Report of the National Transgender Discrimination Survey*, NATIONAL GAY AND LESBIAN TASK FORCE & NATIONAL CTR. FOR TRANSGENDER EQUALITY (2011), http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf.
[20] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, 2016, https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.
[21] Id.

status."[22] Nearly one-quarter of transgender individuals report delaying or avoiding medical care when sick or injured, at least partially due to medical providers' discrimination and disrespect.[23]

The proposed expansion of federal refusal laws' reach will fall hardest on these populations, which already face hurdles in accessing care. As a result, the proposed rule may result in even more marginalized individuals being harmed as a result of not being able to obtain needed healthcare. Therefore, the NPRM should be withdrawn in its entirety.

C. The NPRM's proposed interpretation of religious and moral refusal laws violates international human rights laws and standards.

International human rights law requires that conscientious objections are permitted only to the extent that they do not infringe on others' access to healthcare. This requires the government to ensure that healthcare personnel's refusals to provide reproductive healthcare, including abortion care, on grounds of conscience do not jeopardize women's access to reproductive healthcare. Indeed, international human rights bodies have consistently noted the need for governments to strike a balance between protecting the right to demonstrate one's freedom of conscience and the right of women to obtain safe and legal reproductive health services. By expanding religious and moral refusals while completely failing to address how patient care will still be protected, the proposed rule violates international law.

While international human rights standards recognize the right of medical personnel to conscientiously object to the provision of sexual and reproductive health services, the exercise of this right cannot constitute a barrier to the effective enjoyment of sexual and reproductive rights. United Nations (UN) human rights treaty monitoring bodies have explicitly specified that, at a minimum, regulatory frameworks must ensure an obligation on healthcare providers to refer women to alternative health providers in a timely manner,[24] must not allow institutional refusals of care,[25] and must guarantee that an adequate number of healthcare providers willing and able to provide abortion services are available at all times in health facilities and within reasonable

[22] National Women's Law Center, *Fact Sheet: Health Care Refusals Harm Patients: The Threat to LGBT People and Individuals Living with HIV/AIDS,* May 2014, http://www.nwlc.org/sites/default/files/pdfs/lgbt_refusals_factsheet_05-09-14.pdf (citing Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* (2010), http://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf).

[23] National Center for Transgender Equality, *The Report of the 2015 U.S. Transgender Survey: Executive Summary* 3 (2016), https://transequality.org/sites/default/files/docs/usts/USTS-Executive-Summary-Dec17.pdf; National Women's Law Center, *Fact Sheet: Health Care Refusals Harm Patients: The Threat to LGBT People and Individuals Living with HIV/AIDS,* May 2014, http://www.nwlc.org/sites/default/files/pdfs/lgbt_refusals_factsheet_05-09-14.pdf (citing Jaime M. Grant, et. al., *Injustice at Every Turn: A Report of the National Transgender Discrimination Survey*, NATIONAL GAY AND LESBIAN TASK FORCE & NATIONAL CTR. FOR TRANSGENDER EQUALITY (2011), http://www.thetaskforce.org/downloads/reports/reports/ntds_full.pdf (internal quotations omitted)).

[24] *See, e.g.*, Report of the Committee on the Elimination of Discrimination Against Women, General Recommendation No. 24, 20th-21st Sess., Jan. 19-Feb. 5, June 7-25, 1999, ch. I, ¶ 11, U.N. Doc. A/54/38/Rev.1, GAOR, 44th Sess., Supp. No. 38 (1999) [hereinafter CEDAW, General Recommendation No. 24]; Committee on Economic, Social, and Cultural Rights, General Comment No. 22 (2016) on the Right to Sexual and Reproductive Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights), ¶¶ 14, 43, U.N. Doc. E/C.12/GC/22 (May 2, 2016) [hereinafter CESCR, General Comment No. 22]; Committee on the Elimination of Discrimination Against Women, Concluding Observations on the Combined Fourth and Fifth Periodic Reports of Croatia, ¶ 31, U.N. Doc. CEDAW/C/HRV/CO/4-5 (July 28, 2015); Committee on the Elimination of Discrimination Against Women, Concluding Observations on the Combined Seventh and Eighth Periodic Reports of Hungary, 54th Sess., Feb. 11-Mar. 1, 2013, ¶¶ 30-31, U.N. Doc. CEDAW/C/HUN/CO/7-8 (Mar. 1, 2013); Committee on Economic Social, and Cultural Rights, Consideration of Reports Submitted by States Parties under Articles 16 and 17 of the Covenant (Poland), 43d Sess., Nov. 2-20, 2009, ¶ 28, U.N. Doc. E/C.12/POL/CO/5 (Dec. 2, 2009). *See also* Committee on the Elimination of Discrimination Against Women, Concluding Observations on the Seventh Periodic Report of Italy, ¶¶ 41-42, U.N. Doc. CEDAW/C/ITA/CO/7 (July 24, 2017).

[25] *See* Committee on the Rights of the Child, Concluding Observations on the Combined Third to Fifth Periodic Reports of Slovakia, ¶ 41(f), U.N. Doc. CRC/C/SVK/CO/3-5 (July 20, 2016).

geographical reach.[26] In addition, any regulations must ensure that allowing conscientious objections does not inhibit the performance of services in urgent or emergency situations.[27]

For example the UN Human Rights Committee, which is charged with interpreting and monitoring countries' implementation of the International Covenant on Civil and Political Rights ("ICCPR"), has affirmed that governments must ensure that medical professionals' refusals to provide abortion care on grounds of conscience do not impede women's access to legal abortion services.[28] The United States has ratified the ICCPR, meaning that the United States is obligated to comply with and implement the provisions of the treaty subject to any reservations. The UN Human Rights Committee and the UN Committee on Economic, Social and Cultural Rights ("CESCR Committee") have found that states must introduce regulations and implement appropriate referral mechanisms in cases of provider conscientious objection.[29] The Committee on the Elimination of All Forms of Discrimination Against Women[30] has echoed the need for adequate referral mechanisms and has noted that "[i]t is discriminatory for a state party to refuse to provide legally for the performance of certain reproductive health services for women."[31] Similar findings have also been reached by other UN human rights experts.[32] Likewise, the European Court of Human Rights has found that states are obligated to organize health services in such a way as to ensure that conscience-based refusals do not prevent women from obtaining reproductive health services, including abortion services, to which they are legally entitled.[33]

UN human rights experts have noted the United States' particular obligations in this regard. While conducting a fact-finding visit to the country in 2015, the UN Working Group on Discrimination Against Women examined U.S. federal and state policies and found that they do not adequately protect women's access to reproductive health services. The Working Group's report on the visit provided recommendations for improving efforts to eliminate discrimination and reiterated that:

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[26] Committee on Economic, Social, and Cultural Rights, General Comment No. 22 (2016) on the Right to Sexual and Reproductive Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights), ¶¶ 14, 43, U.N. Doc. E/C.12/GC/22 (May 2, 2016).
[27] Id., at ¶ 43.
[28] Human Rights Committee, Consideration of Reports Submitted by States Parties under Article 40 of the Covenant (Poland), 100th Sess., Oct. 11-29, 2010, ¶ 12, U.N. Doc. CCPR/C/POL/CO/6, (Nov. 15, 2010); Human Rights Committee, Concluding Observations on the Seventh Periodic Report of Poland, ¶¶ 23-24, U.N. Doc. CCPR/C/POL/CO/7 (Nov. 23, 2016).
[29] *See* Human Rights Committee, Concluding Observations on the Sixth Periodic Report of Italy, ¶¶ 16-17, U.N. Doc. CCPR/C/ITA/CO/6 (May 1, 2017); Human Rights Committee, Concluding Observations on the Seventh Periodic Report of Colombia, ¶¶ 20-21, U.N. Doc. CCPR/C/COL/CO/7 (Nov. 17, 2016); Committee on Economic, Social and Cultural Rights, Concluding Observations on the Sixth Periodic Report of Poland, ¶¶ 46-47, U.N. Doc. E/C.12/POL/CO/6 (Oct. 26, 2016). *See also* Human Rights Committee, Concluding Observations on the Seventh Periodic Report of Poland, ¶¶ 23-24, U.N. Doc. CCPR/C/POL/CO/7 (Nov. 23, 2016).
[30] Although the United States has not yet ratified the Convention on the Elimination of All Forms of Discrimination Against Women or the International Covenant on Economic, Social, and Cultural Rights, as a signatory, it nevertheless has international obligations with respect to each. Michael H. Posner, Assistant Sec'y of State, Bureau of Democracy, Human Rights, and Labor, *Address to the American Society of International Law: The Four Freedoms Turn 70* (Mar. 24, 2011) (transcript available at https://2009-2017.state.gov/j/drl/rls/rm/2011/159195.htm) ("While the United States is not a party to the [ICESCR], as a signatory, we are committed to not defeating the object and purpose of the treaty."). Specifically, a country that has signed a treaty has an obligation "to refrain from acts which would defeat the object and purpose of a treaty" until it expresses its intention not to become a party. Vienna Convention on the Law of Treaties art. 18, Jan. 27, 1980, 1155 U.N.T.S. 331. While the United States is not a party to the Vienna Convention, it recognizes that many of the Convention's provisions have become customary international law and has signaled its intention to abide by the principles contained in treaties it has signed. *See Vienna Convention on the Law of Treaties*, U.S. DEP'T OF STATE, http://www.state.gov/s/l/treaty/faqs/70139.htm.
[31] Report of the Committee on the Elimination of Discrimination Against Women, General Recommendation No. 24, 20th-21st Sess., Jan. 19-Feb. 5, June 7-25, 1999, ch. I, ¶ 11, U.N. Doc. A/54/38/Rev.1, GAOR, 44th Sess., Supp. No. 38 (1999).
[32] *See* Interim Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, ¶¶ 24, 65(m), U.N. Doc. A/66/254 (Aug. 3, 2011).
[33] *See* R.R. v. Poland, No. 27617/04 Eur. Ct. H.R (2011); P. and S. v. Poland, No. 57375/0 Eur. Ct. H.R. (2012).

> [l]aws on religious or conscience based refusals to provide reproductive health care in the United States should be reconciled with international human rights standards. Refusal to provide sexual and reproductive health services on the grounds of religious freedom should not be permitted where such refusal would effectively deny women immediate access to the highest attainable standard of reproductive health care and affect the implementation of rights to which they are entitled under both international human rights standards and domestic law.[34]

The NPRM moves in the opposite direction of the recommendations, and instead prioritizes religious and moral refusals at the cost of patients' well-being by allowing a healthcare entity's moral or religious beliefs to supersede a patient's access to healthcare. Furthermore, the proposed rule appears to allow healthcare entities to refuse to provide information about available healthcare options, without disclosing the fact that they are choosing to withhold some information to patients, thus lacking safeguards to ensure continuity of quality patient care when a provider objects on religious or moral grounds.

In addition to attempting to allow providers to refuse to provide care or information without any consideration of patient needs, the NPRM, as further explained below, expands the scope of who can lodge a complaint alleging a violation of religious and moral beliefs to the HHS Office for Civil Rights ("OCR"), what practices or policies they can complain about, and the consequences of such complaints against providers and healthcare institutions. This dangerous expansion will create a chilling effect on providers of certain types of healthcare, leading to further reductions in healthcare access. The NPRM should therefore be withdrawn in its entirety.

II. The Proposed Rule Violates the Administrative Procedure Act

The proposed rule violates the Administrative Procedure Act ("APA") on multiple grounds. Not only does the NPRM suffer from several procedural defects, HHS fails to justify the proposed rule based on underlying facts and data, and it fails to engage in an appropriate cost-benefit analysis. Moreover, the proposed rule is arbitrary and capricious, an abuse of discretion, and not in accordance with law, because it mischaracterizes and inappropriately expands the scope of underlying federal refusal laws. For all of these reasons, HHS must withdraw the proposed rule in its entirety.

A. The proposed rule exhibits procedural flaws under the APA and the Paperwork Reduction Act (PRA).

Under the APA, "agency action, findings, and conclusions found to be . . . without observance of procedure required by law" shall be "held unlawful and set aside."[35] The NPRM suffers from multiple procedural defects. First, HHS failed to include any mention of an intent to regulate on this issue within the Unified Regulatory Agenda, as required by Executive Order 12866.[36]

[34] Human Rights Council, 33d Sess., Report of the Working Group on the Issue of Discrimination Against Women in Law and in Practice on Its Mission to the United States of America, ¶¶ 71, 95(i), U.N. Doc. A/HRC/32/44/Add.2 (Aug. 4, 2016).
[35] 5 U.S.C.§ 706(2)(D).
[36] Exec. Order No. 12866, 58 F.R. 51735 at Sec. 4(b)-(c) (Oct. 4, 1993).

Through this omission, HHS failed to put impacted entities, including other federal agencies, on notice of possible rulemaking in this area.

Second, prior to publication in the Federal Register, rules must be submitted to the Office of Information and Regulatory Affairs ("OIRA") within the Office of Management and Budget ("OMB") to provide "meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law…and do not conflict with the policies or actions of another agency."[37] According to OIRA's website, HHS submitted the proposed rule to OIRA for review on January 12, 2018, one week prior to the proposed rule being issued in the Federal Register.[38] Standard review time for OIRA is upward of 45 days (and often closer to 90 days).[39] One week was plainly insufficient time for OIRA to review the proposed rule and provide "meaningful guidance and oversight."

In particular, it is extremely unlikely that within that one-week timeframe, OIRA could or would have conducted the interagency review necessary to ensure that this proposed rule does not conflict with other federal statutes or regulations. This is evidenced by the NPRM lacking key review and analysis on how the notice and compliance requirements interact with existing law such as EMTALA (discussed in more detail in Section IV. B. of this comment) or Title VII of the Civil Rights Act of 1964, which prohibits employment discrimination based on race, color, religion, sex and national origin. In promulgating a regulation that is inconsistent with federal statutes and regulations, HHS engaged in arbitrary and capricious rulemaking, and their conduct was further compounded by a complete failure by OIRA to engage in appropriate review.

Finally, the proposed rule would also impose burdens that are inconsistent with the Paperwork Reduction Act ("PRA"). The PRA was in part established to minimize the federal paperwork burden for individuals, small businesses, and state, local, and tribunal governments; minimize the cost of collecting and disseminating information; and maximize the usefulness of the information collected by the federal government.[40] For paperwork that is required by any new regulations, agencies must minimize the burden on the public to the extent "practicable"[41] and must obtain OMB approval before requesting or collecting most types of information from the public. This NPRM requires recipients and sub-recipients to post a new notice, as well as requiring certain assurances and certifications from recipients. The costs associated with the paperwork burden created by the proposed rule could be substantial, and the practical utility of the information that HHS seeks may be negligible to the proper performance of the functions of HHS, but it is not clear that OMB has even analyzed the impacts of the NPRM under the PRA.[42]

B. This proposed rule violates the APA because it is not justified by underlying facts and data, and it fails to engage in an appropriate cost-benefit analysis.

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[37] Id. at Sec. 6(b).
[38] OIRA Conclusion of EO 12866 Regulatory Review, *Ensuring Compliance with Certain Statutory Provisions in Health Care; Delegations of Authority*. HHS/OCR. RIN: 0945-ZA03. Received date: 01/12/18. Concluded date: 01/19/18. https://www.reginfo.gov/public/do/eoDetails?rrid=127838.
[39] Exec. Order No. 12866, 58 FR 51735 at Sec. 6(b) (Oct. 4, 1993).
[40] 44 U.S.C. § 3501.
[41] 44 U.S.C. § 3507 (a)(1).
[42] The NPRM currently lacks a PRA control number, which would notify the public that OMB has approved the rule's information collection requirements under the Paperwork Reduction Act of 1995.

Under the APA, "agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" shall be set aside.[43] An agency must provide "adequate reasons" for its rulemaking, in part by "examin[ing] the relevant data and articulat[ing] a satisfactory explanation for its action including a rational connection between the fact found and the choice made."[44] The proposed rule is arbitrary and capricious because HHS failed to consider relevant data and articulate a satisfactory basis for the promulgation of this NPRM. As stated in the proposed regulation itself, HHS OCR only received ten complaints based on religious and moral refusal laws from 2008 to 2016, and only 34 complaints from November 2016 to early January 2018. These numbers pale in comparison to the total number of complaints OCR receives annually alleging civil rights violations and Health Insurance Portability and Accountability Act ("HIPAA") violations. For example, from Oct 1, 2016 through Sept. 30, 2017, OCR received approximately 30,166 complaints.[45] If 34 of them were complaints alleging a violation of religious or moral exemption laws, that constitutes less than one percent of the total volume. These data do not justify or support the NPRM, nor the related addition of a new office dedicated exclusively to these types of complaints.

Further, as the proposed rule details, under the existing regulatory scheme, HHS already investigates complaints, and has found violations and negotiated resolutions. The evidence of past enforcement where complaints were filed and violations found confirms there is no lack of enforcement here that would warrant rulemaking. In addition, HHS' existing grant-making documents already "make clear that recipients are required to comply with the federal health care provider conscience protection laws."[46] The proposed rule is therefore arbitrary and capricious because it is not justified by relevant data or facts.

Additionally, this NPRM is arbitrary and capricious because it fails to adequately assess the costs imposed by this proposed rule by underestimating certain quantifiable costs and completely ignoring the significant additional costs that would result from delayed or denied care. Executive Order 13563 requires that each agency make a "reasoned determination that its benefits justify its costs."[47] It also states that "each agency is directed to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible."[48] But this NPRM makes no attempt to conduct a reasoned cost-benefit analysis. For example, the cost-benefit analysis provides no quantifiable benefit for the rule's very purpose—expanding religious and moral refusal rights—as HHS could not find any quantifiable data to support the purported benefit of such an expansion.

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[43] 5 U.S.C.A. § 706(2)(A).

[44] Encino Motorcars, LLC v. Navarro, 136 S. Ct. 2117, 2125 (June 20, 2016) (citing Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co., 463 U.S. 29, 103 (1983)). Typically, a court will find an agency action to be arbitrary and capricious if the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (internal citations omitted); Envtl. Def. Fund, Inc. v. Costle, 657 F.2d 275, 283 (D.C. Cir. 1981) ("While we are admonished from rubber stamping agency decisions as correct, our task is complete when we find that the agency has engaged in reasoned decisionmaking within the scope of its Congressional mandate.") (internal citations and quotations omitted).

[45] U.S. Department of Health and Human Services FY19 Budget in Brief 124, https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf.

[46] Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 76 Fed. Reg. 9968, 9972 (2011).

[47] Exec. Order No. 13563, 76 FR 3821 at Sec. 1(b) (Jan. 18, 2011).

[48] Id. at Sec. 1(c).

More importantly, the cost-benefit analysis omits entirely any mention of the significant costs the rule would impose on women and other patients who are denied access to care, despite well-documented research that shows the significant healthcare costs women experience when they face healthcare denials, discussed in more detail in Section IV. D. of this comment.[49] Service denials result in delays for patients, who must then spend additional time and resources searching for a willing provider. Delays also have the effect of increasing the cost of an abortion.[50] Moreover, delays raise the cost of each step of obtaining an abortion—not just the cost of the procedure, but also incidental costs such as being required to travel farther to obtain an abortion, thereby incurring additional travel and related expenses, such as lost wages and childcare.[51] As a result, healthcare denials that result in a delay in care can significantly drive up the cost of care for a woman seeking an abortion.

Healthcare refusals without adequate safeguards may also have negative consequences on the long-term socioeconomic status of women. A recent study in the American Journal of Public Health found that women who were denied a wanted abortion had higher odds of poverty six months after denial than did women who received abortions, and that women denied abortions were also more likely to be in poverty for four years following denial of abortion.[52] The agency does not even attempt to quantify these broader medical, social, and economic costs that result from service refusals, and entirely fails to take these costs into account in justifying this NPRM. Thus, this NPRM should be withdrawn for failing to consider, and put the public on notice of, all relevant costs.

C. The NPRM is arbitrary and capricious, an abuse of discretion, and not in accordance with law, because it mischaracterizes and inappropriately expands the scope of underlying federal refusal laws.

Although agencies have broad authority to engage in rulemaking, that authority is not without limits. Under the Administrative Procedure Act, "agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "contrary to a constitutional right," or "in excess of statutory jurisdiction, authority, or limitations" shall be held unlawful and set aside. In proposing an expanded enforcement scheme for the Church amendments (42 U.S.C. § 300a-7), the Coats-Snowe amendment (42 U.S.C. § 238n.) and the Weldon amendment (Consolidated Appropriations Act, 2017, Public Law 115-31, Div. H, sec. 507(d)(1), 131 Stat. 135.), the NPRM inappropriately exceeds the parameters of the plain text of these statutes, as well as their legislative intent, in a manner that violates the APA. As a result, the proposed rule should be withdrawn in its entirety.

i. The NPRM misinterprets, and exceeds the parameters and intent of, the Church amendments.

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[49] National Women's Law Center, *When health care providers refuse: The impact on patients of providers' religious and moral objections to give medical care, information or referrals*, Apr. 2009, https://www.nwlc.org/wp-content/uploads/2015/08/April2009RefusalFactsheet.pdf.

[50] Rachel K. Jones et al., *Differences in Abortion Service Delivery in Hostile, Middle-Ground and Supportive States in 2014*, WOMEN'S HEALTH ISSUES (2018), http://www.whijournal.com/article/S1049-3867(17)30536-4/abstract.

[51] Rachel K. Jones & Jenna Jerman, *How Far Did US Women Travel for Abortion Services in 2008*, 22 J. WOMEN'S HEALTH 706 (2013).

[52] Diana Greene Foster et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 108 AM. J. PUB. H. 407 (2018), http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2017.304247.

Consisting of four substantive provisions codified at 42 U.S.C. § 300a-7, the Church amendments prohibit recipients of federal funding from discriminating against entities and individuals who refuse to perform, or "assist in the performance" of, sterilizations or abortions on the basis of religious or moral objections. The Church amendments also prohibit discrimination against those who do choose to provide abortion or sterilization. Although the operative text of the proposed rule prohibits, as the Church amendment requires, discrimination on the basis of past performance of abortion or sterilization in addition to refusals to perform these services, the silence on this topic in the proposed rule's preamble speaks volumes. The preamble entirely neglects to mention the Church amendment's protection of individuals and entities that choose to provide abortion and sterilization services, indicating clearly that HHS intends to prioritize enforcement with respect to complaints related to religious and moral refusals over discrimination against providers who choose to give care.[53]

In the NPRM, HHS proposes to define certain terms that appear in the Church amendments in a manner that greatly expands the universe of individuals covered by the statute and controverts the actual text of the statute and the intent of Congress. Therefore, the NPRM is arbitrary and capricious, an abuse of discretion, and is not in accordance with law.

