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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, 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 One Colorado Education Fund (OCEF) in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26. OCEF is Colorado's leading advocacy organization dedicated to advancing equality for lesbian, gay, bisexual, transgender, and queer (LGBTQ) Coloradans and their families. Since its inception in early 2010, OCEF has made significant progress mobilizing the LGBTQ community in the state, including building a list of more than 60,000 supporters statewide. OCEF also built a coalition of 200 organizations representing two million Coloradans and 200 faith leaders in support of civil unions and full marriage equality, which came to Colorado in October 2014. In addition to relationship recognition, OCEF led a coalition of 30 organizations to successfully advocate for a comprehensive anti