As a threshold matter, the Church amendments are, as discussed further below, specifically and deliberately tailored. Nothing in the statutory text or legislative history supports the broadening of scope attempted by the NPRM. Even what is arguably the most expansive provision, 42 U.S.C. § 300a-7(d), was meant to apply only to biomedical and behavioral research contexts, as it was enacted under the National Research Service Award Act of 1974, under Title II of the Act which was specifically titled "Protection of Human Subjects of Biomedical and Behavioral Research."[54] Legislative debates at the time of passage confirm this limitation. Then-Senator Biden, stating his support for an exemptions amendment to the Biomedical Research Act—which eventually became codified as 42 U.S.C. § 300a-7(c)(2) through 42 U.S.C. § 300a-7(d)—stated the goal of the amendment was to ensure that "no individual or entities shall be required to participate in biomedical research or experimentation if such activities are contrary to the intended participants' religious beliefs or moral convictions."[55] Thus, it is arbitrary and capricious, and not in accordance with law for HHS to conclude that any part of the Church amendments authorize the agency's overbroad interpretations as follows:

"Individual" and "Workforce." Neither "individual" nor "workforce" is defined by the Church amendments. The proposed rule defines "individual" as "member of the workforce of an entity

[53] The substantive provisions of the Church amendments, which begin at 42 U.S.C. § 300a-7(b), are as follows: § 300a-7(b) states that those receiving federal funds cannot require an individual to "perform or assist in the performance of any sterilization procedure or abortion" if it would be against the individual's religious or moral beliefs, and entities similarly cannot be forced to make their facilities available or provide any personnel for the performance or assistance in the performance of sterilization or abortion. § 300a-7(c) prohibits discrimination in the "employment, promotion, or termination of employment," of physicians or other "health care personnel," and discrimination "in the extension of staff or other privileges," on the basis of one's past performance or past refusal to perform a sterilization or abortion. § 300a-7(c) further specifies that any entity receiving a grant or contract for biomedical or behavioral research is prohibited from discriminating in the same context (employment, staff privileges, etc.) because of a physician or healthcare personnel's past performance or past refusal to perform a sterilization or abortion. § 300a-7(d) states that no individual shall be required to perform or assist in the performance of "any part of a [federally funded] health service program or research activity" if it would be contrary to the individual's religious or moral beliefs. Finally, § 300a-7(e) specifies that no entity that receives certain federal funds may deny admission or otherwise discriminate against any applicant for training or study because of the applicant's unwillingness to participate in the performance of abortions or sterilizations contrary to the applicant's religious or moral beliefs.
[54] National Research Service Award Act of 1974, Pub. L. No. 93-348, 353-54 (1974).
[55] 120 Cong. Rec. 16, 21540 (June 27, 1974) (Statement of Sen. Biden).

or health care entity;" "workforce" is defined as "employees, volunteers, trainees, contractors, and other persons whose conduct, in the performance of work for an entity or health care entity, is under the direct control of such entity or health care entity, whether or not they are paid by the entity or health care entity, as well as health care providers holding privileges with the entity or health care entity." By including volunteers, contractors, and other non-employees within these definitions, the proposed rule attempts to significantly and inappropriately broaden the universe of people who could now claim to be assisting in a procedure under the Church amendments.

The Church amendments' legislative history demonstrates that only hospitals themselves and individual physicians and nurses were intended to be protected by the original statute, now consisting of 42 U.S.C. § 300a-7(b) through 42 U.S.C. § 300a-7(c)(1). On the Senate floor, the amendment sponsors focused on whether federal funding could be used to force religiously affiliated hospitals or individual medical personnel to provide abortions or sterilizations against their beliefs.[56] In clarifying to whom the Church amendments would apply, Senator Frank Church specified that the amendments were "meant to give protection to the physicians, to the nurses, to the hospitals themselves, if they are religious affiliated institutions."[57]

The articulation of "physicians, . . . nurses, . . . hospitals" stands in clear contrast with the NPRM's proposed class of individuals within the workforce. The NPRM's definitions open the door for religious and moral refusals from precisely the type of individuals that the amendments' sponsor sought to exclude. This arbitrary and capricious broadening of the amendments' scope goes far beyond what was envisioned when the Church amendments were enacted.

"Assist in the performance." This term is undefined in the text of the Church amendments. Words that are not terms of art and that are not statutorily defined are customarily given their ordinary meaning.[58] The proposed rule provides a definition of "assist in the performance" that goes far beyond the common understanding of the term. By defining the term as meaning "to participate in any activity with an articulable connection to a procedure, health service, health program, or research activity," the NPRM proposes an unreasonably broad and vague standard that could allow virtually any member of the healthcare workforce to argue that they are assisting in the performance of a procedure, from the nurse who sanitizes instruments to a receptionist scheduling appointments or to a contractor who disposes of a hospital's waste. The phrase "articulable connection to a procedure" also disregards the meaning of the word "performance," attempting to cast a wider net to those not directly responsible for performing the health care service.

Legislative history demonstrates that the NPRM's definition is contrary to the intended scope of "assisting in the performance." On the floor of the Senate, Senator Long asked Senator Church, "[T]his would not, in effect, say that one who sought such an operation would be denied it because someone working in the hospital objected who had no responsibility, directly or indirectly, with regard to the performance of that procedure." Senator Church replied, "The

[56] 119 Cong. Rec. 8, 9595-9596 (1973).
[57] 119 Cong. Rec. 8, 9597 (1973); *see also* statement from Sen. Buckley, 119 Cong. Rec. 8, 9601 ("In this amendment, we seek to protect the right not only of institutions, but of individual doctors and individual nurses.").
[58] In the absence of a statutory definition, "we construe a statutory term in accordance with its ordinary or natural meaning." FDIC v. Meyer, 510 U.S. 471, 476 (1994).

Senator is correct."[59] Senator Church went on to assert: "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."[60] The NPRM proposes to broaden the amendments' scope by permitting anyone with a mere "articulable connection" to a procedure to file a complaint. But a connection that is no more than "articulable" is exactly the kind of frivolous objection that the amendment's sponsor sought to avoid. From its inception, the Church amendments have demanded a clear and direct connection to the performance of the procedure—and the NPRM's proposed definition is plainly not in accordance with that statutory intent.

ii. The NPRM misinterprets, conflicts with, and exceeds the parameters of the Coats-Snowe amendment.

The Coats-Snowe amendment (42 U.S.C. § 238n) prohibits governments from discriminating against any "health care entity" that refuses to train for abortion care, or that attends a medical training program that does not provide abortion training or "refer for" training or abortion care. It also prevents a government from denying accreditation of a physician training program based on its refusal to provide abortion training. It is intentionally tailored solely to the context of medical training. As demonstrated below, the proposed rule's definitions of "health care entity" and "referral or refer for" go far beyond the plain language of the Coats-Snowe amendment and the intent of Congress in passing it, and as such the NPRM is not in accordance with law.

"Health care entity." The proposed rule's definition of "health care entity" conflicts with and far exceeds the statutory bounds set by Congress. The Coats-Snowe amendment defines "health care entity" as "an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions."[61] The proposed rule's definition of the same term expands, without justification or rationale, to add healthcare personnel, laboratories, plan sponsors and third-party administrators, as well as components of state and local governments. This definition could allow virtually any staff member of a healthcare facility to refuse to provide or participate in training for abortion care or abortion-related referrals, or to provide such care.

"Referral or *refer for."* This term is undefined in the Coats-Snowe amendment. The proposed rule's definition seeks not only to allow providers to opt out of referring patients to a non-objecting physician, but also to allow providers to withhold any medical information that could lead a patient to choose a healthcare service, activity, or procedure to which the treating physician objects. As explained below, this definition is arbitrary and capricious, and not in accordance with law.

The legislative history of the Coats-Snowe amendment demonstrates an intent to protect, not undermine, access to care. Debates on the Senate floor demonstrate that the amendment was a compromise provision intended to protect women's health while maintaining the status quo for,

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[59] 119 Cong. Rec. 8, 9597 (1973).
[60] Id. Sen. Church went on to reiterate that "[t]his amendment makes it clear that Congress does not intend to compel the courts to construe the law as coercing *religious affiliated hospitals, doctors, or nurses* to perform surgical procedures against which they may have religious or moral objection," 9601 (emphasis added); *see also* statement from Sen. Buckley, 119 Cong. Rec. 8, 9601 ("In this amendment, we seek to protect the right not only of institutions, but of individual doctors and individual nurses.").
[61] 42 USC § 238n(c)(2).

not expanding, providers' refusal rights. The amendment was a direct response to a provision passed by the House of Representatives that threatened women's access to care.[62] Senator Olympia Snowe, lead sponsor of the Coats-Snowe amendment, described the amendment's purpose as ensuring access to healthcare services even where a provider opted out:

> "[. . . T]his amendment would not only make sure that women have access to quality health care with the strictest of standards when it comes to quality and safety but it also will ensure that they have access to physicians who specialize in women's health care."[63]

Senator Snowe's remarks demonstrate an intent to protect and prioritize women's access to care, particularly in the context of refusals. In the NPRM, HHS completely fails to address how it will ensure this access to care. Moreover, HHS lacks the authority to interpret the terms "health care entities" or "referral or refer for" so broadly, because the legislative intent of these amendments was to create a targeted, narrow carve out that will still protect women's health. The NPRM's interpretation of the Coats-Snowe amendment is therefore arbitrary and capricious, and not in accordance with law, and the NPRM should therefore be withdrawn in its entirety.

iii. The NPRM misinterprets and exceeds the parameters of the Weldon amendment.

The Weldon amendment prohibits federal funds appropriated annually as part of the HHS Appropriations Act from being made available to any federal agency or program, or state or local government that discriminates against any "institutional or individual healthcare entity" on the basis that the entity does not "provide, pay for, provide coverage of, or refer for abortions."[64] As set forth below, the proposed rule's definitions of "health care entity" and "refer for" arbitrarily and inappropriately exceed both the statutory text and Congressional intent of this amendment.

"Health care entity." The Weldon amendment defines "health care entity" as an "individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan."[65] As noted above, the proposed rule goes far beyond this definition, adding healthcare personnel, laboratories, plan sponsors, and third-party administrators, as well as components of state and local governments, to the list of protected parties. This goes directly against Congressional intent. Plan sponsors and third-party

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[62] Sen. Snowe: "[I]n the House of Representatives they have already passed legislation that would allow Federal funds to go to an unaccredited institution. [. . .] So the choice was not to address the reality of what is taking place in the House or making sure, more importantly, that the Senate was on record in opposition to that kind of language and developing a compromise with the Senator from Indiana to ensure that we maintained the accreditation standards for all medical institutions to advance the quality health care for women and at the same time to allow training for abortion for those who want to participate in that training or for the institutions who want to provide it. Because that is the way it is done now. That is the status quo, and that is not changing. [. . .] This is a compromise to preserve those standards. This is a compromise to ensure that it does not jeopardize the 273 ob-gyn programs that otherwise would have been affected if this compromise was not before us. That is the risk, and that is why I worked with the Senator from Indiana to ensure that would not happen." 142 Cong. Rec. 38, 2269 (Mar. 19, 1996).
[63] 142 Cong. Rec. 38, 2268 (Mar. 19, 1996).
[64] Consolidated Appropriations Act of 2017, Pub. L. 115-31, Div. H, sec. 507(d)(1), 131 Stat. 135 (2017).
[65] Id.

administrators are not themselves health insurers, health plans, or even health organizations and therefore cannot and should not naturally be considered healthcare entities. By expressly defining the term "health care entity," Congress implicitly rejected the inclusion of the other terms and meanings HHS now attempts to insert. Further, at the time the amendment was adopted, Rep. Weldon himself repeatedly enumerated the entities he intended to protect, and listed only entities that are themselves providers of healthcare, but never the recipients of insurance benefits or purchasers of insurance.[66]

Moreover, the proposed definition contradicts OCR's prior conclusion that the Weldon amendment's protection of health insurance plans "included issuers of . . . plans but not institutions or individuals who purchase or are insured by those plans."[67] Without justification or basis, the NPRM now proposes to newly protect even plan sponsors—e.g., employers or universities—and third-party administrators in this category.[68] An agency can only change an existing policy if it provides a "reasoned explanation" for disregarding or overriding the basis for the prior policy—but HHS never offers this reasoned explanation in the NPRM.[69] Instead, the proposed rule seeks to allow individuals as far removed as lab workers and ambulance drivers to refuse to perform their essential job duties because, for example, the results of analyzing an amniocentesis could lead to a woman choosing an abortion, or transporting a pregnant, miscarrying woman to a hospital could allow the woman's treatment to include a pregnancy termination. The NPRM's proposed definition plainly exceeds the definition that Congress intended and the Department's own prior policy without justification or basis, in a manner that is arbitrary and capricious, and not in accordance with law.

"Referral or *refer for."* This term is undefined in the Weldon amendment. As mentioned previously, terms that are not statutorily defined are customarily assigned their ordinary meanings.[70] Extraordinary interpretations are generally not in accordance with law. The term "referral" in the medical context is understood to mean "A written order from [a] primary care doctor for [the patient] to see a specialist or get certain medical services."[71] When a "deeply held, well-considered personal belief leads a physician to also decline to refer," medical ethics require providers to "offer impartial guidance to patients about how to inform themselves regarding access to desired services."[72] But the proposed rule's definition stretches the plain meaning beyond recognition and in violation of medical practice and principles of medical ethics. HHS proposes that a definition of "referral" would include "the provision of any information…by any method…pertaining to a service, activity, or procedure" when the referring entity "understands that particular health care service, activity, or procedure to be a purpose or possible outcome of the referral."[73]

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[66] 150 Cong. Rec. 135, 10090 (Nov. 20, 2004) (Statement of Rep. Weldon).
[67] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3890 (Jan. 26, 2018).
[68] "Because the Weldon Amendment protects not only the health insurance issuer, but also the health plan itself, it can also be raised, at minimum, by the plan sponsor on behalf of the plan." Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3890 (Jan. 26, 2018).
[69] Encino Motorcars, 136 S. Ct. at 2125-2126.
[70] In the absence of a statutory definition, "we construe a statutory term in accordance with its ordinary or natural meaning." FDIC v. Meyer, 510 U.S. 471, 476 (1994).
[71] Healthcare.Gov, *Glossary: Referral.*, last visited March 22, 2018, https://www.healthcare.gov/glossary/referral/.
[72] American Medical Association, *Code of Medical Ethics Opinion 1.1.7,* AMA CODE OF MEDICAL ETHICS, last visited March 22, 2018 at https://www.ama-assn.org/delivering-care/physician-exercise-conscience.
[73] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3894-95 (Jan. 26, 2018).

With this definition of referral, HHS seeks to allow providers not only to opt out of referring patients to a non-objecting physician, but also to allow healthcare personnel to withhold any medical information that could create even a possibility that the patient would choose a healthcare service, activity, or procedure to which that individual or entity objects. The average reasonable person would not assume that a medical referral includes just about anything that might eventually, down the line, allow the patient to obtain the services they need, nor that a provider could single-handedly decide that a patient may not access the care they need. This definition goes far beyond the common understanding of the term and violates medical ethics in a manner that will cause significant harm to patients. Here and throughout, the NPRM's construction of the Weldon amendment is arbitrary and capricious, and not in accordance with law.

iv. HHS's definition of "discrimination" is arbitrary, capricious, an abuse of discretion, and not in accordance with law.

"Discrimination." In the NPRM, "discrimination" is defined as "to withhold, reduce, exclude, terminate, restrict, or otherwise make unavailable or deny any grant, contract, subcontract, cooperative agreement, loan, license, certification accreditation, employment, title, or other similar instrument, position or status;" withholding . . . "any benefit or privilege . . . utilize any criterion, method of administration, or site selection, including the enactment, application, or enforcement of laws, regulations, policies, . . ., that *tends to* subject individuals or entities to any adverse effect . . . or to *have the effect of* defeating or substantially impairing accomplishment of a health program or activity with respect to individuals, entities, or conduct protected . . . or *otherwise engage in any activity* reasonably regarded as discrimination" (emphasis added).[74]

HHS adopts a definition unsupported by any federal refusal statute. The word "discrimination" is not defined in any of the Church, Coats-Snowe, or Weldon amendments or any of the other underlying statutes the rules purport to enforce. When combined with the definitions of other terms in the NPRM, including "assist in the performance," "referral," and "workforce," this extremely broad definition of discrimination takes on a whole new and unprecedented force, giving HHS authority to take action against recipients whenever virtually any employee who can claim an "articulable connection" to a procedure makes an objection. The proposed rule appears to give these religious and moral refusals precedence over all other interests, taking no account of the negative impact on patients, other employees, or the burdens on health care providers. This is a significant expansion beyond the scope of the underlying statutes that will impact all healthcare providers who receive federal funding through HHS, including, for example, both public and private hospitals, Medicaid/Medicare recipients, and Title X recipients.

As noted above, the authors of federal refusal laws such as Church, Coats-Snowe, or Weldon amendments envisioned granting certain healthcare entities and individuals the option to opt out of providing abortion or sterilization care or coverage, not to control the conduct of others.[75] This proposed definition of discrimination, in contrast, would expand religious and moral refusal

[74] Id. at 3892.
[75] *See, e.g.*, 119 Cong. Rec. 8, 9603 (1973). (Sen. Javits: "I wish to make it clear that that particular amendment [on discrimination] simply will protect anybody who works for that hospital against being fired or losing his hospital privileges if he does not agree with the policy of the hospital and goes elsewhere and does what he wishes to do" Sen. Church: "I am in full accord with that.").

rights at the expense of a protected liberty interest—access to healthcare—with devastating consequences for women and members of the LGBTQ community who may be denied access to necessary and even emergency healthcare, as described in greater detail throughout these comments. Under this definition, important practices and policies that ensure access to healthcare—such as a basic hospital policy requiring that employees must provide care to anyone who walks through the door—could be deemed discriminatory. Further, such a vague and inappropriate definition provides no functional guidance to entities on how to comply with the applicable requirements, thereby fostering confusion. Further, compliance with the NPRM, based on what the rules appear to require, is in conflict with other federal antidiscrimination laws, as discussed in greater detail below. It will not be feasible for recipients to comply with the NPRM and, for example, EMTALA, Title VI, Title VII, and a host of other requirements that entities face when seeking accreditation.

To conclude, many of the definitions in the NPRM, but particularly the definitions of "health care entity," "assist in the performance," "individual," "workforce," "referral or refer for," and "discrimination," expand the federal healthcare refusal laws beyond their stated and intended parameters. Together, these definitions significantly and inappropriately broaden the scope and application of the underlying statutes, attempting to extend religious and moral refusal protections to individuals and entities that were plainly not contemplated. These definitions are arbitrary and capricious, and not in accordance with law, and because they inform the entire enforcement scheme proposed by the NPRM, the proposed rule must be withdrawn in its entirety.

III. The NPRM Proposes a Set of Compliance and Enforcement Mechanisms that Are Arbitrary, Capricious, an Abuse of Discretion, and Not in Accordance with Law

A. The NPRM proposes an enforcement scheme that lacks due process and is therefore unconstitutional.

In the proposed rule, HHS states that as a remedial measure for a violation, HHS will consider using all "legal options, up to and including termination of funding and return of funds," which could include "the temporary withholding of cash payments in whole or part, pending correction of the deficiency, the denial of funds and any applicable matching credit in whole or in part, the suspension or termination of the Federal award in whole or in part, the withholding of new Federal financial assistance or other Federal funds from HHS," and other remedies.[76] The NPRM does not include any notice, hearing or appeal procedures to govern such termination or withholding of funds.

The lack of notice, hearing, and appeal procedures violates the due process clause enshrined in the 5th and 14th amendments to the U.S. Constitution.[77] Recipient and sub-recipients of HHS' federal financial assistance have a protected property interest in federal financial assistance,

[76] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3898 (Jan. 26, 2018).
[77] U.S. CONST. amend. V, XIV.

which triggers certain procedural due process requirements.[78] These procedural due process requirements commonly consist of timely and adequate notice, the right to counsel, opportunity to address the fact-finder, an explanation of the decision, and chance for appeal.[79] The fact that HHS is requesting specific comment on whether the proposed rule should establish notice, hearing, and appeal procedures similar to those established in other HHS-administered programs indicates that the agency already is aware of procedural due process requirements, yet has explicitly chosen to exclude due process from its proposed rule. Failure to include mechanisms to ensure due process renders the NPRM unconstitutional. Therefore, the NPRM should be withdrawn in its entirety.

B. Many of the NPRM's proposed enforcement and compliance procedures are coercive, exceed enforcement norms, and create a chilling effect that would harm patients.

The NPRM contains certain proposed enforcement and compliance requirements that are arbitrary and capricious, an abuse of discretion, and not in accordance with law because they are coercive, exceed other enforcement norms, and create a chilling effect.

Restricting a broader range of funds and/or a broader category of entities
In its proposed rule, HHS asserts that, in order to enforce federal healthcare refusal laws, OCR may restrict "a broader range of funds or broader categories of covered entities" for "noncompliant entities."[80] HHS does not clarify what the "broader range of funds" or the "broader categories of covered entities" would encompass. Rather, the deliberate vagueness of the phrase suggests that HHS is attempting to grant itself the power to withhold not only the type of funding used in violation of program terms, but also withhold any other federal funding, even if unrelated to the offense. It also indicates that HHS would like to be free to withhold or terminate funding not only to those entities found to have committed a violation, but also those entities who may somehow be tangentially related to an entity that has been found to have committed a violation.

This proposed text has no basis in the underlying statutes the NPRM seeks to enforce, and in fact OCR has previously found this type of broad withholding of federal funding to raise "substantial questions about constitutionality" under the Spending Clause.[81] In addition, this proposed enforcement mechanism is wholly inconsistent with, and far exceeds, the regulations that govern implementation and enforcement of civil rights laws, *see e.g.* 45 C.F.R. 80. In civil rights enforcement, suspension or termination of federal funding assistance is limited to the particular grantee and the particular program or part thereof in which noncompliance was found.[82] By

[78] *See* Perry v. Sindermann, 408 U.S. 593 (1972); *see also* Citizens Health Corp. v. Sebelius, 725 F.3d 687 (7th Cir. 2013) (holding that a legitimate claim of entitlement "may arise from a contract, a statute, or a regulation, provided the source of the claim is specific enough to require the provision of the benefit on a nondiscretionary basis.").
[79] Goldberg v. Kelly, 397 U.S. 254 (1970).
[80] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3898 (January 26, 2018).
[81] Letter from OCR Director to Complainants (June 21, 2016) available at http://www.adfmedia.org/files/CDMHCInvestigationClosureLetter.pdf. ("A finding that CDMHC has violated the Weldon Amendment might require the government to rescind all funds appropriated under the Appropriations Act to the State of California – including funds provided to the State not only by HHS but also by the Departments of Education and Labor, as well as other agencies. HHS' Office of General Counsel, after consulting with the Department of Justice, has advised that such a rescission would raise substantial questions about the constitutionality of the Weldon Amendment.").
[82] 45 C.F.R. § 80.8.

potentially putting all HHS funding streams at jeopardy if a single refusal violation is found, and by putting similar entities who themselves have not committed a violation at jeopardy, the proposed rule attempts to create a blunt tool with the apparent intention of intimidating federal funding recipients and sub-recipients. Such unusually harsh and coercive compliance mechanisms render this proposed rule arbitrary and capricious, an abuse of discretion, and not in accordance with law.

Proactive reporting requirements
Under the NPRM, if a recipient or sub-recipient is subject to an OCR compliance review, investigation, or complaint filed with OCR based on religious and moral refusal laws, the recipient or sub-recipient must inform any Departmental funding component of such review, investigation, or complaint and must in any new or renewed application disclose and report on the existence of such reviews or complaints for *five years* from such complaints' filing.[83] This applies even when a violation is not found; anyone subject to a Department-initiated compliance review, investigation, or even subject to a complaint would have to undergo this process.

This compliance requirement is dangerous and likely to create a chilling effect, given that the definitions described above broadly expand the universe of those who might file complaints, and given further that anyone can file a complaint on behalf of another covered individual or entity. The proposed rule does not narrow the reporting requirement to credible instances in which the agency concluded that there was a violation; even the most frivolous complaint would have to be disclosed and reported on every funding application for five years. This is again an inappropriate compliance measure that seeks not only to intimidate recipients and sub-recipients, but also encourage outsiders to make complaints in bad faith against healthcare entities in order to mount more regulatory hurdles for such entities. It also raises concerns over whether frivolous complaints could influence a grant recipient's eligibility for future grants. These types of extreme compliance measures have no basis in the underlying statutes, exceed other enforcement norms, and are wholly inappropriate for HHS, whose mission is to ensure that Americans can get the healthcare they need. Therefore, the NPRM should be withdrawn.

IV. The Proposed Rule Should be Withdrawn Because It Harmfully Prioritizes Healthcare Provider Objections Above the Needs of Patients

A. The proposed rule is designed to have a chilling effect on the provision of abortion care.

The proposed rule seeks to intimidate abortion providers by significantly and inappropriately broadening the pool of individuals who may avail themselves of the complaint process. As articulated above, from the overly broad definitions to the excessively punitive enforcement measures, the proposed rule seeks to ensure that virtually anyone in the workforce of a healthcare entity that provides abortions—and even workers outside of an entity's core workforce, such as contractors—would be permitted to file a complaint. The proposed rule seems designed to make providers hesitant to perform abortion care for fear that their funding may be jeopardized by a

[83] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3930 (Jan. 26, 2018).

tenuously connected employee who may not even be involved in the performance of abortion care.

The chilling effect is strengthened by the enhanced compliance requirements the rule proposes. Because many clinics depend heavily on federal financial funds to serve low-income populations in their family planning programs, they may be reluctant to continue offering or referring for abortion services for fear of entrapment by anti-abortion extremists.

The types and varieties of institutions and care potentially affected by this NPRM are numerous. Below are lists of just some of the entities and care that may be affected.

Types and variety of institutions where access to care may be impacted:

- Hospitals
- Nursing facilities
- Family planning centers
- Freestanding ambulatory surgical and emergency centers
- Pharmacies
- HMO medical centers
- Medical laboratories
- Diagnostic imaging and screening centers
- Ambulance services
- Outpatient care centers
- Continuing care retirement communities and hospices
- Colleges, universities, and professional schools
- Individual physicians, nurses, and health practitioners

Types and variety of care potentially affected, including counseling for such care:

- Abortion and post-abortion care
- Miscarriage management and ectopic pregnancy care
- Sterilization care, such as tubal ligation
- Gender confirmation surgery
- Hormone therapy
- Contraceptive care
- Assisted reproductive technologies, such as in-vitro fertilization
- Hysterectomy and other reproductive care
- Amniocentesis and other prenatal diagnostic care
- Advanced directives and end-of-life care
- HIV prophylaxis, including pre-exposure and post-exposure prophylaxis
- Sexually transmitted infections screening and care
- Mental health services

The far reach of this NPRM means anyone receiving federal funding—from hospitals to independent providers—is likely to be impacted. If finalized as written, the rule could ultimately result in barriers to care for women and other individuals at multiple access points in the

healthcare system, compounding limitations to care and making it difficult for some individuals to access care at all.

B. The proposed rule fails to safeguard access to care, including information about available or optimal care and access to emergency treatment.

The proposed rule entirely fails to evaluate or consider the potential impact on access to healthcare. The foreseeable and anticipated result of the proposed rule's attempted vast expansion of religious and moral healthcare refusal rights will likely be that a larger number of individuals will use refusal laws as a basis to deny care—in addition to the number of entities that the rule seeks to intimidate into not providing certain healthcare services at all. In promulgating this rule, HHS is prioritizing the religious and moral beliefs of healthcare providers over the needs of patients in violation of its own mission statement—to "enhance and protect the health and well-being of all Americans."[84]

The proposed rule also fails to ensure the treatment of patients facing emergency health situations, including emergencies requiring miscarriage management or abortion. 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.[85] Every hospital that has a Medicare provider agreement and an emergency room—even those that are religiously-affiliated—is required to comply with EMTALA. Because the proposed rule does not mention EMTALA or safeguard emergency care in any way, it creates confusion that may lead some institutions to mistakenly believe they are not required to comply with EMTALA. As articulated earlier in this comment, failure to comply with EMTALA has resulted in harm to women. Moreover, because religious institutions have violated EMTALA in the past,[86] the NPRM's failure to address a healthcare entity's legal obligation to follow EMTALA's directives is a critical omission.

In adopting the religious and moral refusal laws that the NPRM now misappropriates, Congress explicitly considered and sought to protect against the types of harm that can result from service refusals, particularly in an emergency situation. As previously discussed, congressional records on the Church amendment indicate that some Senators, even back in 1973, anticipated and sought to curb the negative health impacts that the proposed amendment could have in rural and underserved areas, and the problems with informed consent that could arise.[87] Between the limitation on access to care that this NPRM will likely create and the complete failure to address emergency situations, the proposed rule is plainly not in accordance with underlying statutes it seeks to enforce.

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[84] U.S. Department of Health and Human Services, *About HHS*, visited Mar. 26, 2018, https://www.hhs.gov/about/index.html.
[85] *See* 42 U.S.C. § 1395dd(a)-(c).
[86] *See, e.g.* Julia Kaye et al., *Health Care Denied: Patients and physicians speak out about Catholic hospitals and the threat to women's health and lives*, May 2016, https://www.aclu.org/report/report-health-care-denied?redirect=report/health-care-denied.
[87] Senator Church based his amendment, and reassured other Senators, on the assumption that "no area of [my home state] would be without a hospital within a reasonable commuting distance which would perform abortion or sterilization procedures. Moreover, in an emergency situation—life or death type—no hospital, religious or not, would deny such services. There is no problem here."

Even for non-emergency care, the Supreme Court has held that religious objections must be balanced against their impact on women's healthcare. In *Zubik v. Burwell*,[88] the Court reviewed alternative approaches to respecting religious objections while ensuring women maintain seamless contraceptive coverage, and ordered the parties to resolve those cases in a way that ensured there would be no impact on women's access to health care.[89] The Court in *Zubik* required that an accommodation of religious exercise must still ensure that women "receive full and equal health coverage, including contraceptive coverage.'"[90] Similarly, *Burwell v. Hobby Lobby*[91] rejected the notion that for-profit corporations' religious beliefs must be accommodated regardless of the impact—specifically noting that a new accommodation at issue in the case would have an impact on women that "would be precisely zero."[92]

Undeniably, the impact on women's health under this rule would be greater than zero. While abortion is an extremely safe procedure throughout pregnancy,[93] abortion in the earliest stages of pregnancy is safest: major complications in first-trimester abortions occur at a rate of less than 0.5 percent.[94] In fact, a comprehensive report on the safety and quality of abortion care in the United States released by the National Academies of Sciences, Engineering and Medicine this month found that "safety and quality are enhanced when the abortion is performed as early in pregnancy as possible."[95] Denying a woman an abortion—and thus forcing her to carry the pregnancy to term—increases the risk of injury and death. Approximately 28.6 percent of hospital deliveries involve at least one obstetric complication, compared to the one percent to four percent for first-trimester abortion.[96] A woman is 14 times more likely to die from giving birth than as a result of an abortion.[97] Yet the proposed rule is likely to lead to increased delays and denials of abortion care, resulting in increased harm to women.

C. The proposed rule undercuts fundamental principles of patient care.

The proposed rule's new and expanded definitions interact to encourage entities and individuals who seek to refuse care on religious grounds, and intimidate providers who want to provide care.

In addition, the proposed definition of "referral or refer for" puts informed consent at risk. Informed consent is a necessary principle of patient-centered decision-making intended to help balance the power dynamics between health providers and patients and ensure patients have full autonomy over what is to happen to their bodies. Informed consent requires providers to disclose relevant and medically accurate information about treatment choices and alternatives so that

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[88] Zubik v. Burwell, 136 S. Ct. 1557 (2016).
[89] Id. at 1560; Catholic Health Care Sys. v. Burwell, 195 L. Ed. 2d 260 (2016).
[90] *Zubik*, 136 S. Ct. at 1559.
[91] Burwell v. Hobby Lobby, 134 S.Ct. 2751 (2014).
[92] Id.
[93] *See, e.g.*, Advancing New Standards In Reproductive Health (ANSIRH), *Safety of abortion in the United States* (Dec. 2014), https://www.ansirh.org/sites/default/files/publications/files/safetybrief12-14.pdf.
[94] Guttmacher Institute, *Fact sheet: Induced Abortion in the United States* (Jan. 2018), https://www.guttmacher.org/fact-sheet/induced-abortion-united-states.
[95] National Academies of Sciences, Engineering and Medicine, *Press Release: The Quality of Abortion Care Depends on Where a Woman Lives, Says One of Most Comprehensive Reviews of Research on Safety and Quality of Abortion Care in the U.S.* (Mar. 16, 2018), http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=24950.
[96] Cynthia J. Berg et al., *Overview of Maternal Morbidity During Hospitalization for Labor and Delivery in the United States,* 113 OBSTETRICS & GYNECOLOGY 1075, 1077 (2009).
[97] Raymond & Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 OBSTETRICS & GYNECOLOGY 215, 216-217 & tbl. 1 (2012) (analyzing data from 1998 to 2005).

patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.

The proposed rule puts this important principle at risk by allowing health care entities to opt out of providing any information when the entity understands that an objected-to healthcare service, activity, or procedure is even a "possible outcome of the referral."[98] For example, the proposed rule could allow entities to refuse to provide information about any other entity that might refer for an abortion, or to withhold pertinent medical information about a woman's pregnancy if the provider fears that the woman may choose to seek out an abortion or sterilization provider. It could also allow providers to not inform patients that they are withholding medical information.

Further, the proposed definition could negatively impact states' efforts to increase transparency and informed consent in pregnancy counseling. The proposed rule specifically singles out California's FACT Act, which requires all centers that provide pregnancy counseling to post information about the availability of free or low-cost family planning and abortion services under California's public programs, but targets all states' efforts to regulate fake women's health centers. These fake clinics mislead and misinform women in an attempt to prevent them from accessing abortion care. It is well-documented that many of these so-called "crisis pregnancy centers" operate under false pretenses, luring pregnant women onto their premises with the promise of free medical care and then regaling them with misinformation about abortion care and their pregnancy status.[99] Nonetheless, the rule seeks to allow such fake medical clinics to opt out of providing critical information to patients and continue their practice of deceit.

By allowing providers, including hospital and healthcare institutions, to refuse to provide patients with information, the proposed rule seeks to deprive patients of full information regarding their treatment options. While HHS claims the rule will improve 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.

The proposed rule also contravenes key and well-established principles of quality care: that care must be timely, in the best interest of the patient, and according to medical need.[100] With regards to abortion specifically, the World Health Organization has stated that:

> "Information, counselling and abortion procedures should be provided as promptly as possible without undue delay . . . The woman should be given as much time as she needs to make her decision, even if it means returning to the clinic later. However, the advantage of abortion at earlier gestational ages in terms of their greater safety over abortion at later ages should be explained. Once the decision is made by the woman, abortion should be provided as soon as is possible to do so."[101]

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[98] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3924 (Jan. 26, 2018).
[99] *See, e.g.* Brief For Planned Parenthood Federation of America and Physicians for Reproductive Health As Amici Curiae Supporting Respondents, No. 16-1140, NIFLA v. Becerra, No. 16-1140 (U.S. 2018).
[100] Institute of Medicine (now the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine). *Crossing the Quality Chasm: A New Health System for the 21st Century* (Mar. 2001) http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf.
[101] World Health Organization, *Safe Abortion: Technical and Policy Guidance for Health Systems* (2nd ed.) 36 (2012), http://apps.who.int/iris/bitstream/10665/70914/1/9789241548434_eng.pdf.

Moreover, the current proliferation of mergers between Catholic and secular hospitals is resulting in a dangerous spread of healthcare refusals, as the subsidiary secular hospitals agree to operate under the Directives. The number of Catholic owned or affiliated hospitals increased by 22 percent between 2001 and 2016—while the overall number of acute care hospitals decreased by six percent.[102] In 46 geographic regions, hospitals operating under the Directives are now the sole community healthcare providers of short-term acute hospital care; [103] nationwide, one in six acute care hospital beds is in a Catholic owned or affiliated hospital.[104] Under the proposed rule, some patients seeking life-saving treatment may be left with no place to turn for emergency care.

By permitting providers to refuse to provide or refer for care, and utterly failing to build any safeguards for patients seeking care, the proposed rule arbitrarily and capriciously undermines the best interests of the patient.

D. The proposed rule's potential increase in healthcare refusals would increase healthcare costs.

Healthcare refusals can result in significant costs for patients. When a patient is turned away at the doctor's office or a hospital without a referral, they must find a willing provider to access the healthcare they need. This means potentially significant time researching other available providers, and taking additional time off from work for a new appointment. In areas with a limited number of healthcare providers, a patient may need to drive long distances in order to access care, requiring additional expenses for overnight stays and childcare. The additional time and expense falls most heavily on low income individuals and those without the job flexibility to take paid sick time.

There may also be a significant increase in the healthcare costs themselves. For example, a woman who has a cesarean section and wishes to have a post-partum tubal ligation immediately following delivery cannot do so at a Catholic hospital, even though having the procedure at that time is medically recommended, presents fewer risks to the patient, and is more cost-effective than delaying the procedure to a later time. If the patient cannot have the procedure immediately following delivery, she must first recover from the cesarean surgery and then schedule the tubal ligation at least six weeks later when she is busy caring for her newborn. She will be required to go to another hospital and possibly a different doctor, and will have to transfer her medical records.[105]

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[102] Lois Uttley & Christine Khaikin, *Growth Of Catholic Hospitals And Health Systems: 2016 Update Of The Miscarriage Of Medicine Report,* MergerWatch (2016), http://static1.1.sqspcdn.com/static/f/816571/27061007/1465224862580/MW_Update-2016-MiscarrOfMedicine-report.pdf?token=sNLtMbWH41ZXGppQwJUb6n2ztV8%3D.
[103] Id.
[104] Id.
[105] National Women's Law Center, *When health care providers refuse: The impact on patients of providers' religious and moral objections to give medical care, information or referrals* (Apr. 2009), https://www.nwlc.org/wp-content/uploads/2015/08/April2009RefusalFactsheet.pdf. *See also*, Debra B. Stulberg et al., *Tubal Ligation in Catholic Hospitals: A Qualitative Study of Ob-Gyns' Experiences*, 90 CONTRACEPTION 422 (2014) ("Cesarean delivery in Catholic hospitals raised frustration for obstetrician-gynecologists when the hospital prohibited a simultaneous tubal ligation and, thus, sent the patient for an unnecessary subsequent surgery. [. . .] Some obstetrician-gynecologists reported that Catholic policy posed greater barriers for low-income patients and those with insurance restrictions.").

Because of the national shortage of abortion providers in the United States, a woman who is denied abortion care may also find it difficult to find an available provider in a reasonable timeframe. Eighty-nine percent of counties in the United States do not have a single abortion clinic, and some counties that have a clinic may only provide abortion services on certain days.[106] Several states have only one clinic that provides abortion care.[107] Because of the provider shortage, many women must travel long distances to access care.[108] In addition, in some areas, the shortage results in significantly increased wait times[109] and, in some cases, patients may be turned away altogether.[110]

When women face delays in obtaining an abortion, the logistical and financial burdens they face multiply. On average, a woman must wait at least a week between when she attempts to make an appointment and when she receives an abortion.[111] Delays also have the effect of increasing the cost of an abortion. Abortion in the first trimester is substantially less expensive than in the second trimester: the median price of a surgical abortion at ten weeks is $508, while the cost rises to $1,195 at week 20.[112] The rising cost of abortion as gestational age increases poses a profound challenge to the affordability of the procedure for lower-income women. As one Utah woman explained: "I knew the longer it took, the more money it would cost . . . We are living paycheck to paycheck as it is, and if I [had] gone one week sooner, it would have been $100 less."[113] Moreover, delays raise the cost of each step of obtaining an abortion—not just the cost of the procedure. For example, one recent study found that Utah's mandatory waiting period caused 47 percent of women having an abortion to miss an extra day of work.[114] More than 60 percent were negatively affected in other ways, including increased transportation costs, lost wages by a family member or friend, or being required to disclose the abortion to someone whom they otherwise would not have told.[115] And because many clinics do not offer second-trimester abortions, a woman who has been delayed into the second trimester will typically be required to travel farther to obtain an abortion, thereby incurring additional travel and related costs, such as lost wages.[116] As a result, healthcare denials that result in a delay in care can significantly drive up the cost of care for a woman seeking abortion care.

In addition, healthcare refusals without adequate safeguards may also have negative consequences on the long-term socioeconomic status of women. A recent study in the American

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[106] National Partnership for Women & Families, *Bad Medicine: How a Political Agenda is Undermining Abortion Care and Access* 13 (Mar. 2018), http://www.nationalpartnership.org/research-library/repro/bad-medicine-third-edition.pdf.
[107] Id.
[108] Id.
[109] *See generally, e.g.*, Texas Policy Evaluation Project, *Research Brief: Abortion Wait Times in Texas: The Shrinking Capacity of Facilities and the Potential Impact of Closing Non-ASC Clinics* (Oct. 2015), http://sites.utexas.edu/txpep/files/2016/01/Abortion_Wait_Time_Brief.pdf.
[110] *See, e.g.*, Brief for National Abortion Federation and Abortion Providers as Amici Curiae in Support of Petitioners at 20, Whole Woman's Health v. Cole, 136 S. Ct. 499 (2015) (No. 15-274), *sub nom.* Whole Woman's Health v. Hellerstedt, 136 S. Ct. 2292 (2016).
[111] The median is seven days, while the average is 10 days. Moreover, poorer women wait two to three days longer than the typical woman. See Lawrence B. Finer et al., *Timing of Steps and Reasons for Delays in Obtaining Abortions in the United States*, 74 CONTRACEPTION 334, 338-43 (2006).
[112] Rachel K. Jones et al., *Differences in Abortion Service Delivery in Hostile, Middle-Ground and Supportive States in 2014,* WOMEN'S HEALTH ISSUES (2018), http://www.whijournal.com/article/S1049-3867(17)30536-4/abstract.
[113] Sarah C.M. Roberts et al., *Utah's 72-Hour Waiting Period for Abortion: Experiences Among a Clinic-Based Sample of Women*, 48 PERSPECTIVES ON SEXUAL & REPRODUCTIVE HEALTH 179, 184 (2016).
[114] Jessica N. Sanders et al., *The Longest Wait: Examining the Impact of Utah's 72-Hour Waiting Period for Abortion*, 26 WOMEN'S HEALTH ISSUES 483, 485 (2016).
[115] Id.; *Accord* Deborah Karasek et al., *Abortion Patients' Experience and Perceptions of Waiting Periods: Survey Evidence Before Arizona's Two-Visit 24-hour Mandatory Waiting Period Law*, 26 WOMEN'S HEALTH ISSUES 60 (2016).
[116] Rachel K. Jones & Jenna Jerman, *How Far Did US Women Travel for Abortion Services in 2008*?,22 J. WOMEN'S HEALTH 706 (2013).

Journal of Public Health found that six months after denial of abortion, women were less likely to be employed full time and were more likely to receive public assistance than were women who obtained abortions, differences that remained significant for 4 years.[117] The study also found that women who were denied a wanted abortion were almost four times more likely to be below the federal poverty level compared to those who received an abortion.[118] Women who were denied a wanted abortion were also less likely to achieve aspirational plans for the coming year,[119] and more likely to remain in relationships with partners who subject them to physical violence.[120] Healthcare refusals that lead to delays or effective denials of care, particularly reproductive health care, therefore not only affect women's immediate health costs but also have fundamental negative economic and social consequences over many years—factors that HHS completely fails to acknowledge or take into account in this proposed rule.

The proposed rule's potential impact on women's healthcare, related healthcare costs, and economic security is substantial. Nonetheless, the NPRM entirely disregards these costs, particularly in the cost-benefit analysis portion of the rule. HHS's priorities are clear: to expand the healthcare refusals, no matter the consequence. The NPRM's failure to properly consider the very real and severe costs to women that could result from this regulatory proposal constitutes arbitrary and capricious rulemaking, and therefore the proposed rule should be withdrawn in its entirety.

E. The proposed rule would have negative health impacts on vulnerable populations worldwide.

The proposed rule seeks to expand the definition of healthcare entities in a way that potentially covers global health providers, encouraging individuals working under global health programs funded by HHS to refuse critical care in international settings. By including organizations that receive foreign aid funds through global health programs, the proposed rule extends the harm of refusals to vulnerable populations abroad. For example, in many of the countries where HHS implements global AIDS relief programs ("PEPFAR"), the populations served already face numerous barriers to care, including the broad and harmful refusal provision contained within the statute governing PEPFAR.[121]

The proposed rule opens up an additional front for discrimination against these populations by encouraging individual healthcare providers to deny the information and services they need. Such action undermines the purpose of global health programs and the rights of those they intend to serve. This is particularly harmful in developing countries where many health systems are weak, there are shortages of healthcare providers and supplies, and individuals often travel long

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[117] Diana Greene Foster et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 108 AM. J. PUB. H. 407 (2018), http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2017.304247.
[118] Id.
[119] Ushma D. Upadhyay et al., *The Effect of Abortion on Having and Achieving Aspirational One-Year Plans*, 15 BMC WOMEN'S HEALTH, no.102, 1 (2015).
[120] Sarah C.M. Roberts et al., *Risk of Violence from the Man Involved in the Pregnancy after Receiving or Being Denied an Abortion*, 12 BMC MEDICINE no. 144, 1 (2014).
[121] 22 U.S.C. 7631(d) ("(d) Eligibility for assistance: An organization, including a faith-based organization, that is otherwise eligible to receive assistance . . . (1) shall not be required, as a condition of receiving such assistance—(A) to endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or (B) to endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection").

distances to obtain the services they need. Many of the individuals that encounter refusals will have nowhere else to go.

F. Provisions in the proposed rule go against HHS' own mission statement/purpose.

By its own statement, HHS' mission is to "enhance and protect the health and well-being of all Americans [. . .] providing for effective health and human services."[122] But the proposed rule does not make even a feeble attempt at addressing how the rule would preserve, much less enhance, the health of patients who are treated by providers who avail themselves of federal refusal laws.

It is well-documented that discrimination already limits access to services for more vulnerable populations, and some religious entities have demonstrated a willingness to flout laws that seek to protect access to care. In the past, HHS' OCR has investigated numerous complaints from transgender patients about being denied certain health services, ranging from routine to life-saving care, due to the patient's gender identity.[123] In one such case, a transgender patient was denied a genetic screening for breast cancer because the insurer said the test was only for women, even though the screening was recommended by a doctor.[124] Similarly, as articulated earlier in this comment, many women seeking emergency care for their pregnancies have had their care severely delayed, or outright denied, at Catholic hospitals.[125] HHS should focus on enforcing EMTALA and other healthcare laws that make sure that patients get the care they need, not encourage entities to refuse to provide care. HHS's failure to ensure that above all, patients receive the care they require indicates that the proposed rule is driven by ideology, instead of HHS' mission to enhance the health of all Americans.

Finally, the proposed rule's preamble fails to clarify protections for individuals and entities whose religious and moral values compel them to provide care—even though the Church amendment's statutory text explicitly protects providers and entities that choose to provide abortion and sterilization services. The imbalance exposes the administration's clear bias against abortion providers and foreshadows an OCR that will enforce federal refusal of care laws with an entirely one-sided focus that seeks to undermine access to care.

V. The Proposed Rule Is Unconstitutional

In additional to the constitutional issues previously raised in this comment, including the proposed rule's violation of due process rights and the substantial questions about constitutionality under the Spending Clause, the proposed rule is likely impermissible because it creates exemptions that run afoul of the Establishment Clause.

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[122] U.S. Department of Health and Human Services, *About HHS*, last visited Mar. 26, 2018, https://www.hhs.gov/about/index.html.
[123] Dan Diamond, *Transgender patients' complaints to HHS show evidence of routine discrimination*, POLITICO, Mar. 7, 2018, https://www.politicopro.com/health-care/article/2018/03/transgender-patients-complaints-to-hhs-show-evidence-of-routine-discrimination-390755.
[124] Id.
[125] *See, e.g.*, Julia Kaye et al., *Health Care Denied: Patients and physicians speak out about Catholic hospitals and the threat to women's health and lives*, May 2016, https://www.aclu.org/report/report-health-care-denied?redirect=report/health-care-denied.

Federal law, and all regulations promulgated under federal law, must comply with the Constitution, including the Establishment Clause, which prohibits the government from creating religious exemptions to neutral, generally applicable rules in a manner that imposes burdens on third parties.[126] Yet that is precisely what the NPRM proposes: HHS seeks to allow providers not only to opt out of providing care, but also to refuse to refer patients to a non-objecting physician and to even withhold information that could lead a patient to choose healthcare to which the provider objects. As a result, this rule would effectively constitute imposing a provider's religious belief on a patient in a manner that burdens the patient, acting as a veto on the patient's access to the care they request and need.

As discussed previously, denials and delays in healthcare, especially reproductive care, result in serious medical and even socioeconomic costs—burdens on third parties that this proposed rule completely fails to mitigate or even account for. But in this case, HHS has chosen to unconstitutionally prioritize certain religious ideologies that would impose harms on women over the government's interest in eliminating discrimination, advancing women's equality, and promoting access to healthcare. By granting a greater universe of objecting institutions and individuals the power to deny healthcare without ensuring that the patients will receive care, and thereby imposing harms on these third parties, the proposed rule violates the Establishment Clause of the U.S. Constitution and therefore should be withdrawn.

VI. Conclusion

In conclusion, we strongly oppose this proposed rule. For all the reasons stated above, we urge HHS to withdraw this regulation in its entirety. Thank you for the opportunity to comment.
Sincerely,

The Center for Reproductive Rights

[126] U.S. CONST. amend. I.

Exhibit 50

CENTER
ON 3656 N.
HALSTED

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, S.W.
Washington, D.C. 20201

March 27, 2018

RE: Public Comment in Response to the Proposed Regulation, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03

To Whom it May Concern:

I am writing on behalf of Center on Halsted in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26. Center on Halsted is the Midwest's most comprehensive community center dedicated to advancing community and securing the health and well-being of the Lesbian, Gay, Bisexual, Transgender and Queer (LGBT/HIV+) people of Chicagoland. More than 1,400 community members visit the Center every day, located in the heart of Chicago's Lakeview Neighborhood. As with many LGBT/HIV+ community centers, Center on Halsted provides services for far more people from across a larger geographic expanse than the neighborhood in which it is located.

There are **385,142** LGBT/HIV+ adults living in Illinois. At 3.8%, this places the state toward the top of percentages of adult LGBT/HIV+ populations in the country. Twenty-five percent of these adults are raising children.[1] Illinois rates a 25.5/37 on the Movement Advancement Project's Equity Profile, indicating a strong support for LGBT/HIV+ communities.[2] A new report from the Chicago Department of Health reveals that there is a much higher percentage of LGBT/HIV+ people in Chicago than either the Illinois or the national average. Approximately **146,000** Chicago adults identify as LGBT, representing 7.5% of the city's population. Of these, 138,000 identify as LGB (7.1%) and 10,500 identify as transgender (0.5%), although these groups are not mutually exclusive. With the rise in youth identifying as LGBT, the percentage is likely higher.

As a beacon for LGBT/HIV+ people across Illinois, Center on Halsted provides a safe haven as well as a place of celebration. In direct services alone, Center on Halsted provides nearly 35,000 individuals an array of services from LGBT/HIV+ culturally competent Behavioral Health and HIV testing to Youth and Senior housing and wrap around services. These services exist in great part because even prior to this most recent set of options for health care professionals to deny LGBT/HIV+ services, jeopardizing their health and safety, Center on Halsted understood that access to culturally competent services limited opportunities for LGBT/HIV+ people to have their health-related needs met. As important as our services are, they are by no means adequate to serve all those in need.

In addition to direct services, Center on Halsted has one of the oldest LGBT/HIV+ Anti Violence Programs in the country. Launched in 1988, the COH Anti-Violence Project empowers LGBT/HIV+, HIV-affected

[1] Movement Advancement Project http://www.lgbtmap.org/equality-maps/lgbt_populations accessed 3. 21.18

[2] ibid

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communities, and allies to end all forms of violence through organizing and education, while supporting survivors through a broad range of direct core services and advocacy.

As the data indicates, LGBT/HIV+ individuals experience higher incidents to both intimate partner violence and community based violence than their heterosexual peers. Such exposure increases the likelihood of needing to engage health related services.

LGBT/HIV+ individuals constitute 7.5% of Chicagoans across demographics yet, Chicago Police Department data indicates in 2016 a disproportional 32.1% of hate crimes in were anti-LGBT/HIV+[3]. LGBT/HIV+ individuals experience community violence both as part of a high incident population and as residents of high incident areas.

According to the 2016 Illinois Criminal Justice Information Authority (ICJIA) *Victim Needs Assessment*, LGBT/HIV+ individuals report significantly higher rates of victimization. Those who do identify as LGBT/HIV+, when compared with non LGBT/HIV+ populations, are more likely to be a victim of a violent crime, with 11%, the highest rates in Illinois, of victimization occurring in Chicago. ICJIA describes nearly one-quarter of victims of sexual assault, 22%, identify as LGBT/HIV+. 18% of LGBT/HIV+ individuals are victims of child abuse, 16% victims of domestic violence, 13% of physical assault, and 11% victims of homicide. Often, in DV and SV, hate violence is a factor, both in targeting and carrying out violence. These victims have double the risk of developing PTSD from violence exposure[4].

In addition to direct services, Center on Halsted provides trainings to health care professionals across fields because the constellation of: negative social determinants of health, resulting health disparities, and lack of provider knowledge, that put LGBT/HIV+ in Illinois at such high risk for needing not only culturally competent health care, but healthcare access that does not further traumatize them or exacerbate the reasons for engaging healthcare, creating a need for more and longer engagement. In FY17, Center on Halsted trainers provided twenty-five trainings to nearly 600 health and safety professionals.

In preparing for trainings, the staff of Center on Halsted speak with organization and agency leadership to craft educational materials specific to the needs of their staff while also taking into account what we are told by clients regarding their experiences in 1) defining their need against culturally normative definitions (eg: heterosexual men abuse heterosexual women); 2) knowing what services are open to them (eg: can a gay man access rape crisis services?); and 3) access to culturally competent services. At any one of these points, religion-based objections to LGBT/HIV+ people by health care and social services workers could negatively alter a person's life for many years.

For instance, defining both victims and their needs through the normalizing lens of heterosexual, cis gender culture has been used to silence, erase, and deny rights to LGBT/HIV+ people. At the very basic level, after years of anti LGBT/HIV+ messaging, including from faith communities and leaders, young people internalize that there is something wrong with who they are. This works toward erode their ability to trust that they can make decisions that support their health and well being; many come to thus rely on outside assessment more so

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[3] Significant underreporting is a widely accepted fact within criminology. (Herek, G. M. (2017). Documenting hate crimes in the united states: Some considerations on data sources. Psychology of Sexual Orientation and Gender Diversity, 4(2), 143-151. doi: http://dx.doi.org.proxy.cc.uic.edu/10.1037/sgd0000227)

[4] [1] Roberts, A. L., Austin, S. B., Corliss, H. L., Vandermorris, A. K., & Koenen, K. C. (2010). Pervasive Trauma Exposure Among US Sexual Orientation Minority Adults and Risk of Posttraumatic Stress Disorder. American Journal of Public Health. [2] Lesbian, Gay Bisexual and Transgender Health, Center for Disease Control and Prevention. Retrieved March 30, 2016 from http://www.cdc.gov/lgbthealth/youth.htm [3] Dragowski, E. A., Halkitis, P. N., Grossman, A. H., D'Augelli, A. R. (2011). Sexual Orientation Victimization and Posttraumatic Stress Symptoms Among Lesbian, Gay, and Bisexual Youth. Journal of Gay & Lesbian Social Services Volume 23, Issue 2, 2011 pages 226-249.

than their heterosexual peers. Health care providers are therefore often uniquely positioned to help LGBT/HIV+ people to identify and address their needs in a way that affirms their decision making processes. To have a provider who reaffirms the negative messaging about self worth, particularly during the stress of a health related need, furthers erodes a person's confidence and self trust in decision making which in turn compounds health related issues.

In addition to concern regarding the direct services to LGBT communities, Center on Halsted worries about the potential impact on funding for HIV/AIDS related services through the Centers for Disease Control. Currently, Center on Halsted receives money through the Illinois and Chicago Departments of Health to run one of Chicago's most active and robust HIV/AIDS testing and referral programs. The Center on Halsted was an integral part of dramatically reducing the number of new HIV cases in the city, providing over 4,000 tests in FY17. Losing the CDC money would essentially shut down this program and jeopardize the progress made in Chicago.

Every day too many LGBT/HIV+ people face discrimination and other barriers to accessing lifesaving care. These barriers are especially pronounced for transgender patients. The proposed regulation ignores the prevalence of discrimination and damage it causes and will undoubtedly lead to increased discrimination and flat-out denials of care for some of the most vulnerable members of our community. We all deeply value freedom of religion, but sweeping exemptions that obstruct access to care are a fundamental distortion of that principle. Americans deserve better.

1. Expanding religious refusals can exacerbate the barriers to care that LGBT/HIV+ individuals already face.

LGBT/HIV+ people, women, and other vulnerable groups around the country already face enormous barriers to getting the care they need.[5] Accessing quality, culturally competent care and overcoming outright discrimination is even a greater challenge for those living in areas with already limited access to health providers. The proposed regulation threatens to make access even harder and for some people nearly impossible.

Patients living in less densely populated areas already face a myriad of barriers to care including less access to health insurance coverage, lower incomes, and lower rates of paid sick leave. This is in addition to the universal costs of transportation, taking time from work, and other incidentals that go along with obtaining care in the first place. For many, the sheer distance to a healthcare facility can be a significant barrier to getting care. For example, more than half of rural women live more than 30 minutes away from a hospital that provides basic obstetric care.[6] Patients seeking more specialized care like that required for fertility treatments, endocrinology, or HIV treatment or prevention are often hours away from the closest facility offering these

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[5] *See, e.g.*, Institute of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (2011), http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx; Sandy E. James et al., *The Report of the U.S. Transgender Survey* 93–126 (2016), www.ustranssurvey.org/report; Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* (2010), http://www.lambdalegal.org/publications/when-health-care-isnt-caring; Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBT/HIV+ People from Accessing Health Care* (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-LGBT/HIV+-people-accessing-health-care.

[6] American College of Obstetrics and Gynecologists, *Health Disparities in Rural Women* (2014), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Disparities-in-Rural-Women#17.

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services. For example, a 2015 survey of nearly 28,000 transgender adults nationwide found that respondents needed to travel much further to seek care for gender dysphoria as for other kinds of care.[7]

This means if these patients are turned away or refused treatment, it is much harder—and sometimes simply not possible—for them to find a viable alternative. In a recent study, nearly one in five LGBT/HIV+ people, including 31% of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away. That rate was substantially higher for LGBT/HIV+ people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider.[8] For these patients, being turned away by a medical provider is not just an inconvenience: it often means being denied care entirely with nowhere else to go.

2. The regulation attempts to inappropriately broaden religious exemptions in a way that can lead to dangerous denials of medically necessary treatments.

The regulation purports, among other things, to clarify current "religious refusal clauses" related to abortion and sterilization in three federal statutes. Each of these statutes refers to specific, limited circumstances in which health care providers or health care entities may not be required to participate in abortion and sterilization procedures. The regulation, however, creates ambiguity about these limited circumstances and encourages an overly broad misinterpretation that goes far beyond what the statutes permit.

For example, section (d) of the Church Amendments refers to circumstances when a person may refuse to participate in any part of a health service program or research activity that "would be contrary to his religious beliefs or moral convictions." Even though longstanding legal interpretation applies this section singularly to participation in abortion and sterilization procedures, the proposed rule does not make this limitation clear. This ambiguity can encourage an overly broad interpretation of the statute that empowers a provider to refuse to provide *any* health care service or information for a religious or moral reason—potentially including not just sterilization and abortion procedures, but also Pre-Exposure Prophylaxis (PrEP), infertility care, treatments related to gender dysphoria, and even HIV treatment. Some providers may try to claim even broader refusal abilities, as a recent analysis of complaints to HHS showed that transgender patients are most often discriminated against simply for being who they are rather than for the medical care they are seeking.[9]

Doctors may be misled into believing they may refuse on religious grounds to administer an HIV test or prescribe PrEP to a gay or bisexual man, or refuse screening for a urinary tract infection for a transgender man.[10] In fact, medical staff may interpret the regulation to indicate that they can not only refuse, but decline to tell the patient where he would be able to obtain these lifesaving services or even inform patients of their treatment options. This puts the health of the patient, and potentially that of others, at risk. The regulation could lead a physician to refuse to provide fertility treatments to a same-sex couple, or a pharmacist to refuse to fill a prescription for hormone replacement therapy for a transgender customer. In addition, by unlawfully redefining the statutory term "assisting in the performance" of a procedure, the rule could encourage health care workers to obstruct or delay access to a health care service even when they have only a tangential connection to delivering that service, such as scheduling a procedure or running lab tests to monitor side-effects of a medication. The extension and broadening of this clause will impair LGBT/HIV+ patients' access

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[7] Sandy E. James et al., *The Report of the U.S. Transgender Survey* 99 (2016), www.ustranssurvey.org/report

[8] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBT/HIV+ People from Accessing Health Care* (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-LGBT/HIV+-people-accessing-health-care.

[9] https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-LGBT/HIV+-nondiscrimination-regulations-prove-crucial/

[10] https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-LGBT/HIV+-nondiscrimination-regulations-prove-crucial/

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to care services if interpreted—as the proposed rule improperly appears to do—to permit providers to choose patients based upon sexual orientation, gender identity, or family structure.

We are particularly concerned that the proposed rule will be used to refuse medically necessary care to transgender patients. We are concerned that the rule's sweeping terms and HHS's troubling discussions of a case involving a transgender patient will encourage the mistaken belief that treatments that have an incidental impact on fertility, such as some procedures used to treat gender dysphoria, are sterilization procedures. Treatments for serious medical conditions may have the incidental effect of causing or contributing to infertility: for example, a hysterectomy to treat gender dysphoria, chemotherapy to treat cancer, and a wide range of medications can have the incidental effect of temporarily or permanently causing infertility. The primary purpose of such procedures, however, is not to sterilize, but to treat an unrelated medical condition. If religious or moral exemptions related to sterilization are misinterpreted to include treatments that have simply an incidental effect on fertility—as the vague and sweeping language of this rule encourages—it can lead to refusals that go even further beyond what federal law allows and unlawfully encourages individuals and institutions to refuse a dangerously broad range of medically needed treatments.

3. The proposed rule tramples on states' and local governments' efforts to protect patients' health and safety, including their nondiscrimination laws.

The Department claims that its unwarranted new interpretations of federal law supersede laws passed by state and local governments to ensure patients' access to health care. By claiming to allow individuals and institutions to refuse care to patients based on the providers' religious or moral beliefs in such a sweeping way, the proposed rule creates conflicts with hundreds of state and local nondiscrimination laws around the country that apply to health care. It therefore is disingenuous for the Department to claim that the proposed rule "does not impose substantial direct effects on States," "does not alter or have any substantial direct effects on the relationship between the Federal government and the States," and "does not implicate" federalism concerns under Executive Order 13132.

4. The regulation lacks safeguards to protect patients from harmful refusals of care.

The proposed regulation is dangerously silent in regards to the needs of patients and the impact that expanding religious refusals can have on their health. The proposed regulation includes no limitations to its sweeping exemptions that would protect patients' rights under the law and ensures that they receive medically warranted treatment. Any extension of religious accommodation should always be accompanied by equally extensive protections for patients to ensure that their medical needs remain paramount, and that they are able to receive both accurate information and quality health services.

Indeed, the Establishment Clause of the First Amendment requires the government to adequately account for burdens a religious accommodation may impose on others, including patients, and prohibits granting accommodations when they would materially harm any third party. As detailed at length above, the proposed regulation would cause significant harm by interfering with patients' access to healthcare and thus, conflicts with this constitutional bar.

The expanded religious exemptions in the proposed regulations also conflict with many patient protections in federal laws like the Affordable Care Act and the Emergency Medical Treatment and Active Labor Act. While protections under these laws are subject to religious exemptions provided under federal statute, they are not subject to exemptions whose scope goes beyond federal law—including many of the exemptions expanded in this rule. Additionally, the proposed regulation's approach to religious exemptions—which appears to allow for no limitations even when those exemptions unjustifiably harm patients or employers—conflict with the well-established standard under other federal laws, like Title VII of the Civil Rights Act. Title VII ensures that employers can consider the effect that providing a religious accommodation would have on coworkers, customers, and patients, as well as factors like public safety, public health, and other legal obligations. A standard that appears to allow for none of these considerations, and instead appears to require broad, automatic

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exemptions, would create confusion and undermine the federal government's ability to properly enforce federal laws.

5. The Department's rushed rulemaking process failed to follow required procedures.

The Department rushed to publish this rule without first publishing any notice regarding in its Unified Regulatory Agenda, as is normally required. The failure to follow proper procedure reflects an inadequate consideration of the rule's impact on patients' health.

The timing of the proposed rule also illustrates a lack of sufficient consideration. The proposed rule was published just two months after the close of a public comment period for a Request for Information closely related to this rule. The 12,000-plus public comments were not all posted until mid-December, a month before this proposed rule was released. Nearly all of the comments submitted at that time related to the subjects covered by the proposed rule—namely, the refusal of care by federally funded health care institutions or their employees on the basis of personal beliefs. This short period of time calls into question the comprehensiveness of the review of the Request for Information and whether the proposed rule was developed in an arbitrary and capricious manner.

Conclusion

If the HHS proposed conscience rule moves forward, it will exacerbate the experiences of LGBTQ individuals that they must participate fully in society as tax paying, law abiding individuals while not being afforded the same safety nets and expectations that our lives be valued by healthcare professionals paid to provide care to those in need. For organizations like Center on Halsted, this will strain our already limited services, increase the amount of work needed to vet provider referrals, and compound the amount of time and effort needed to educate our community about a rule being put in place by HHS that will erode their confidence in the healthcare system and put their lives and the lives of their loved ones in potential jeopardy. Not only will this increase our operating costs, it will take a toll on the health and well being of the LGBTQ community.

The proposed rule goes far beyond established law, appears to have been developed in a rushed and arbitrary manner, and most importantly will put the health and potentially even the lives of patients at risk. We urge you to withdraw the proposed rule.

Modesto Valle

CEO, Center on Halsted

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Exhibit 51

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

ATTENTION: Conscience NPRM, RIN 0945-ZA03

To Whom It May Concern:

The Child Welfare League of America is a coalition of private and public entities and individuals dedicated to ensuring the safety, permanency, and well-being of children, youth and their families. CWLA advocates for policies, best practices, and collaborative strategies that advance positive outcomes for children and youth. We offer the following comments on a proposed rule published in January 2018.

On Friday, January 26, 2018 the Office of Civil Rights (OCR) in the Department of Health and Services issued a proposed rule that seeks to instill power and new enforcement authority in the OCR to enforce and initiate compliance regarding conscience rights in health care.

We are concerned with some of the ramification s about this NPRM as it applies to the child welfare system at the state and local level especially in regard to issues of sexual orientation and gender identity. An overly broad interpretation based on religious, moral personal conviction could in some instances be used to discriminate and potentially deny important and basic health care services.

During the past several decades, lesbian, gay, bisexual, and transgender (LGBT) adolescents have become increasingly visible in our families, communities, and systems of care. A significant number of these young people are in the custody of child welfare or juvenile justice agencies. Child welfare, child protection, adoption and post placement services are provided through a combination of private, public and non-profit agencies. A fundamental principle in the provision of these services is that the decisions shaping a child placement and influencing that child's well-being is always driven by what is in the best interest of each child in each individual case.

By taking children into foster care, the government has accepted an obligation to care for these children. Agencies providing services on behalf of the government have an obligation to serve all children regardless of their religion, race, ethnic background, sexual orientation, or gender identity.

We are concerned that the way these new proposed regulations and authority is crafted could and likely will deny some children this basic right and obligation. As noted in the CWLA Best Practices Guidelines, it is important that "guidelines are grounded in a youth development approach that provides services and supports designed to promote young people's competencies and connect them to families and communities (Mallon, 1997). LGBT youth in out-of-home care need these same supports and services regardless of the system in which they are involved."[1]

As noted in CWLA Best Practices Guidelines, "LGBT youth often are afraid to disclose their sexual orientation or gender identity to health care providers. Unfortunately, many health care providers have negative attitudes toward LGBT patients and clients, and a range of studies have reported provider bias and discriminatory care (Ryan and Futterman, 1997.) When gay or lesbian youth disclose their sexual orientation, some providers minimize or deny their concerns on the grounds that same-gender sexual behavior is simply a phase that adolescents will grow out of. Other providers are simply ignorant of the experiences and health concerns that affect LGBT youth and do not recognize the relevance of sexual orientation or gender identity to the youth's health status."[2]

We highlight the following specific sections of the NPRM which we feel create overly broad authority and flexibility to practitioners and individual to ignore the best interests of the child in child welfare decisions making:

We are concerned about two specific sections in the definition within Section 88:

88.1 Purposes, "health care services or research activities" are referred to a category that providers may choose to deny based or refuse to perform based on an objection based on "religious, ethical, ***or other reasons****."*

This language opens the possibility that health care providers may choose to deny appropriate health care. Children who have experienced abuse and neglect and who have been removed from their family have been traumatized. Denying them care does not address the underlying trauma and may add to that trauma.

In the following section, 88.2., Definitions, the NPRM makes clear that a provider or individual can object for religious ethical or moral reasons to the referral of services:

"Referral or refer for" includes the provision of any information by any method (including but not limited to notices, books, disclaimers, or pamphlets, online or in print), pertaining to a health care services, activity, or procedure, including related to the availability, location, training, information resources, private or public funding or financing, or directions that could provide any assistance in a person obtaining assisting, training in, funding, financing, or performing a particular health care service, activity, or procedure, where the entity or health care entity

[1] CWLA Best Practice Guidelines, Wilber, S., Ryan,C., and Marksamer, J., Washington DC: Child Welfare League of America, 2006
[2] CWLA Best Practice Guidelines, Wilber, S., Ryan,C., and Marksamer, J., Washington DC: Child Welfare League of America, 2006, pg. 54

making the referral sincerely understands that a particular health care service, activity, or procedure to be a purpose or possible outcome of the referral.

As an example of how this can have a negative effect, according to the National Foster Youth Institute, seven out of ten girls who eventually age out of the foster care system will become pregnant before the age of age twenty-one. "*Young women in foster care are more than twice as likely as their peers not in foster care to become pregnant by age 19.*[2] *Even more troubling, many of those who become pregnant experience a repeat pregnancy before they reach age 19.*"[3]

We have made significant progress in the last two decades in reducing the number of unplanned pregnancies. Much of this progress has been based on evidence-based strategies. Despite the progress we have made in the United States there is much more that needs to be done. Certain populations and parts of the country still face challenges. One of these populations includes youth in care.

In February 2018, Congress expanded services to youth in foster care who are expectant or new mothers. The Families First Prevention Services Act offers the potential for greater services and support to these young people, the implementation and effectiveness of these services should not be undercut with regulation that would allow a denial of important intervention and support services.

We are concerned about proposed language under section 88.3 Applicable Requirement and Prohibition:

(v) Pursuant to 42 U.S.C. 300a–7(c)(2), entities to whom this paragraph (a)(2)(v) applies shall not discriminate against any physician or other health care personnel in employment, promotion, termination of employment, or extension of staff or other privileges because such physician or other health care personnel performed or assisted in the performance of any lawful health service or research activity or ***refused to perform or assist*** *in the performance of such service or activity on the grounds that doing so would be contrary to his or her religious beliefs or moral convictions, or because of his or her religious beliefs or moral convictions.*

We again reference CWLA Best Practices Guidelines on why this is significant.

"Researchers from the Family Acceptance Project—the first major study of LGBT adolescence and their families—documented the significance of family responses to children's emerging LGBT identities on the young people's health and mental health (Ryan and Diaz 2005). Ryan and Diaz 2005 find that family and caregiver acceptance is an important protective factor, and family and caregiver rejection has serious negative health outcomes for LGBT youth. LGBT young people whose families and caregivers rejected their sexual orientation during adolescence were much more likely to report higher rates of depression, suicidality, substance-abuse problems, and risk for HIV infection than their peers who reported having families and caregivers we had acceptance with excepted their sexual identity."

[3] The Guttmacher Institute (2011)

Access to important health care including behavioral health services can be critical and must be provided without prejudice.

Again, we have concerns under Section VI of this Regulation:

(vi) Pursuant to 42 U.S.C. 300a–7(d), entities to whom this paragraph (a)(2)(vi) applies shall not require any individual to perform or assist in the performance of any part of a ***health service program or research activity if such performance or assistance would be contrary to the individual's religious beliefs or moral convictions.***

Counseling and referral provisions *of 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B))—(1) Applicability. (i) The Department is required to comply with paragraphs (h)(2)(i) through (ii) of this section and §§88.5 and 88.6 of this part. (ii) Any State agency that administers a Medicaid program is required to comply with paragraph (h)(2)(ii) of this section and §§88.4, 88.5, and 88.6 of this part.*

Counseling is a critical element to the mental health and well-being of LGBTQ youth. Some counseling services are used as conversion therapy, and we fear that these services may be classified under "counseling and referral provisions."

"All major national mental health organizations have officially expressed concerns about therapies promoted to modify sexual orientation. To date, there has been no scientifically adequate research to show that therapy aimed at changing sexual orientation (sometimes called reparative or conversion therapy) is safe or effective. Furthermore, it seems likely that the promotion of change therapies reinforces stereotypes and contributes to a negative climate for lesbian, gay, and bisexual persons. This appears to be especially likely for lesbian, gay, and bisexual individuals who grow up in more conservative religious settings."[4]

If the counseling services do not align with the patients' needs, or when a provider attempts to change or modify one's sexual orientation or gender identity, the services can cause detrimental harm to the patient's mental health.

"In the past, some practioners tried to 'cure' individuals with gender identity disorder through aversion therapies and other techniques intended to altar cross-gender identification (Gelder & Marks, 1969). These efforts were not only unsuccessful, but caused severe psychological and, in some cases, even physical damage (Mallon, 1999c). Today, efforts to alter a person's core gender identity are viewed as both futile and unethical (Israel & Tarver, 1997; Mallon, 1999c)."[5]

Due to the level of distress on LGBTQ youth when subjected to these types of services, there becomes higher risk factors associated to the treatment. "They may also experience significant distress because their body does not correspond to their gender identity. Some transgender youth may be at high risk for HIV transmission, infection, and related health problems after obtaining

[4] American Psychological Association. (2008). Answers to your questions: For a better understanding of Sexual Orientation and Homosexuality. Washington, DC: Author. Committee on Lesbian, Gay, Bisexual, and Transgender Concerns
[5] CWLA Best Practice Guidelines; Shannan Wilber, Caitlin Ryan, and Jody Marksamer, pg. 56

hormones from the streets and using them without medical supervision. (footnote: CWLA Best Practice Guidelines; Shannan Wilber, Caitlin Ryan, and Jody Marksamer, pg. 56)

There is also a high prevalence of children diagnosed with STIs and HIV within the foster care system. The Guttmacher Institute (2014) found that, "youth and young adults ages 15-24 account for nearly half (9.1 million) of the 18.9 million new cases of STIs each year. Manlove and colleagues (2011) reported that, "compared girls nationwide, girls in foster care were three times as likely to report having had a sexual partner with an STD… In addition, young adult women who were ever in foster care were more than 50% more likely to test positive for an STD, than were young women who were never in foster care."[6]

Finally, under the (ii):

(ii) Pursuant to 42 U.S.C. 1396u– 2(b)(3)(B), entities to whom this paragraph (h)(2)(ii) ***applies shall not require a Medicaid managed care organization to provide, reimburse for, or provide coverage of, a counseling or referral service if the organization objects to the provision of such service on moral or religious grounds.***

.
Medicaid is a vital provider of health care services for children in foster care and children who exit foster care to adoptions. Giving agencies permission to discriminate against a class of people—that is, lesbians, gays, bisexuals, and transgender (LGBT) individuals—is not in the best interest of the more than 427,000 children in foster care, and the more than 20,000 youth who age out of foster care each year without family or permanent connections. Children deserve every opportunity to be cared for in a family, and blocking LGBT prospective foster and adoptive parents limit that opportunity.

While we can appreciate the efforts to assure non-discrimination in the funds of programs, we expect that at a time when there are greater calls to only fund evidence-based and effective services. It would be wrong to re-allocate or restrict funding based on a provider's personal opinions. It is critical that we continue to base child welfare services and support, especially those that cover health and behavioral health, on the best interest of the child and young person.

Sincerely,

John Sciamanna
Child Welfare League of America

[6] The Guttmacher Institute; Center for the Study of Social Policy, Expectant & Parenting Youth in Foster Care

Exhibit 52

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www.christianacare.org

March 27, 2018

Roger Severino
Director, Office for Civil Rights
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 515F
Washington, DC 20201

Re: HHS—OCR—2018—0002, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority; Proposed Rule (Vol. 83, No. 18) Jan. 26, 2018.

Dear Mr. Severino:

I write on behalf of Christiana Care Health System, headquartered in Wilmington, Delaware, a nationally recognized and leading regional health system with two academic hospitals, four campuses, and more than 50 outpatient sites of care to serve our community.

Thank you for the opportunity to comment on the Department of Health and Human Services (HHS) Office for Civil Rights' (OCR) proposed rule (hereinafter the "Proposed Rule") regarding certain statutory conscience protections, including requirements that Christiana Care and other health systems post notices of protections against religious discrimination on employee manuals and other documents, and gives HHS and OCR the ability to enforce protections for the exercise of religious conscience rights of medical providers.

Christiana Care's mission is simple, and begins with the statement that "we serve our neighbors as respectful, expert, caring partners in their health." We are concerned that the scope of the Proposed Rule is significantly broader than existing federal and state regulations and is contrary to our longstanding commitment to health equity and non-discrimination, which includes a commitment to provide equitable care to members of our community regardless of their race, religion, national origin, gender identity, LGBTQ status, and other legally protected classifications.

We are proud of our status as a nationally recognized Leader in LGBTQ Healthcare Equality,[1] and are concerned that the open-ended protections for providers to decline to care for patients on the basis of religious objections in the Proposed Rule could jeopardize our ability to continue to provide respectful, expert care to patients and their families, our commitment to non-discrimination, and our ability to provide equitable access to health care services for all of the members of our community.

Our mission is well known to our 11,600 employees, as is our commitment to ensuring that our caregivers' needs are met. To that end, Christiana Care has developed and implemented policies and procedures that balance the provision of conscience protections and other reasonable accommodations for the religious beliefs of our caregivers with our obligations to provide appropriate and necessary care to our patients. Our Patient Rights and Responsibilities Policy, for example, informs patients of the "right to quality care regardless of [the patient's] race, religion, sex, national origin, age, disability, veteran status, sexual orientation, gender identity or expression, source of payment or any other status that is an illegal basis for discrimination."

Existing federal and state laws protect health care workers who express religious objections related to performing certain procedures. In addition to our substantive concerns, we are concerned that the Proposed Rule, in its current form, will require significant revisions to our existing policies and procedures, with considerable compliance, training and communications costs associated therewith.[2]

We appreciate your consideration of these comments on this important issue.

Sincerely,

Bettina Tweardy Riveros, Esq.
Chief Health Equity Officer
Christiana Care Health System

[1] https://news.christianacare.org/2017/05/christiana-care-hospitals-earn-leader-in-lgbtq-healthcare-equality-designation/

[2] We are aware of the HHS estimate that the Proposed Rule will cost $312.3 million to implement in the first year alone. https://www.federalregister.gov/documents/2018/01/26/2018-01226/protecting-statutory-conscience-rights-in-health-care-delegations-of-authority#open-comment.

Exhibit 53

RESOLUTION 2018-30233

A RESOLUTION OF THE MAYOR AND CITY COMMISSION OF THE CITY OF MIAMI BEACH FLORIDA, OPPOSING A RULE PROPOSED BY THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ENTITLED "PROTECTING STATUTORY CONSCIENCE RIGHTS IN HEALTH CARE; DELEGATIONS OF AUTHORITY" WHICH, AMONG OTHER THINGS, WOULD BROADLY EXPAND OPPORTUNITIES FOR HEALTH CARE WORKERS TO REFUSE TO PARTICIPATE IN CERTAIN MEDICAL PROCEDURES ON THE BASIS OF A MORAL OR RELIGIOUS OBJECTION; AND DIRECTING THE CITY ATTORNEY TO TRANSMIT THIS RESOLUTION AND THE COMMENTS SET FORTH HEREIN TO THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES.

WHEREAS, the City of Miami Beach ("City") Human Rights Ordinance, codified in Chapter 62 of the City Code, declares that "there is no greater danger to the health, morals safety and welfare of the city and its inhabitants than the existence of prejudice against one another and antagonistic to each other because of actual or perceived differences of race, color, national origin, religion, sex, intersexuality, gender identity, sexual orientation, marital and familial status, age, disability, ancestry, height, weight, domestic partner status, labor organization membership, familial situation, or political affiliation"; and

WHEREAS, the Human Rights Ordinance also declares that "prejudice, intolerance, bigotry and discrimination and disorder occasioned thereby threaten the rights and proper privileges of its inhabitants and menace the very institutions, foundations and bedrock of a free, democratic society"; and

WHEREAS, in view of this policy, the City's Human Rights Ordinance prohibits discrimination in employment, public accommodations, housing, and public services, on the basis of the classification categories identified above; and

WHEREAS, the City is a longstanding municipal leader in ensuring the civil rights of its diverse and cosmopolitan population; and

WHEREAS, on January 28, 2018, the Office of Civil Rights ("OCR"), Office of Secretary of Health and Human Services ("HHS") published a notice of proposed rule, entitled "Protecting Statutory Conscience Rights in Health Care; Delegation of Authority" ("Proposed Rule"); and

WHEREAS, the Proposed Rule creates a new "Conscience and Religious Freedom Division" in the HHS OCR; and

WHEREAS, the stated purpose of the Proposed Rule is to "protect the rights of persons, entities, and health care entities to refuse to perform . . . health care services or research activities to which they may object for religious, moral, ethical, or other reasons"; and

WHEREAS, the Proposed Rule authorizes HHS and, specifically, the OCR to protect workers and penalize organizations that do not allow workers to express their religious and moral objections; and

WHEREAS, the Proposed Rule will also allow providers and facilities to opt out of providing counselling services, referring services in Medicaid and Medicare Advantage programs, advance directives, Global Health Programs, and compulsory health programs, such as immunization, hearing screening, occupational illness testing, and mental illness testing; and

WHEREAS, the Proposed Rule is estimated to impact somewhere between 364,640 to 571,412 entities, including public and private hospitals, specialty hospitals (substance abuse, maternity, cancer), youth services, shelters, nursing and hospice facilities, offices of mental health practitioners, and family planning centers; and

WHEREAS, the Proposed Rule may have far-reaching consequences and be used to justify discrimination against the City's constituents, including women, members of the LGBTQ+ community, and persons living with HIV; as well as individuals seeking birth control prescriptions, emergency contraception, lifesaving abortion, in-vitro fertilization (including for unmarried patients, same-sex couples, and interracial couples), hormone therapy for transgender or intersex patients, gender confirmation surgery, human papillomavirus ("HPV") vaccines, counseling, mental health care or a reference for mental health services; and

WHEREAS, the City Commission of the City of Miami Beach respects the right of individuals to freely practice their religion but opposes any measure that permits the use of religion to perpetuate prejudice and authorize discrimination against others.

NOW, THEREFORE, BE IT DULY RESOLVED BY THE MAYOR AND CITY COMMISSION OF THE CITY OF MIAMI BEACH, FLORIDA, that the Mayor and the City Commission hereby oppose the rule proposed by the U.S. Department of Health and Human Services, entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" which, among other things, would broadly expand opportunities for health care workers to refuse to participate in certain medical procedures on the basis of a moral or religious objection; and direct the City Attorney to transmit this Resolution and the comments set forth herein to the U.S. Department of Health and Human Services.

PASSED and **ADOPTED** this 7 day of March, 2018.

ATTEST:

3/16/18
Rafael Granado
City Clerk

Dan Gelber
Mayor

(Sponsored by Commissioner Michael Góngora)

APPROVED AS TO
FORM & LANGUAGE
& FOR EXECUTION

City Attorney 3-5-18
Date

NK

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Exhibit 54

March 27, 2018

Via electronic submission

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (Docket No.: HHS-OCR-2018-0002)

To Whom It May Concern:

The New York City Commission on Human Rights, the New York City Department of Health and Mental Hygiene, the New York City Department of Social Services, and NYC Health + Hospitals write to express our opposition to the United States Department of Health and Human Services' (HHS) proposed regulations entitled, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority.

HHS' proposed rule will cause serious harm to the health and well-being of New Yorkers. It will erect barriers to the delivery and receipt of timely, high quality health care. It will foster a new standard of selective and discriminatory treatment for many of our most vulnerable populations. It will also multiply the administrative burdens that health care organizations shoulder to address time-sensitive health conditions. Finally, it will infringe on the ability of state and local governments to enforce their laws and policies. In the face of these significant harms, we urge HHS to rescind this rule.

The Proposed Rule Will Harm Patients

The proposed rule elevates healthcare providers' personal beliefs over patient health. It gives providers wide latitude in opting out of treating patients. Undoubtedly, providers will deny care to patients who need it. At a minimum, a denial will mean that patients who are turned away will experience delays and increased expenses in receiving care. But in many cases, delay will effectively mean denial, particularly where time is of the essence or locating a suitable alternate provider is not feasible. The denial of care will be the end of the road in many patients' search for treatment.

Indeed, finding an alternate provider is no simple task. Health plans have limited provider networks, caps on the number of specialty visits, and steep cost-sharing obligations. Workers have limited or no sick leave, and forcing them to visit a second provider to accommodate the first provider's beliefs means that many patients will have to decide between taking care of their health and making a living. That is no choice at all, and many patients will forego care that they otherwise would have received.

Similarly, many people live in areas with a limited number of primary care doctors, specialists, and specialty care facilities. They may be forced to travel great distances to find a provider willing to treat them. Patients who are elderly, patients with disabilities, and patients under the age of majority may be completely unable to access an alternate healthcare provider if refused

care. During an emergency such as a national disaster, there may be only one accessible provider.

The denials of care that will result if the proposed rule is adopted will have severe and often irreversible consequences: unintended pregnancies, disease transmission, medical complications and anguish in the last days of life, and death. For example:

- Post-exposure prophylaxis for HIV should be initiated within 36 hours, but not beyond 72 hours after potential exposure.
- Emergency contraception is most effective at preventing pregnancy if taken as soon as possible after sexual intercourse.
- Contraceptives and pre-exposure prophylaxis for HIV are effective only if accessed prior to a sexual encounter.
- There is a window for a safe, legal abortion, and a narrower window for medication abortion. In the case of ectopic pregnancy or other life-threatening complication, an abortion may need to be performed immediately.
- Opiate users denied methadone or buprenorphine remain at increased risk of overdose, and naloxone must be administered quickly to reverse drug overdose.
- Persons with suicidal ideation need immediate care to prevent self-harm.
- Refusing to honor a person's end-of-life wishes prolongs suffering.

In short, the proposed rule will cause long-lasting and irreparable harm to patients.

The breadth of the proposed rule is extraordinary, all but guaranteeing that patients will be denied essential health care. Extending protections to health plans, plan sponsors, and third-party administrators that receive federal funds may prompt health plans to cease coverage for abortion, contraceptives, health care related to gender transition, and other services. Allowing anyone "with an articulable connection to a procedure, health service, health program or research activity" to raise an alleged conscience objection, means that the myriad of participants in a healthcare encounter—from intake and billing staff to pharmacists, translators, radiology technicians, and phlebotomists—can refuse to participate in service delivery. This will cause untold disruptions and delays for patients. And the expansive definitions of "assist in the performance" and "referral" mean that healthcare providers – after refusing to care for a patient – will not even need to provide a referral or other necessary information for a patient to seek care elsewhere.

The negative health impact of denied care is profound. In the case of infectious disease, there is societal impact: delays in diagnosis, prophylaxis and treatment increase the likelihood of individual disease progression and transmission to others. The consequences of untreated substance use disorders are likewise far-reaching. Compounding matters, the harmful effects of the proposed rules will be felt most acutely by individuals and communities that already face great challenges accessing the care that they need: people of color, low-income persons, women, children, people with substance use disorders, and lesbian, gay, bisexual, transgender, queer, intersex and gender nonconforming ("LGBTQI") persons.

The Proposed Rule Will Lead to Discrimination Against Already Vulnerable Populations

The rule gives healthcare providers a free pass to discriminate based on a patient's identity and against any patient whose actions or decisions conflict with the provider's alleged conscience objection.

Discrimination by health care providers marginalizes and stigmatizes patients, driving them away from care systems. It has long-term destructive consequences for the health and well-being of patients and communities that already bear the brunt of discrimination. Women and LGBTQI people will find themselves denied care at alarming rates. Providers may refuse to prescribe contraceptives to women who are not married, fertility treatment to same-sex couples, pre-exposure prophylaxis to gay men, or counseling to LGBTQI survivors of hate or intimate partner violence. Transgender patients are likely to be refused medically necessary care like hormone therapy, and substance users may be denied medications to treat addiction or reverse drug overdose.

The impact of such discrimination extends far beyond the individual patient encounter. For example, LGBTQI youth that are denied services and psychosocial support show a lasting distrust of systems of care.[i] Concerns regarding stigma may also make patients reluctant to reach out to loved ones for support, as has been shown with women who have had abortions.[ii]

This never-before-seen license to pick and choose the type of patient and nature of care that a clinician or organization will provide runs counter to principles of comprehensiveness and inclusion that have long guided the federal government's oversight of key health care programs and the operation of the country's health care delivery system.

The Proposed Rule Creates New Administrative Burdens for a Strained Health Care System

The extraordinary breadth of the proposed rule will result in significant and costly administrative burdens on an already-strained healthcare system. The proposed rule places healthcare entities in the precarious position of having to accommodate various ethical beliefs held by thousands of staff, regardless of how tenuous those staffs' connection to the clinical encounter. Also, by prohibiting employers from withholding or restricting any title, position or status from staff that refuse to participate in care, healthcare entities are limited in being able to move staff into positions where they will not disrupt care and harm patients. Thus, doctors in private practice will be prohibited from firing any staff who refuses to assist, and thereby stigmatizes and harms, LGBTQI patients. Emergency departments, ambulance corps, mental health hotlines, and other urgent care settings may need to increase the number of shift staff to ensure sufficient coverage in case of a refusal to work with a patient. This will have a very real financial impact on healthcare facilities, including government-run and subsidized clinics and hospital systems. This is a costly proposition that flies in the face of the federal government's stated goal of reducing administrative burdens within the health care system.

The Proposed Rule Infringes on State and Local Governments' Ability to Enforce Their Laws and Policies and Conflicts with Patient Protections

The proposed rule may impact the ability of State and local governments to enforce the full scope of their health- and insurance-related laws and policies by conditioning the receipt of federal funding on compliance with the rule. Similarly, it may leave providers caught between conflicting mandates. The New York City Human Rights Law ("City Human Rights Law"), for example, like many state and local nondiscrimination laws, protects patients from discrimination based on sexual orientation, gender (including gender identity), marital status, and disability.

Protecting vulnerable populations from discrimination and misinformation is of paramount importance to New York City. The City Human Rights Law is one of the most comprehensive civil rights laws in the nation, prohibiting discrimination in health care settings based on, among other things, a patient's race, age, citizenship status, and religion. A provider's refusal to serve a patient pursuant to the proposed rule may be a violation of state and local laws, some of which are enforced through the imposition of injunctive relief and substantial financial penalties. Violations of the City Human Rights Law, for example, can lead to the imposition of penalties of up to $250,000 per violation.

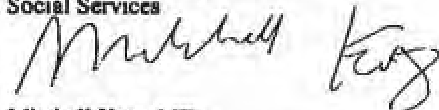
We oppose regulations that allow personal beliefs to trump science at the expense of vulnerable populations' access to health care. We oppose systems that compromise our duty to protect and improve the health of City residents. We oppose actions that sanction discrimination against patients based on who they are or what health conditions they have.

We urge HHS to rescind the proposed rule.

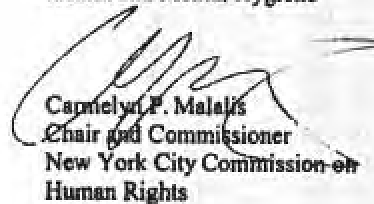
Sincerely,

Steven Banks
Commissioner
New York City Department of Social Services

Mary T. Bassett, MD, MPH
Commissioner
New York City Department of Health and Mental Hygiene



Mitchell Katz, MD
President and Chief Executive Officer
New York City Health and Hospitals



Carmelyn P. Malalis
Chair and Commissioner
New York City Commission on Human Rights

[1] Substance Abuse and Mental Health Services Administration. Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth. HHS Publication No. (SMA) 15-4928. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015.

[8] Shellenberg KM, Tsui AO. Correlates of perceived and internalized stigma among abortion patients in the USA: an exploration by race and Hispanic ethnicity. *Int J Gynaecol Obstet*. 2012;118(2):60015-60010.

Exhibit 55

PUBLIC SUBMISSION

As of: June 22, 2019
Received: March 27, 2018
Status: Posted
Posted: March 29, 2018
Tracking No.1k2-929a-2gvn
Comments Due: March 27, 2018
Submission Type:API

Docket:HHS-OCR-2018-0002
Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Comment On:HHS-OCR-2018-0002-0001
Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Document:HHS-OCR-2018-0002-71443
Comment on FR Doc # 2018-01226

Submitter Information

Name: Cathy Alderman
Address:80205
Email: calderman@coloradocoalition.org
Organization: Colorado Coalition for the Homeless

General Comment

Thank you for the opportunity to comment on an amendment to RIN 0945-ZA03, which would expand moral and conscience objections for medical professionals. As an advocate for vulnerable populations including people experiencing homelessness and those in protected classes, we are very concerned about this proposed rule. I have attached the signatures of over 200 people in Colorado that are joining us in our opposition to this rule.

People experiencing homelessness are already the victims of discrimination and biases that create challenges to attaining services to lead a healthy and successful life. We know that denying care does not negate the health needs of these vulnerable populations and instead costs taxpayers significantly more money. For example, a recent survey by the Center for American Progress showed that LGBTQ people experience discrimination in health care settings; that discrimination discourages them from seeking care; and that LGBTQ people may have trouble finding alternative services if they are turned away. In that same study, 8 percent of respondents said that a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation. I am gravely concerned that this number would increase at an alarming rate, forcing the LBGTQ community into the shadows.

This rule would allow for any staff person to claim a moral objection to a client based on biases around medical treatment for critical health issues including HIV/AIDS, Hepatitis C, tuberculous, and substance use disorders. In 2017, more than 10,000 people experiencing homelessness nationwide reported having HIV/AIDS in 2017; and between 2000 and 2015, over half million people died from drug overdoses in the United States. We have a moral obligation to work to protect our neighbors from preventable deaths.

While I understand the proposed rule is intended to protect medical professionals, I am concerned about the unintended consequences of people experiencing homelessness, often those in a protected class, falling victim to discrimination and losing access to the health care they desperately need.

Please reconsider the amendment RIN 0945-ZA03 and protect vulnerable populations receiving medical care.

Attachments

Petition Sign On

Cathy	Alderman	Denver	Colorado	80211-2529
Charlotte	Alexandre	Thornton	Colorado	80229-8450
Jeff	Andersen	Centennial	Colorado	80121-2456
Neal	Anderson	Lakewood	Colorado	80232
Sarah	Augustinsky	Denver	Colorado	80228
SARAH	AVANT	Denver	Colorado	80205-2529
Patrick	Ayers	Colorado Springs	Colorado	80906-5967
Sharon	Baldwin	Arvada	Colorado	80004
ELIZABETH	BALL	Boulder	Colorado	80301
Donna Mae	Baukat	Durango	Colorado	81301-3709
Susan	Behrendt	Denver	Colorado	80209-5541
Patricia	Bell	Arvada	Colorado	80003-5307
Bonnie	Benjamin	Denver	Colorado	80212-2504
Caroline	Bliss-Kandel	Englewood	Colorado	80113-6015
Jessica	Bombardier	Denver	Colorado	80211-1453
Beatriz	Bonnet	Highlands Ranch	Colorado	80126-5515
MARK	Bowman	Lakewood	Colorado	80214-2229
Shirley	Bramhall	Denver	Colorado	80202-6249
Laura	Brassie	Denver	Colorado	80205
Lynda	Brechtbill	Denver	Colorado	80203
Evan	Bridgford	Laramie	Wyoming	82072
David	Brody	Denver	Colorado	80220-1422
Barbara	Caley	Denver	Colorado	80209
Geovana	Cano	Denver	Colorado	80239
Liszandra	Carlton	Denver	Colorado	80205
Kaylanne	Chandler	Denver	Colorado	80205-4756
Betsy	Chavez	Pagosa Springs	Colorado	81147
Anne	Christner	Littleton	Colorado	80127
Janet	Clarke	Denver	Colorado	80247

Tona	Cloyd	Denver	Colorado	80205-2627
C	Cole	Denver	Colorado	80210
Rickelle	Collins	Denver	Colorado	80226
Ca'la	Connros	Aurora	Colorado	80013
Donna	Cook	Thornton	Colorado	80229-2935
Mollie	Cook	Denver	Colorado	80220-2408
Richard	Creswell	Lakewood	Colorado	80227-3161
Jenny	Davies	Denver	Colorado	80211-3101
Cary	Carner	Denver	Colorado	80210
Kelly	Carlson	Aurora	Colorado	80010
Richard	Deitrich	Denver	Colorado	80231
Clara	Lexis	Highlands Ranch	Colorado	80130-2592
John	S.	Westminster	Colorado	80031-4370
Stevi	Gray	Denver	Colorado	80232-6209
Dede	Frain	Denver	Colorado	80212
Heather	B	Denver	Colorado	80203
Brittany	Bayes	Littleton	Colorado	80126
Todd	Kaanta	Evergreen	Colorado	80439
Kylie	Degnan	Englewood	Colorado	80113
Kristen	Duboc	Arvada	Colorado	80007
Diane	Howald	Denver	Colorado	80203
Joy	peter	Arvada	Colorado	80004
Patricia	Hayes	Highlands Ranch	Colorado	80130-6881
Merrill A.	C.	Lakewood	Colorado	80226-2961
Sara	Dasugo	Denver	Colorado	80247
Jake	Hyman			
Jennifer	Schwekeberg	Denver	Colorado	80207
Elfriede	Leicht	Denver	Colorado	80247-7218
Kay	J.	Denver	Colorado	80219-3035
Lori	Hight	Longmont	Colorado	80503-9235
Margaret	Robinson	Denver	Colorado	80215
Melanie	A.	Denver	Colorado	80229

Jerrold	G.	Aurora	Colorado	80012-5303
Lynn	Rider	Las Animas	Colorado	81054-0502
Emily	P.	Denver	Colorado	80211-4316
Lacey	A.	Denver	Colorado	80237-2141
Landon	Ledbetter	Englewood	Colorado	80113
Christopher	R.	Westminster	Colorado	80023-8729
Joshua	Staller	Centennial	Colorado	80122-3890
Laszlo	Soos	Littleton	Colorado	80127-1669
Matthew	Lurch	Aurora	Colorado	80012
Emilia	Volz	Denver	Colorado	80210
Blaine	Molsen	Denver	Colorado	80220-4618
Katherine	D.	Denver	Colorado	80205
Margaret	Post	Golden	Colorado	80401-6577
Jan	Schiller	Fort Morgan	Colorado	80701-7201
Patricia	M.	Denver	Colorado	80210-3342
Nikki	Brabins	Denver	Colorado	80224
Ann	D.	Broomfield	Colorado	80020
Russell	DeWitt	Denver	Colorado	80209-2635
Kelly	Eisentraut	Denver	Colorado	80205
Kevin	Emery	Aurora	Colorado	80013
Barton	Emery	Denver	Colorado	80212
Paul	Erlendson	Denver	Colorado	80220-5330
Mackenzie	Feehan	Denver	Colorado	80219
Kate	Fitch	Lakewood	Colorado	80214
Michael	Fitzgerald	Boulder	Colorado	80302-4458
Sandra	Fitzpatrick	Centennial	Colorado	80121-2545
Jennifer	Foster	Lakewood	Colorado	80228-3767
Jim	Francis	Centennial	Colorado	80121-3244
Cherise	Frazier	Denver	Colorado	80202

PETER	FREITAG	Lakewood	Colorado	80227-5690
Kurt	Freund	Loveland	Colorado	80537-2950
Gretchen	Frey	Littleton	Colorado	80120
Michelle	Fuller	Littleton	Colorado	80120
Jean	Gore	Boulder	Colorado	80303-3828
Carolyn	Green	Foxfield	Colorado	80016-1630
Nora	Groeneweg	Lakewood	Colorado	80228-2937
Jill	Gulotta	Denver	Colorado	80231-5605
Kappy	Hall	Lafayette	Colorado	80026-2227
Nancy	Harcourt	Delta	Colorado	81416-2285
Shawn	Hayes	Denver	Colorado	80205
tricia	hellstrom	Highlands Ranch	Colorado	80126-7012
Daniel	Henderson	Parker	Colorado	80134-2555
Dick	Hess	Denver	Colorado	80206-3333
Joan	Huie	Denver	Colorado	80220-3661
JANIS	HUNTER	Littleton	Colorado	80128-0742
Sonia	ImMasche	Fort Collins	Colorado	80524-1517
John	Iwanicki	Golden	Colorado	80401-6577
Claudia	Jacobson	Denver	Colorado	80247-6527
Beverly	Jahn	Denver	Colorado	80204-2970
Ken	Jahner	Denver	Colorado	80215
JoLynn	Jarboe	Denver	Colorado	80222-7304
Gwynneth	Johnson	Denver	Colorado	80203
Janet	Johnson	Golden	Colorado	80401
JM	Jones	Denver	Colorado	80218-3139
William	Kelly	Westminster	Colorado	80030-5122
Jennifer	Klein	Denver	Colorado	80210

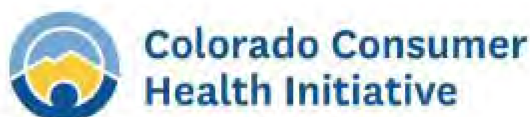
David	Klimut	Sarasota	Florida	34239
Susan	Knight	Littleton	Colorado	80127
Denise	Kupcho	Littleton	Colorado	80126
Melissa	Labrie	Denver	Colorado	80204-4042
First Name	Last Name	City	State	Zip Code
Patty	Lawless	Denver	Colorado	80205
Julie	Leonard	Boulder	Colorado	80305
William	Leslie	Dearborn	Michigan	48120-1303
Carol	Lobato	Englewood	Colorado	80113-2810
Leslie	Lomas	Boulder	Colorado	80304-0912
Martin	Lubojacky	La Junta	Colorado	81050-1662
Rachel	Lucero	Denver	Colorado	80214-1362
Susan	Luerssen	Denver	Colorado	80212-1457
Mary	Macneal	Denver	Colorado	80247
jessica	marcy	Denver	Colorado	80204-3204
Phil	Martin	Littleton	Colorado	80121
Martin	Martinez	Wheat Ridge	Colorado	80033
Trina	Mauchmar	Denver	Colorado	80205
John	Maulbetsch	Denver	Colorado	80203-3218
Glenn	McCaslin	Highlands Ranch	Colorado	80126-2220
Marlena	McElhaney	Denver	Colorado	80237-6369
Kathy	McGee	Colorado Springs	Colorado	80919
Michelle	McGraw	Denver	Colorado	80228
Kathy	McIntyre	Englewood	Colorado	80111
James	McKeever	Littleton	Colorado	80121
Judith	McQueen	Denver	Colorado	80247-1714
Shawna	Miller	Denver	Colorado	80216
Michael	Mitcham	Denver	Colorado	80205
Mindy	Mohr	Arvada	Colorado	80004
Thomas	MOORE	Boulder	Colorado	80304
Geoffrey	Moore	Denver	Colorado	80202
Gregory	Morris	Colorado Springs	Colorado	80903
Dave	Mueller	Golden	Colorado	80401

Margaret	Mullen	Littleton	Colorado	80120-3067
Kathleen	Mullen	Denver	Colorado	80210-5616
Jan	Myers	Centennial	Colorado	80111-4333
Pamela	Nichols	Denver	Colorado	80237
Deb	Nicklaus	Denver	Colorado	80231-5621
Carol	Niforatos	Denver	Colorado	80247
Kathleen	Odefey	Centennial	Colorado	80112-1154
Peg	Oldham	Denver	Colorado	80247-1224
Natalie	Onuffer	Parker	Colorado	80138
robert	ostrowski	Golden	Colorado	80401-2758
Stella	Padilla	Denver	Colorado	80321
Catherine	Peraino	Denver	Colorado	80249
Diana	Peters	Highlands Ranch	Colorado	80126-2154
Nancy	Peters	Englewood	Colorado	80113-2856
Roxanne	Peterson	Boulder	Colorado	80308-4611
Leslie	Petrovski	Denver	Colorado	80211
Cheryl	Pluta	Littleton	Colorado	80129
Evan	Ravitz	Boulder	Colorado	80305-4027
Richard	Real	Denver	Colorado	80205
Kelly	Reed	Denver	Colorado	80203
Lesley	Reeder	Denver	Colorado	80203
Paula R	Rhodes	Denver	Colorado	80237-2212
Piorello	Rimando	Northglenn	Colorado	80234-2926
Meredith	Ritchie	Denver	Colorado	80205-2529
Alan	Rodriguez			
Arya	Roerig	Denver	Colorado	80206-3438
P	S	Denver	Colorado	80215
Janelle	Sahli	Thornton	Colorado	80602-7239
Mary	Sanders	Denver	Colorado	80204-3919

Janice	Sandoval	Henderson	Colorado	80640
Kathleen	Saunders	Boulder	Colorado	80304
James and Prudence	Scarritt	Boulder	Colorado	80304-4243
Dennis	Schroeder	Evergreen	Colorado	80439-5533
Cheryl	Smith	Denver	Colorado	80235-3065
Jill	Smith	Aurora	Colorado	80247-2387
Lauren	Snyder	Denver	Colorado	80206
Gayle	Stagnitta	Aurora	Colorado	80012-5032
Sarah	Stella	Denver	Colorado	80204
Jill	SURBER Blackwell	Denver	Colorado	80226
Nadine	Swahnberg	Denver	Colorado	80228
Berkley	Tague	Denver	Colorado	80202-1548
Mary Ann	Thompson	Denver	Colorado	80218-3159
Mary Anna	Thompson	Denver	Colorado	80218-1653
Lisa	Thompson	Lakewood	Colorado	80205-2511
Bruce	Trott	Highlands Ranch	Colorado	80126-3605
William	Uebelher	Denver	Colorado	80227-3808
Joan	Urton	Denver	Colorado	80239-4011
Julia	Vega	Littleton	Colorado	80122
Beverly	Walter	Golden	Colorado	80403-7781
Marty	Waters	Denver	Colorado	80220
Sara	Weil	Boulder	Colorado	80303-1258
Mark	Wessley	Denver	Colorado	80226
Victor	Wheeler	Denver	Colorado	80205-2017
Cynthia	White	Golden	Colorado	80401
John	White	Grand Junction	Colorado	81506-5297
LARRY	WHITE			
Mary	Wilham	Denver	Colorado	80212

Cassie	Williams	Denver	Colorado	80220-3109
Christine	Woessner	Centennial	Colorado	80122-1261
Teri	Wolfe	Broomfield	Colorado	80023

Exhibit 56



March 27, 2018

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Public Comment in Response to the Proposed Regulation, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03

To Whom it May Concern:

The Colorado Consumer Health Initiative (CCHI) is writing in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26, 2018. CCHI is a state-based nonprofit, nonpartisan membership organization dedicated to ensuring access to quality, affordable, and equitable health care for all Coloradans. Through our forty-five member organizations, CCHI represents about 500,000 Coloradans.

This proposed regulation would exacerbate the challenges that many patients—especially women, LGBTQ people, people of color, immigrants and low-income people—already face in getting the timely and affordable health care they need. This rule would expose vulnerable patients to increased discrimination and denials of medically-indicated care by broadening religious health care provider exemptions. Moreover, while protecting health providers who deny care, the rule would provide *no protections for patients who are being denied care—even in emergencies.* As drafted, the rule would not even require that patients be informed of all their potential treatment options and referred to alternative providers of needed care.

This proposal is in direct opposition of the pursuit of "patient-centered care." We urge the administration to put patients first, and withdraw the proposed regulation because of the serious problems enumerated below.

1. **Expanding religious refusals can exacerbate the barriers to care that LGBTQ Coloradans already face and potentially allow denial of any health care service based on a provider's personal beliefs or religious doctrines.**

LGBTQ people, along with other vulnerable groups around the country, already face enormous barriers to getting the care they need.[1] Accessing quality, culturally competent care, and overcoming outright discrimination is an even greater challenge for those living in areas with already limited access to health providers. The proposed regulation threatens to make access to care even harder, and for some people nearly impossible.

For example, a nationwide 2015 survey of nearly 28,000 transgender adults found that respondents needed to travel much further to seek care for gender dysphoria, than for other services.[2] This means if these patients are turned away or refused treatment, it is much harder—and sometimes simply not possible—for them to find a viable alternative. In a recent study, nearly one in five LGBTQ people, including 31% of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away. That rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider.[3] For these patients, being turned away by a medical provider is not just an inconvenience: it often means being denied care entirely with nowhere else to go.

Existing refusal of care laws (such as for abortion and sterilization services) are already being used across the country to deny patients the care they need[4]. The

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[1] See, e.g., Institute of Medicine, The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding (2011), http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx; Sandy E. James et al., The Report of the U.S. Transgender Survey 93–126 (2016), www.ustranssurvey.org/report; Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* (2010), http://www.lambdalegal.org/publications/when-health-care-isnt-caring; Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

[2] Sandy E. James et al., *The Report of the U.S. Transgender Survey* 99 (2016), www.ustranssurvey.org/report

[3] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

[4] *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/;

proposed rule attempts to expand on these laws. Specifically, the Department and its Office for Civil Rights (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."[5]

This expansive interpretation could lead to provider denials based on personal beliefs that are biased and discriminatory, such as objections to providing care to people who are transgender or in same-sex relationships. In Colorado, 21% of surveyed LGBT Coloradans reported health care workers refused services, and 28% reported their sexual orientation prevented them from receiving needed care. [6]

We are concerned about further enabling care denials by providers based on their non-scientific personal beliefs about other types of health services.

2. The proposed rule conflicts state and local government efforts to protect patients' health and safety, including their nondiscrimination laws.

By claiming to allow individuals and institutions to refuse care to patients based on the providers' religious or moral beliefs in such a sweeping way, the proposed rule creates conflicts with hundreds of state and local nondiscrimination laws around the country that apply to health care, including Colorado's own anti-discrimination laws[7]. 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.[8]

3. The regulation lacks safeguards to protect patients from harmful refusals of care, especially in emergency situations.

The proposed regulation is dangerously silent in regards to the needs of patients and the impact that expanding religious refusals can have on their health. The proposed regulation includes no limitations to its sweeping exemptions that would protect patients' rights under the law and ensures that they receive medically

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Uttley, L., et al, *Miscarriage of Medicine*, MergerWatch and the ACLU (2013), https://www.aclu.org/report/miscarriage-medicine.

[5] 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].

[6] http://www.one-colorado.org/wp-content/uploads/2012/01/OneColorado_HealthSurveyResults.pdf

[7] http://www.ncsl.org/research/civil-and-criminal-justice/state-public-accommodation-laws.aspx

[8] *See, e.g.*, Rule, *Supra* note 1, at 3888-89.

warranted treatment. Any extension of religious accommodation should always be accompanied by equally extensive protections for patients to ensure that their medical needs remain paramount, and that they are able to receive both accurate information and quality health services.

The expanded religious exemptions in the proposed regulations also conflict with many patient protections in federal laws like the Affordable Care Act and the Emergency Medical Treatment and Active Labor Act. 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.

4. **Health care institutions would be required to notify employees that they have the right to refuse care,** ***but would not be required to notify patients about the types of care they will not be able to receive at that hospital, pharmacy, clinic or doctor's office***.

The rule sets forth extensive requirements for health care institutions, such as hospitals, to notify employees about their refusal rights, including how to file a discrimination complaint with OCR. The rule requires posting of such notices on the employer's website and in prescribed physical locations within the employer's building. The rule also sets forth the expectation that OCR would investigate or do compliance reviews of whether health care institutions are following the posting rule.[9]

By contrast, the rule contains no requirement that patients be notified of institutional restrictions on provision of certain types of care. Such notification is essential because research has found that patients are often unaware of service restrictions at religiously-sponsored health care institutions. [10]

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[9] The notice requirement is spelled out in section 88.5 of the proposed rule.
[10] *See*, for example, Freedman, Lori R., Luciana E. Hebert, Molly F. Battistelli, and Debra B. Stulberg, *Religious hospital policies on reproductive care: what do patients want to know?* American Journal of Obstetrics & Gynecology 218, no. 2 (2018): 251-e1, accessed here: http://www.ajog.org/article/S0002-9378(17)32444-4/fulltext; also Guiahi, Maryam, Jeanelle Sheeder, and Stephanie Teal, *Are women aware of religious restrictions on reproductive health at Catholic hospitals? A survey of women's expectations and preferences for family planning care*, Contraception and Stulberg, D., et all, accessed here: http://www.contraceptionjournal.org/article/S0010-7824(14)00358-8/fulltext; *Do women know when their hospital is Catholic and how this affects their care? Restrictions in Catholic Hospitals (PARRCH) national*

Conclusion

The proposed rule goes far beyond established law and most importantly will put the health and potentially even the lives of patients at risk. We urge you to withdraw the proposed rule. 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, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons the Colorado Consumer Health Initiative calls on the Department to withdraw the proposed rule in its entirety.

Sincerely,

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Terrell Blei
Policy and Outreach Fellow
Colorado Consumer Health Initiative
tblei@cohealthinitiative.org

survey, Contraception, Volume 96, Issue 4, 268-269,accessed here: http://www.contraceptionjournal.org/article/S0010-7824(17)30235-4/fulltext; a

Exhibit 57

March 27, 2018

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience PROPOSED RULE, RIN 0945-ZA03
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Public Comment in Response to the Proposed Regulation, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03

The Commonwealth of Pennsylvania Departments of Aging, Health, Human Services, Drug and Alcohol Programs, and Insurance have prepared the following in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26, 2018. These agencies have deep concerns that this proposed rule ignores the needs of the patients and individuals served by HHS' programs and creates confusion about the rights and responsibilities of health care providers and entities. Additionally, there is uneasiness in that this proposed rule overstates statutory authority and seeks to dramatically expand the reach of the underlying statutes with potentially disastrous consequences. Not only does this proposed rule put at risk positive health care outcomes and access to health care for tens of thousands of people, it treads on states' efforts to protect patients and constituents and puts millions of federal funds in jeopardy. Thus, the agencies stated above urge the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) to withdraw the proposed rule.

Exacerbating Barriers to Quality Health Care for Vulnerable

Dr. Rachel Levine, Secretary for the Pennsylvania Department of Health, met with Roger Severino, the Director for the HHS Office of Civil Rights, on November 14, 2017 to particularly discuss LGBTQ health issues. Despite this, the proposed rule does not consider the health issues raised during that meeting. Pennsylvania agencies are concerned that this rule will hinder their efforts to address negative and disparate patient health care outcomes and access to health care especially for LGBTQ people, women, and other vulnerable groups that already face enormous barriers to getting competent and affirming care.

For those living in areas with already limited access to health providers, finding quality, culturally competent care is already a challenge. If then they are turned away or refused treatment, it will be harder if not impossible for them to find a viable alternative. For example, in a recent study published by the Center for American Progress, nearly one in five LGBTQ people, including 31% of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away from settings where they currently receive care. That rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider. For these patients, being turned away by a medical provider is not just an inconvenience; it often means being denied care entirely with nowhere else to go.

These populations already experience significant discrimination from health care providers, and in many cases these vulnerable populations have little recourse or resources to seek justice. However, through the Conscience and Religious Freedom Division, health care providers would be able deny patients care and remain protected under the guise of religious liberty according to HHS.

The following are examples of scenarios that have and will occur:

- Doctors refusing to see transgender patients, even for general medical concerns
- Health professionals refusing care to someone living with HIV/AIDS, or refusing prescriptions for pre-exposure prophylaxis
- Pediatricians refusing to treat the children of same-gender couples
- Emergency Department/Emergency Medical Services workers refusing to transport or provide emergency care to minority patients
- Medical professionals refusing to acknowledge homophobic rape (i.e., rape perpetrated due to perceived sexual or gender identity)
- Medical professionals denying care to individuals who have had abortions at any point for any reason, or denying pre- or post- care for terminated pregnancies
- Behavioral health professionals refusing to provide information or counseling

This proposed rule attempts to expand religious exemptions while ignoring the prevalence of discrimination and damage it causes especially in vulnerable communities. If finalized, the rule would significantly expand the ability of heath care providers to withhold treatment or services based on religious or moral ground. And, thus will put thousands of people at risk of facing negative health consequences simply from the increased barriers or steps to acquiring care.

Broad Expansion That Lacks Safeguards

Though religious exemptions can have value, OCR fails to balance the need for exemptions with limitations or safeguards relating to the needs of patients and their own rights. Thus, the rule conflicts with the Establishment Clause of the First Amendment which requires the government to adequately account for burdens a religious accommodation may impose on others, including patients, and prohibits granting accommodations when they would materially harm any third party. Furthermore, the proposed rule is in conflict with many existing patient protections in federal laws like the Affordable Care Act, Emergency Medical Treatment and Active Labor Act, and it conflicts with established standards such as Title VII.

These inconsistencies create confusion and will allow for unprecedented discrimination and refusal of services, which undermines the intent and integrity of health and human services programs, and even runs contrary to HHS' own mission. HHS' belief that it is appropriate to apply the general principles of nondiscrimination on the basis of religious belief or moral conviction is nonsensical. It is unclear how doctors and nurses can adhere to their professional standards and ethics codes while also claiming religious belief or moral conviction as a basis to not provide health care services. A shift in this direction by HHS will increase religious-based mistreatment. It will invite health and human services professionals to ignore existing law and medical standards, and it will go against person-centered approaches and

evidence-based practices that have been at the core of social service and public health delivery for decades.

Ignores States' Efforts to Protect Patients

Pennsylvania agencies are concerned that this proposed rule is an attempt to supersede laws and policies passed by state and local governments to ensure patients' access to health care and human services. Pennsylvania Governor Tom Wolf and his administration are committed to doing right by all Pennsylvanians and providing people the protections and respect they deserve. Since Pennsylvania is one of the states that lacks a comprehensive and consistent framework of legal protections in areas like non-discrimination, the commonwealth is particularly susceptible to shifts of this kind at the federal level. This is why the Governor and his administration have been champions for equal protections. Such efforts include expanding prohibitions in non-discrimination language in employment and contracting, promoting access to affirming and affordable health care through, for example, Medicaid expansion, and calling on the General Assembly to pass comprehensive non-discrimination laws and resource reproductive health programs.

This proposed rule grants OCR broad investigative authority and the ability to expand reporting requirements and allows for harsh penalties. For these reasons, Pennsylvania Health and Human Services Departments have significant concerns with how OCR will use such powers and information gathered by the office. There are concerns that this could lead to prejudice in consideration of future applications for federal funds or penalize a currently funded entity in ways that would be extremely harmful or costly. Additionally, the oversight provisions are vague, which undermines the federal government's own ability to properly enforce its own laws and regulations.

In summary, the Pennsylvania Departments of Aging, Health, Human Services, Drug and Alcohol Programs, and Insurance vehemently oppose the proposed rule entitled "Protecting Statutory Conscience Rights in Health Care" published January 26, 2018 and strongly urge HHS to withdraw the rule. The proposed rule will increase barriers for tens of thousands of people seeking health care of all types and lead to a multitude of adverse health outcomes. The proposed rule is vague and in conflict with numerous federal laws and statutes, which will lead to great confusion among health and human services practitioners and difficulty in enforcing regulations for OCR. Lastly, the proposed rule greatly impedes states' efforts and responsibility to protect their constituents and threatens the distribution and receipt of millions of dollars in federal funds.

Sources:

American College of Obstetrics and Gynecologists, Health Disparities in Rural Women (2014), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Disparities-in-Rural-Women#17

Institute of Medicine, The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding (2011), http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx

Sandy E. James et al., The Report of the U.S. Transgender Survey 93–126 (2016), www.ustranssurvey.org/report;

Lambda Legal, When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV (2010), http://www.lambdalegal.org/publications/when-health-care-isnt-caring

Shabab Ahmed Mirza & Caitlin Rooney, Discrimination Prevents LGBTQ People from Accessing Health Care (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care

Exhibit 58

March 27, 2018

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Public Comment in Response to the Proposed Regulation, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03

To Whom it May Concern:

I am writing on behalf of Community Catalyst in response to the request for public comment on the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26.[1]

Community Catalyst is a national non-profit advocacy organization dedicated to quality affordable health care for all. Since 1997, Community Catalyst has been working to build the consumer and community leadership required to transform the American health system. With the belief that this transformation will happen when consumers are fully engaged and have an organized voice, Community Catalyst works in partnership with national, state and local consumer organizations, policymakers and foundations, providing leadership and support to change the health care system so it serves everyone - especially vulnerable members of society.

This proposed regulation would exacerbate the challenges that many patients -- especially women, LGBTQ people, people of color, immigrants and low-income people -- already face in getting the health care they need in a timely manner and at an affordable cost. The rule would expose vulnerable patients to increased discrimination and denials of medically-indicated care by broadening religious health care provider exemptions beyond the existing limited circumstances allowed by law. Moreover, while protecting health providers who deny care, the rule would provide *no protections for patients who are being denied care – even in emergencies*. As drafted, the rule would not even require that patients be informed of all their potential treatment options and referred to alternative providers of needed care.

[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].

Indeed, this proposal runs in the opposite direction of everything the American health system is striving to achieve in the pursuit of "patient-centered care." We urge the administration to put patients first, and withdraw the proposed regulation because of the serious problems enumerated below.

1. The rule improperly seeks to expand on existing religious refusal exemptions to potentially allow denial of any health care service based on a provider's personal beliefs or religious doctrine.

Existing refusal of care laws (such as for abortion and sterilization services) are already being used across the country to deny patients the care they need.[2] The proposed rule attempts to expand on these laws in numerous ways that are directly contrary to the stated purpose of the existing laws. Specifically, the Department and its Office for Civil Rights (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)."[3]

This expansive interpretation could lead to provider denials based on personal beliefs that are biased and discriminatory, such as objections to providing care to people who are transgender or in same-sex relationships. We are aware of cases in which this type of unjust denial of care has occurred, such as a California physician's denial of donor insemination to a lesbian couple, even though the doctor routinely provided the same service to heterosexual couples. [4]

We are also concerned about potential enabling of care denials by providers based on their non-scientific personal beliefs about other types of health services. For example, certain religiously-affiliated hospitals and individual clinicians have refused to provide rape victims with emergency contraception to prevent pregnancy[5] based on the belief that it can cause an abortion, even though there is no scientific evidence that this is the case. Providers could conceivably be motivated by the proposed rule to object to administering vaccinations or refuse to prescribe or dispense Pre-exposure Profylaxis (PrEP) medication to help gay men reduce the risk of HIV transmission through unprotected sex.

2. The rule would protect refusals by anyone who would be "assisting in the performance of" a health care service to which they object, not just clinicians.

The rule seeks to protect refusals by any "member of the workforce" of a health care institution whose actions have an "articulable connection to a procedure, health services or health service program, or research activity." The rule includes examples such as "counseling, referral, training and other arrangements for the procedure, health service or research activity."

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[2] *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/; Uttley, L., et al, *Miscarriage of Medicine*, MergerWatch and the ACLU (2013), https://www.aclu.org/report/miscarriage-medicine.
[3] *See* Rule *supra* note 1, at 12.
[4] Hardaway, Lisa, *Settlement Reached in Case of Lambda Legal Lesbian Client Denied Infertility Treatment by Christian Fundamentalist Doctors*, Lambda Legal, September 29, 2009, accessed at https://www.lambdalegal.org/news/ca_20090929_settlement-reached.
[5] Erdely, Sabrina, *Doctors' beliefs can hinder patient care*, SELF magazine, June 22, 2007, accessed at http://www.nbcnews.com/id/19190916/print/1/displaymode/1098/

An expansive interpretation of "assist in the performance of" thus *could conceivably allow an ambulance driver to refuse to transport a patient to the hospital for care he/she finds objectionable*. It could mean a hospital admissions clerk could refuse to check a patient in for treatment the clerk finds objectionable or a technician could refuse to prepare surgical instruments for use in a service.

On an institutional level, the right to refuse to "assist in the performance of" a service could mean a religiously-affiliated hospital or clinic could deny care, and *then also refuse to provide a patient with a referral or transfer to a willing provider* of the needed service. Indeed, the proposed rule's definition of "referral" goes beyond any common understanding of the term, allowing refusals to provide *any information,* including location of an alternative provider, that could help people get care they need.[6]

The proposed rule thus could be read as allowing health providers to refuse to inform patients of all potential treatment options. A 2010 publication of the National Health Law Program, "Health Care Refusals: Undermining Quality of Care for Women," noted that "refusal clauses and institutional restrictions can operate to deprive patients of the complete and accurate information necessary to give informed consent."[7]

3. The rule does not address how a patient's needs would be met in an emergency situation.

There have been reported instances in which pregnant women suffering medical emergencies – including premature rupture of membranes (PPROM) and ectopic pregnancies[8] -- have gone to hospital emergency departments and been denied prompt, medically-indicated care because of institutional religious restrictions.[9] This lack of protections for patients is especially problematic in regions of the country, such as rural areas, where there may be no other nearby hospital to which a patient could easily go without assistance and careful medical monitoring enroute.[10]

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

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[6] *See* Rule *supra* note 1, at 183.

[7] The NHeLP publication noted (at page 21) that the Ethical and Religious Directives for Catholic Healthcare Services, which govern care at Catholic hospitals, limit the information a patient can be given about treatment alternatives to those considered "morally legitimate" within Catholic religious teachings. (Directive No. 26).

[8] Foster, AM, and Smith, DA, *Do religious restrictions influence ectopic pregnancy management? A national qualitative study,* Jacob Institute for Women's Health, Women's Health Issues, 2011 Mar-Apri; 21(2): 104-9, accessed at https://www.ncbi.nlm.nih.gov/pubmed/21353977

[9] Stein, Rob, *Religious hospitals' restrictions sparking conflicts, scrutiny,* The Washington Post, January 3, 2011, accessed at https://www.washingtonpost.com/health-environment-science/religious-hospitals-restrictions-sparking-conflicts-scrutiny/2011/01/03/ABVVxmD_story.html?utm_term=.cc34abcbb928

[10] For example, a 2016 study found there were 46 Catholic-affiliated hospitals that were the federally-designated "sole community providers" of hospital care for their geographic regions. Women needing reproductive health services that are prohibited by Catholic health restrictions would have no other easily accessible choice of hospital care. Uttley, L., and Khaikin, C., *Growth of Catholic Hospitals and Health Systems,* MergerWatch, 2016, accessed at www.MergerWatch.org

to another facility.[11] Under EMTALA every hospital is required to comply – even those that are religiously affiliated.[12] 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.

4. Health care institutions would be required to notify employees that they have the right to refuse to provide care, *but would not be required to notify patients about the types of care they will not be able to receive at that hospital, pharmacy, clinic or doctor's office*.

The rule sets forth extensive requirements for health care institutions, such as hospitals, to notify employees about their refusal rights, including how to file a discrimination complaint with OCR. The rule requires posting of such notices on the employer's website and in prescribed physical locations within the employer's building. The rule also sets forth the expectation that OCR would investigate or do compliance reviews of whether health care institutions are following the posting rule.[13]

By contrast, the rule contains no requirement that patients be notified of institutional restrictions on provision of certain types of care. Such notification is essential because research has found that patients often are unaware of service restrictions at religiously-sponsored health care institutions. [14]

5. The rule conflicts with other existing federal laws, including the Title VII framework for accommodation of employee's religious beliefs.

The Proposed Rule generates chaos through its failure to account for existing laws that conflict with the refusals of care it would create. For example, the proposed rule makes no mention of Title VII,[15] the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[16] 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.[17] For decades, Title VII has

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[11] 42 U.S.C. § 1295dd(a)-(c) (2003).

[12] 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 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).

[13] The notice requirement is spelled out in section 88.5 of the proposed rule.

[14] *See*, for example, Freedman, Lori R., Luciana E. Hebert, Molly F. Battistelli, and Debra B. Stulberg, *Religious hospital policies on reproductive care: what do patients want to know?* American Journal of Obstetrics & Gynecology 218, no. 2 (2018): 251-e1, accessed here: http://www.ajog.org/article/S0002-9378(17)32444-4/fulltext; also Guiahi, Maryam, Jeanelle Sheeder, and Stephanie Teal, *Are women aware of religious restrictions on reproductive health at Catholic hospitals? A survey of women's expectations and preferences for family planning care*, Contraception and Stulberg, D., et all, accessed here: http://www.contraceptionjournal.org/article/S0010-7824(14)00358-8/fulltext; *Do women know when their hospital is Catholic and how this affects their care? Restrictions in Catholic Hospitals (PARRCH) national survey*, Contraception, Volume 96, Issue 4, 268-269,accessed here: http://www.contraceptionjournal.org/article/S0010-7824(17)30235-4/fulltext; a

[15] 42 U.S.C. § 2000e-2 (1964).

[16] *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.

[17] *See id.*

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.[18]

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 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.[19] 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.

6. There is no provision protecting the rights of health care providers with religious or moral convictions to *provide* (not deny) services their patients need.

The proposed rule ignores those providers with deeply held moral convictions that motivate them to provide patients with health care, including abortion, transition-related care and end-of-life care. The rule fails to acknowledge the Church Amendment's protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce.[20]

Doctors are, in effect, forced to abandon their patients when they are prevented by health care institutions from providing a service they believe is medically-indicated. This was the case for a doctor in Sierra Vista, Arizona, who was prevented from helping end a patient's wanted, but doomed, pregnancy after she suffered premature rupture of membranes. The patient had to be sent to the nearest non-objecting hospital, which was 80 miles away, far from her family and friends. The physician described the experience as "a very gut wrenching thing to put the staff through and the patient, obviously."[21]

7. The proposed rule carries severe consequences for patients and would exacerbate existing inequities.

a. *Refusals of care make it difficult for many individuals to access the care they need*

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[18] 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.
[19] *See* Rule *supra* note 1, at 180-181.
[20] *See* The Church Amendments, 42 U.S.C. § 300a-7(c) (2018).
[21] Uttley, L, et all, *Miscarriage of Medicine*, MergerWatch and the ACLU (2013), p. 16, https://www.aclu.org/report/miscarriage-medicine.

Across the country, refusals of care based on personal beliefs have been invoked in countless ways to deny patients the care they need.[22] 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.[23] Another woman experiencing pregnancy loss was denied care for 10 days at a religiously affiliated hospital outside Chicago, Illinois.[24] In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy.[25] A 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.[26] 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.[27]

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 obtain health care and have real consequences for those denied the care they need because of a clinician's 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.[28] 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.[29] In rural areas there may be no other sources of health and life preserving medical care.[30] When these individuals encounter refusals of care, they may have nowhere else to go.

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[22] *See, e.g.*, *supra* note 2.
[23] *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.
[24] *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.
[25] *See* Kira Shepherd, et al., *supra* note 23, at 29..
[26] *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), 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.
[27] *See* Kira Shepherd, et al., *supra* note 23, at 27.
[28] 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.
[29] 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, *Nuestra Voz, Nuestra Salud, Nuestro Texas: the Fight for Women's Reproductive Health in the Rio Grande Valley* 1, 7 (2013), http://www.nuestrotexas.org/pdf/NT-spread.pdf.
[30] 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/.

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 In 19 states, women of color are more likely than white women to give birth in Catholic hospitals.[31] Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provide guidance on a wide range of hospital matters, including reproductive health care, and can keep providers from offering the standard of care.[32] 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.[33] The reach of this type of 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.[34]

We concur with the comments submitted by the National Health Law Program (NHeLP) that the regulations fail to consider the impact of refusals on persons suffering from substance use disorders. Rather than promoting the evidence-based standard of care, the rule could allow practitioners to refuse to provide, or even recommend, Medication Assisted Treatment (MAT) and other evidence-based interventions due simply to a personal objection.

Stigma associated with drug use stands in the way of saving lives.[35] America's prevailing cultural consciousness -- after decades of treating the disease of addiction as largely a criminal justice and not the public health issue it is -- generally perceives drug use as a moral failing and drug users as less deserving of care. For example, a needle exchange program designed to protect injection drug users from contracting blood borne illnesses such as HIV, Hepatitis C, and bacterial endocarditis was shut down in October 2017 by the Lawrence County, Indiana County Commission due to their moral objection to drug use, despite overwhelming evidence that these programs are effective at reducing harm and do not increase drug use.[36] One commissioner even quoted the Bible as he voted to shut it down. Use of MAT to reverse overdose has been decried as "enabling these people" to go on to overdose again.[37]

In this frame of mind, only total abstinence is seen as successful treatment for substance use disorders, usually as a result of a 12-step or faith-based program, even though evidence for 12-step

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[31] *See* Kira Shepherd, et al., *supra* note 23, at 12.
[32] *See Id.* at 10-13.
[33] 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/.
[34] *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.
[35] Ellen M. Weber, *Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance*, 13 J. HEALTH CARE L. & POL'Y 49, 56 (2010); German Lopez, *There's a highly successful treatment for opioid addiction. But stigma is holding it back.*, https://www.vox.com/science-and-health/2017/7/20/15937896/medication-assisted-treatment-methadone-buprenorphine-naltrexone.
[36] German Lopez, *An Indiana county just halted a lifesaving needle exchange program, citing the Bible*, VOX, Oct. 20, 2017, https://www.vox.com/policy-and-politics/2017/10/20/16507902/indiana-lawrence-county-needle-exchange.
[37] Tim Craig & Nicole Lewis, *As opioid overdoses exact a higher price, communities ponder who should be saved*, WASH. POST, Jul. 15, 2017, https://www.washingtonpost.com/world/as-opioid-overdoses-exact-a-higher-price-communities-ponder-who-should-be-saved/2017/07/15/1ea91890-67f3-11e7-8eb5-cbccc2e7bfbf_story.html?utm_term=.4184c42f806c.

programs is weak. The White House's own opioid commission found that "negative attitudes regarding MAT appeared to be related to negative judgments about drug users in general and heroin users in particular."[38]

People with substance use disorders already suffer due to stigma and have a difficult time finding appropriate care. This rule, which allows misinformation and personal feelings to get in the way of science and lifesaving treatment, would not help achieve the goals of the administration; it could instead trigger countless numbers of deaths.

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. 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."[39] 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.[40] 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.[41] Because the proposed rule would cause substantial harm, including to patients, it would violate the Establishment Clause.[42]

8. 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.[43] Instead, the proposed rule appropriates language from civil

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[38] Report of the President's Commission on Combating Drug Addiction and the Opioid Crisis, Nov. 1, 2017, https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf

[39] *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.

[40] *See* Rule *supra* note 1, at 94-177.

[41] 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).

[42] 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 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.

[43] *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

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.[44]

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.[45] If finalized, however, the proposed rule will represent a radical departure from the Department's mission to combat discrimination, protect patient access to 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.[46]

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.[47] Black women are three to four times more likely than white women to die during or after childbirth.[48] According to a recent report, doctors often fail to inform Black women of the full range of reproductive health options regarding labor or delivery, possibly due to stereotypes about Black women's sexuality and reproduction.[49] Young Black women said they felt they were shamed by

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programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").

[44] *See* Rule *supra* note 1, at 203-214.

[45] 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.

[46] *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/hiv/index.html; *National Origin Discrimination*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/index.html; *Health Disparities*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/health-disparities/index.html.

[47] *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.

[48] *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.

[49] CTR. FOR REPROD. RIGHTS, NAT'L LATINA INST. FOR REPROD. HEALTH & SISTERSONG WOMEN OF COLOR REPROD. JUSTICE COLLECTIVE, *Reproductive Injustice: Racial and Gender Discrimination in U.S. Health Care* 20-22 (2014), *available at*

providers when seeking sexual health information and contraceptive care, due to their age and in some instances, sexual orientation.[50]

Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.[51] Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a health care provider had refused to see them because of their actual or perceived sexual orientation or gender identity in the year before the survey.[52]

As NHelP's comments note, many people with disabilities receive home and community-based services (HCBS), including residential and day services, from religiously-affiliated providers. Historically, people with disabilities who rely on these services have sometimes faced discrimination, exclusion and a loss of autonomy due to provider objections. Group homes have, for example, refused to allow residents with intellectual disabilities who were married to live together in the group home.[53] Individuals with HIV – a recognized disability under the Americans with Disabilities Act (ADA) – have repeatedly encountered providers who deny services, necessary medications and other treatments citing religious and moral objections. One man with HIV was refused care by six nursing homes before his family was finally forced to relocate him to a nursing home 80 miles away.[54] Given these and other experiences, the extremely broad proposed language at 45 C.F.R. § 88.3(a)(2)(vi) that would allow any individual or entity with an "articulable connection" to a service, referral, or counseling described in the relevant statutory language to deny assistance due to a moral or religious objection is extremely alarming and could seriously compromise the health, autonomy and well-being of people with disabilities.

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]

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https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/CERD_Shadow_US_6.30.14_Web.pdf [hereinafter *Reproductive Injustice*]; IN OUR OWN VOICE: NAT'L BLACK WOMEN'S REPROD. JUSTICE AGENDA, *The State of Black Women & Reproductive Justice* 32-33 (2017), *available at* http://blackrj.org/wp-content/uploads/2017/06/FINAL-InOurVoices_Report_final.pdf.

[50] *Reproductive Injustice*, *supra* note 10, at 16-17.

[51] *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.

[52] *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.

[53] See *Forziano v. Independent Grp. Home Living Prog.*, No. 13-cv-00370 (E.D.N.Y. Mar. 26, 2014) (dismissing lawsuit against group homes, including a religiously affiliated group home, that refused to allow married couple with intellectual disabilities live together). Recent regulations have reinforced protections to ensure available choice of roommates and guests. 42 C.F.R. §§ 441.301(c)(4)(vi)(B) & (D).

[54] NAT'L WOMEN'S LAW CTR., *Fact Sheet: Health Care Refusals Harm Patients: The Threat to LGBT People and Individuals Living with HIV/AIDS,* (May 2014), *available at* https://nwlc.org/wp-content/uploads/2015/08/lgbt_refusals_factsheet_05-09-14.pdf.

[55] *See supra* note 42.

9. 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.[56] 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.[57]

10. 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.[58] For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling[59] and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.[60] 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.[61] The Proposed Rule creates uncertainty about whether Title X grantees may ensure that the sub-recipients 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.[62] 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.[63]

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, ignores

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[56] *See, e.g.*, Rule, *Supra* note 1, at 3888-89.
[57] *See id.*
[58] *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.
[59] *See, e.g.*, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).
[60] *See* What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).
[61] *See, e.g.*, Rule *supra* note 1, at 180-185.
[62] *See* NFPRHA *supra* note 34.
[63] *See id.*

congressional intent, fosters confusion and harms patients, all of which are contrary to the Department's stated mission. For all of these reasons, Community Catalyst calls on the Department to withdraw the proposed rule in its entirety.

Respectfully submitted,

Robert Restuccia
Executive Director
Community Catalyst

Exhibit 59

March 26, 2018

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CompassionAndChoices.org

Health and Human Services Department
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Re: HHS Proposed Rule: *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 83 Fed. Reg. 3880 (proposed Jan. 26, 2018)

To Whom It May Concern:

Compassion & Choices is the nation's oldest, largest and most active nonprofit working to improve and expand healthcare options for the end of life. In our more than 30 years, we have united over 450,000 supporters nationwide to lead the end-of-life choice and care movement. We submit the following in response to a request by the Department of Health and Human Services ("The Department") for public comment on HHS-OCR-2018-0002, a proposed rule entitled "Protecting Statutory Conscience Rights In Health Care." Although agencies have general authority to engage in rulemaking, that authority is not without limits. An agency must provide "adequate reasons" for its rulemaking, in part by "examin[ing] the relevant data and articulat[ing] a satisfactory explanation for its action including a rational connection between the fact found and the choice made."[1] The prospective rule does not solve a pervasive problem in American healthcare, in part, because healthcare workers are already protected from participating in medical procedures that they oppose. Instead, this rule will significantly and unjustly harm American healthcare consumers by allowing medical providers to expand exemptions from critical healthcare services beyond what the law currently allows.

We are deeply concerned that the proposed rule, should it go into effect, will create fundamental barriers for patients seeking to access a host of legally authorized medical options. The proposed rule would mean vulnerable individuals at the end of life and their loved ones must now worry that medical providers will refuse to honor their healthcare decisions, refuse to provide basic services, or even decline to provide them the information they need to make an informed medical decision. Physicians could prevent a patient with a life-threatening or terminal illness from accessing medical treatment without the patient even knowing it. Putting the religious objections of physicians and healthcare providers above their duty to provide care consistent with at least a basic standard of care would set a dangerous precedent. It would compromise patient autonomy, cause confusion for both patients and physicians, erect unnecessary barriers to the continuum of care and seriously damage the patient-physician relationship.

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[1] *Encino Motorcars, LLC v. Navarro*, 136 S.Ct. 2117, 2125 (June 20, 2016) (citing *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 103 (1983)).

Introduction

Since the Church Amendments established in the 1970s[2] in response to the societal debate around the medical practice of abortion and sterilization, federal laws have protected the rights of physicians, nurses, and health care providers from compulsory participation in certain medical procedures that would violate their conscience. As the Department notes in the preamble to the proposed rule, these conscience rights have expanded over the years to include prohibitions against compulsory participation in the criminal acts of assisted suicide, euthanasia, and mercy killing – protections found in the Patient Protection and Affordable Care Act.[3] Other conscience provisions prohibit entities from using a potential hire's conscience objection as the sole basis for rejecting that person from employment within a healthcare entity.[4]

In an effort to clarify and enforce the various conscience protections found throughout federal laws, the Department underwent formal rulemaking in 2008, issuing the first final rule to organize enforcement of those protections on December 19, 2008. This rule designated the HHS Office of Civil Rights ("OCR") as the recipient of conscience-based discrimination complaints. At the outset of the Obama Administration in 2009, the Department began revision of the rule, eventually codifying a new final rule in 2011. The rule still granted the OCR the authority to receive complaints of alleged conscience violations and coordinate with the government-funding agency administering funds to the alleged violator as to how to address complaints. As the Department notes, only 10 complaints alleging a violation of conscience protections were received by the OCR from the establishment of the 2008 rule to the 2016 election. Of significant interest, while 34 complaints alleging violations of conscience were filed with the OCR from November 2016 to January 2018, during roughly that same time period OCR received over *30,000 complaints* alleging either civil rights or HIPAA violations. Additionally, despite the relative paucity of conscience-based complaints to the OCR, an enormous expenditure of taxpayer dollars is being diverted to the office under the 2018 Consolidated Appropriations Act.[5]

The proposed rule, rather than addressing a demonstrable need to protect actual violations of physician and provider conscience rights, instead seeks to expand conscience protections in ways that infringe on fundamental patient rights (such as informed consent), the doctor/patient relationship, and patients' freedom from discrimination in accessing medical care. In a nationwide review of state and federal case law, we did not find a single judgment affirming an allegation that a physician or medical provider had been forced to perform medical procedures in violation of their conscience. Conscience objection litigation has instead sought employment protection for a nurse's refusal to perform functions of their job[6], or alleged violations of free speech because of disagreement with statements in regulations.

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[2] 42 U.S.C. 300a-7 (2010).
[3] 42 U.S.C. 18113 (2010).
[4] *See, e.g.*, "Weldon Amendment," Consolidated Appropriations Act, 2009, Pub. L. No. 111-117, 123 Stat 3034.
[5] Pub. L. No. 115-141 (2018). The HHS's Office of Civil Rights, which monitors violations of the Health Insurance Portability and Accountability Act, was due to receive $33 million under the Trump Administration request, but the new spending bill gives the office $38.7 million.
[6] *See, e.g., Mendoza v. Martell*, No. 2016-6-160 (Winnebago County Cir. Ill. June 8, 2016); *Hellwege v. Tampa Family Health Centers*, 103 F. Supp. 3d 1303 (M.D. Fla. 2015).

Because courts have consistently held that there is no private right of action for alleged violations of conscience protections, it is abundantly clear that the Department seems intent on expanding administrative remedies for conscience objectors at the expense of patients by fundamentally undermining healthcare principles, such as informed consent and the sanctity of the doctor/patient relationship.

<u>Informed consent requires patients receive *all* relevant information, not just information a medical provider wants to share based on their own personal beliefs</u>

A foundational principle of medical care is the ability of patients to make fully informed decisions about what treatments or procedures they do or do not want. Informed consent, including the right to refuse treatment, "has become firmly entrenched in American tort law."[7] Although what constitutes informed consent under state law varies between jurisdictions, informed consent generally requires physicians to provide any and all information that a "reasonable patient" would need to know to make a decision about their care or treatment, or what the standard of care requires a "reasonable physician" to disclose.[8]

Not only does the prospective rule under Section 88.3 fail to protect the patients' fundamental right to information prior to consent for their medical care, it also creates access barriers for patients to information. Physicians may feel emboldened to withhold information a reasonable patient would need in order to understand the medical treatment decision their physician is asking them to make. Failure to provide this information could subject the medical provider to civil and criminal liability under state medical malpractice laws. Additionally, unwanted and unnecessary medical treatment could also increase both physician medical malpractice insurance rates and patient dissatisfaction with the medical system. This negative outcome is in addition to the increase in malpractice rates often attributed to medical negligence litigation[9], which could certainly arise if physicians must defend their denial to follow a patient's wishes or inform their patient of necessary information for informed decision making for conscience reasons.

The danger in allowing physicians to withhold information at the end of life is real. A study examining care given to critically ill patients with high risk of death concluded that, when the treatment available was either life-prolonging or comfort-oriented, roughly half of clinicians surveyed failed to provide information on comfort-oriented care to the patient or surrogate.[10] The only predictor of whether or not a patient received information on comfort care was the strength of the physician's belief that life support should be withdrawn, regardless of the patient's or surrogate's desires.[11] In essence, patients were denied all of their medically available options,

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[7] *Cruzan v. Dir., Missouri Dep't of Health*, 497 U.S. 261, 269, 110 S.Ct. 2841, 111 L.Ed.2d 224 (1990).
[8] Nadia N. Sawicki, *Mandating Disclosure of Conscience-Based Limitations on Medical Practice*, 42 Am. J.L. & Med. 85, 111 (2016).
[9] *See* Brian A. Peterson, *The Malpractice Surcharge A Simple Answer to Rising Malpractice Rates or A Greater Threat to Quality Patient Care?*, 27 J. Legal Med. 87, 88 (2006).
[10] Yael Schenker et al., *Association Between Physicians' Beliefs and the Option of Comfort Care for Critically Ill Patients*, Intensive Care Med 38: 1607 (2012). https://doi.org/10.1007/s00134-012-2671-4.
[11] *Id.*

including those options aimed at relieving suffering, because physicians substituted their beliefs for their patients.

Access to all aspects of end-of-life medical care are in jeopardy by allowing physicians to withhold basic services and information

The proposed rule places into question many critical aspects of end-of-life medical care. By claiming a proposed treatment, or information about that treatment, violates some tenet of conscience, physicians are encouraged under the proposed rule to supplant their religious beliefs for those of the patient, thereby disregarding the patient's own religious beliefs. Patients and physicians have made great strides in discussing the various treatment options that arise at the end of life[12], but under this new rule those gains will undoubtedly be compromised. An erosion of patients' trust in the healthcare system, and in their physician's commitment to share needed information, is reason enough to withdraw the proposed rule.

In addition to the traditional informed consent laws, many states have enacted laws that govern what information must be shared regarding end-of-life care. These laws, which often apply in settings outside the traditional medical office such as hospice care or long-term care facilities, trigger protections for patients to receive information regarding options related to end-of-life decision-making in certain situations, such as during intake or admission or after the diagnosis of a terminal illness. These laws protect the patient's right to execute advance directives specifying what medical treatments the person wishes to have should they lose the ability to communicate those wishes themselves.[13] In some states, healthcare providers – under the duty to obtain informed consent – must inform patients of medically appropriate, lawful forms of end-of-life treatment, palliative care, and the person's right to refuse unwanted medical intervention at the end of life. In states where medical aid in dying (also known as "death with dignity" in some jurisdictions) is permitted for individuals with terminal illness who voluntarily request medication to end their suffering at a time of their choosing, states require physicians who write the prescription for the terminally ill person to fully inform the person of the risks and probable result from self-ingesting the medication, as well as alternative treatment and care options.[14] For patients participating in clinical trials, informed consent requirements mandate the person be informed of probable risks and benefits, possible treatment outcomes, and the right to withdraw from the trial at any time, among other mandatory declarations.[15] This information is "aimed at

[12] Linda Ganzini, *Oregon Physicians' Attitudes About and Experiences with End-Of-Life Care Since Passage of the Oregon Death With Dignity Act*, JAMA. (2001).
[13] *See, e.g.,* Ala. Admin. Code § r. 420-5-10-.05(3)(h) (2018); Ark. Admin. Code § 007.05.4-11(F) (2018); Ark. Admin. Code § 007.05.11-10(F) (2018); Ark. Admin. Code § 016.06.35-136.000 (2018); Cal. Health & Safety Code § 1569.156(a)(3) (2018); 6 Colo. Code Regs. § 1011-1:XXVI-6.4(d)(2) (2018); Fla. Stat. § 765.110(1)
(2018); Idaho Admin. Code § 16.03.09.235.01(a)(2) (2018); N.J. Stat. § 26:2H-65(a)(2) (2018); N.M. Admin. Code § 7.27.6.6-6.8 (2018); Okla. Admin. Code § 310:661-5-4.1(b)(2) (2018); Okla. Admin. Code § 317:30-3-13(a)(2) (2018); Or. Rev. Stat. § 127.649(1)(a)(A) (2018); Vt. Admin. Code § 12-4-200:3.8 (2018); Wash. Admin. Code § 388-97-0280(3)(c)(ii) (2018).
[14] *See, e.g.,* Cal. Health & Safety Code § 443.5(a)(2) (West 2018); Or. Rev. Stat. § 127.815(1)(c) (2018); Vt. Stat. Ann. tit. 18 § 5283(a)(6) (2018); Wash. Rev. Code § 70.245.040(1)(c) (2018).
[15] Umesh Chandra Gupta, *Informed consent in clinical research: Revisiting few concepts and areas*, Perspectives in Clinical Research 4.1, 26-32 (2013).

enabling the patients to make an informed, rational, and logical decision in the light of their cultural, psychological, and social values and beliefs."[16] Thus, a physician could deny a patient from the gay, lesbian, or transgender community the full range of information on clinical trials for late-stage illnesses because of the physician's religious beliefs against sexual minorities.

With the proposed rule in Section 88.3, patient protections ensuring they receive relevant medical information at the end of life are all jeopardized. Physicians and medical providers have already used the existing conscience rules to restrict their patient's access to relevant treatment information on numerous occasions, many cases of which are cited by the Department as justification for the proposed rule.[17] Medical providers have used religious objections not just as justification for rejecting patient information requests about medical aid in dying, but also as justification for rejecting a patient's desire to refuse life-sustaining or life-supporting treatment. Additionally, medical providers could prevent a patient from receiving a wide array of less controversial treatments because of varied religious beliefs held by the healthcare provider such as blood transfusions, vaccinations and antibiotics. Physicians could refuse to de-activate a patient's pacemaker or prescribe sufficient opioids necessary to alleviate the escalating pain of dying. Patients who voluntarily stop eating and drinking, the process known as VSED, risk being unable to find the medical attention necessary to complete this completely legal process for ending their suffering. Physicians who object to the practice of palliative sedation, in which a terminally ill patient is given a continuous infusion of sedative medication to ease distress and suffering at the very end of life by inducing unconsciousness, may refuse to discuss this ethically-accepted option[18] with a patient based entirely on the physician's objection. All of this is to say that medical providers with sincerely held beliefs are entitled to those beliefs, but these beliefs should not enable them to impose broad restrictions on the medical care patients receive and the information the patient needs to make informed medical decisions.

<u>Patient preferences must be the focus of medical care and should guide conversations about their treatment goals, values and wishes</u>

There is one glaring omission in the Department's rationale for promulgating the proposed rule impermissibly gifting the Office of Civil Rights with overly broadened authority to protect the rights of medical providers and physicians to deny patient's healthcare wishes on the basis of religion: It does not even discuss the rights of patients to access all of their own healthcare options and determine their medical treatment. Indeed, the proposed rule places the conscience protections of healthcare providers over any rights of the patient to make healthcare decisions for their medical care consistent with the patients' values.

The relationship between the patient and physician is even more intimate at the end of life. Studies have shown that in jurisdictions where medical aid in dying is a legally authorized medical option, patients and physicians report a marked increase in positive communication about the full range of issues facing the patient at the end of life.[19] These conversations do not focus exclusively

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[16] *Id.*

[17] *See Vermont Alliance for Ethical Healthcare, Inc. et al v. Hoser et al*, No. 5:16-cv-205 (D. Vt. Apr. 5, 2017); *See Also Ahn v. Hestrin*, RIC 1607135 (Sup. Ct. CA., Riverside, June 8, 2016).

[18] Am. Med. Ass'n Council on Ethical and Judicial Affairs, *Sedation to Unconsciousness in End-of-Life Care*, CEJA Report 5-A-08 (2008).

[19] Ganzini, *supra* note 12.

on medical aid in dying, but on the entire scope of end-of-life care options, including hospice and palliative care, pain management, and emotional support. This is vitally important, as physicians have also shown that, in the absence of direction from a patient, or even in spite of information to the contrary from the patient or patient's proxy, doctors make end-of-life decisions for patients based on their own beliefs without consideration for the patient's wishes.[20] For some options at the end of life, failure to inform patients of those options has deprived terminally ill patients of relief from suffering, based solely on the physician's disagreement with the practice.[21]

A danger in the proposed rule is that it expands the definition of "referral" to include providing information. This exceedingly broad interpretation of a common medical practice has been espoused by physicians who have argued the mere giving of information on end of life options makes them morally complicit in the actions of the patient, regardless of what those actions might be. It is not hyperbole to suggest there is a danger in allowing physicians to control the flow of information to patients, as there have been numerous lawsuits around the nation predicated on physicians refusing to share necessary information to patients due to their personal objections to the treatment in question. For example, in *Hoser*, two doctors argued that following Vermont's informed consent law that requires physicians to answer a terminally ill patient's questions about end of life options was a line they could not cross due to their own religious beliefs, regardless of the beliefs of their patients.[22]

As the Department notes, increasing communication between patients and their healthcare providers is a stated goal of the proposed rule[23], and we agree that "[o]pen communication in the doctor-patient relationship will foster better over-all care for patients."[24] Yet, the Department argues that placing barriers between patients and physicians that allow physicians to refrain from open and honest conversations about a patient's wishes somehow *increases* the effectiveness of the communication. Allowing physicians to "hide the ball" by refusing to disclose information because they place their moral principles above those of their patients only increases the risk that patients will not be able to make fully-informed choices about their care. This shutting down of necessary communication between doctors and their patients compromises patient safety and permits physicians to violate the standard of care owed to patients.

The autonomy of patients to control all aspects of their medical care, including those that a provider may disagree with, depends upon the ability of the patient to understand all their available options. Not only does the proposed rule shield providers under the cloak of religious protection, it subverts the wishes of the patient.

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[20] Niels Douglas Martin et al., *Contrasting patient, family, provider, and societal goals at the end of life complicate decision making and induce variability of care after trauma*, 77 J. Trauma & Acute Care Surgery 2 (2014).
[21] *Id.*
[22] *Hoser*, *supra* note 17.
[23] Protecting Statutory Conscience Rights in Health Care; Delegation of Authority, 83 Fed. Reg. 3880, 150 (Jan. 26, 2018).
[24] *Id.* at 151.

Advance directives allow patients to declare their medical care wishes, yet the proposed rule curbs their efficacy

An advance directive is a healthcare planning tool that allows patients to express their end-of-life medical care values and wishes so that they can receive care consistent with their own deeply held beliefs when they don't have the physical or mental capacity to express them. Advanced directives have played a key role in changing social expectations and legal policy about end-of-life care. Yet the Department seeks to invalidate the inherent authority of advance directives by allowing physicians and providers to ignore these documents merely because they disagree with a patient's decision.

There are already numerous protections for medical providers in advance directive laws around the nation, and the Department has failed to articulate sufficient reason for expanding these protections through the proposed rule. Current protections include civil immunity for providers who participate in good faith in honoring the stated wishes in the document and immunity from criminal prosecution for providers whose adherence to a patient's expressed wishes lead to the ultimate death of the patient. Federal Medicare and Medicaid rules require facilities to inform patients and residents of their rights who have completed advance directives, including these facilities to provide their patients and residents written information about whether or not the provider objects on conscience grounds to honoring the directive.[25] Under many current state laws governing the administration of advance directives, physicians and providers are generally able to refuse to follow a validly executed advance directive if it would violate their conscience or "sincerely held religious beliefs," provided that the physician or provider informs the patient and, in many cases, assists in arranging a transfer to another provider who will honor the patient's wishes. The proposed rule suggests a radical change to the status quo.

State laws that require objecting medical providers to arrange patient transfers would likely violate the proposed rule. The effect of this interpretation will no doubt force patients, in their most vulnerable moments, to spend valuable time trying to access medical care in the hope of finding a provider who will follow their wishes. This scenario assumes that the patient is even aware of the fact that the medical provider will deny the treatment they expect when they ultimately need it. Given that one out of every nine acute care beds in this country belongs to a medical facility that follows the Ethical and Religious Directives[26] promulgated by the United States Congress of Catholic Bishops, patients in many areas of the country are already disadvantaged when seeking medical care that places their wishes front and center. The proposed rule adds another barrier for those patients, many facing the end of life, who merely seek medical care that honors and respects their wishes.

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[25] *See* 42 U.S.C. § 1395cc(f)(1) (2000); 42 C.F.R. § 489.102(a)(1)(ii) (2018); 42 C.F.R. § 418.52(a)(2) (2018).

[26] Lois Uttley et al, *Miscarriage of Medicine: The Growth of Catholic Hospitals and the Threat to Reproductive Health Care*, p.1 (Dec. 2013); available at http://static1.1.sqspcdn.com/static/f/816571/24079922/1387381601667/Growth-of-Catholic-Hospitals-2013.pdf?token=%2Fh8oG7GKyIBkXHr8o7UsSpWnZvI%3D

Medical Aid in Dying is not suicide and no physician is required to participate in providing this end-of-life care option in violation of their conscience

Throughout the proposed rule, reference is made to "assisted suicide" and the provision in the Patient Safety and Affordable Care Act that prohibits discrimination against those providers who decide not to participate in assisting in the lawful death of a patient.[27] Medical aid in dying is often described by the media and opponents as "assisted suicide." This nomenclature is inaccurate, as most jurisdictions in which medical aid in dying is explicitly authorized also explicitly denote that "assisted suicide" is a criminal act. This difference is important because medical aid in dying is a separate and distinct medical procedure in which a physician writes a prescription for medication for a mentally capable, terminally ill adult who can then decide if they want to self-administer the medication if their suffering becomes too great. "Assisted suicide" is a criminal act in which someone encourages and facilitates the self-inflicted death of a clinically depressed or mentally ill "suicidal" individual irrespective of their life expectancy.

Dying patients who want to access medical aid in dying find "suicide" language inaccurate and deeply offensive. They desperately want to live, but a terminal illness is taking their life. They are not committing suicide. They are just asking for the option to self-administer medication to peacefully shorten an agonizing dying process if their pain and suffering becomes too great. The American Association of Suicidology, a national organization devoted to understanding, preventing, and supporting those who have been affected by suicide, issued a policy brief recognizing the difference between suicide and medical aid in dying and, as concluded by the organization's executive director, the phrase "'physician-assisted suicide'...should be deleted from use."

The humane option of medical aid in dying is already explicitly authorized in California, Colorado, Montana, Oregon, Vermont, Washington and the District of Columbia. According to 2015 census data, over 18% of the country lives in a jurisdiction in which medical aid in dying is explicitly authorized. Medical aid in dying has been practiced for 40 combined years across these seven jurisdictions without a single instance of abuse or coercion. According to nearly 50 different surveys, the American public has embraced medical aid in dying: about seven out of 10 adults support the option.

However, the proposed rule places barriers that will prevent terminally ill patients in those authorized states from being able to fully utilize the law. Under the law in every authorized jurisdiction, no medical provider is required to write a prescription for aid-in-dying medication. In fact, each and every state in which medical aid in dying is authorized has explicit conscience provisions that protect physicians from writing such a prescription against their wishes. However, under the proposed HHS rule, ambiguity exists as to where the duties of a physician to ensure their patients know all of their healthcare options so they can make fully informed healthcare decisions end. When asked questions, physicians who object to providing medical aid in dying should still engage with patients who raise the issue to understand why a patient is making such an inquiry. To comply with a standard of care, the physician would need to do their best to address such questions. This duty wouldn't bar the physician from then also sharing their view on various end-of-life care options. But the Department impermissibly equates the sharing of information on medical options with participating in a medical procedure and, thus, those

[27] 42 U.S.C. 18113 § 1553.

providers who object to participation also are encouraged to refuse to share information on conscience grounds. The effect of a physician's lack of candor in communication with a patient will lead the patient to feel uncertain they are receiving all pertinent information on their options at the end of life, or just the information the physician endorses.

It should *not* be acceptable for physicians to withhold information from their terminally ill patients by refusing to provide patient-requested information about available medical options for which a patient may qualify, including palliative care and medical aid in dying. Refusing to discuss the patient's healthcare options and wishes, including the reason for those wishes, frustrates the very nature of medical inquiry. Studies have shown that, in states where medical aid in dying is authorized, a request for medical aid-in-dying information often prompts deep, meaningful conversation between the physician and patient about all aspects of the patient's condition.[28] A physician who refuses to participate in the process of medical aid in dying is free to share that reasoning with their patient, but what cannot be acceptable is for the physician to, in essence, lie by omission and yet claim they have fulfilled their duty to their patient.

Conclusion

The freedom of religion is just that: the freedom to believe as one believes, worship as one worships, pray as one prays, or the option to do none of the above. That freedom does not, and we argue *cannot*, wholly override the rights of patients to receive complete and accurate health information and to receive quality care.

Simply put, the Department's arbitrary and capricious rationale for the proposed rule fails to protect the interests of patients, and instead caters to a vocal minority of medical practitioners. As the Department itself notes, between 2008 when the initial rule was drafted until 2016, OCR received only 10 total complaints about alleged violations of federal conscience protection laws, yet these proposed rule has the potential to affect millions of Americans receiving medical care in our country. Patients, especially those facing the end of their lives, should not be forced to worry over whether their clear, expressed treatment decisions will be compromised because a physician places their moral beliefs over a patient's well-being. Similarly, patients should not have to worry that they might not be receiving complete and accurate information, which is critical to making sound, informed medical decisions.

A patient-driven approach to handling conscience-based objections is the only approach that respects the values of both the patient seeking medical care and the medical providers dispensing those services. We implore the Department to reject the proposed rule in favor of a rule that truly empowers ALL participants in our healthcare system.

Sincerely,

Kimberly Callinan
Chief Executive Officer
Compassion & Choices

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[28] Melinda A. Lee & Susan W. Tolle, *Oregon's assisted suicide vote: The silver lining*, Annals of Internal Medicine, 124(2), 267-269 (1996).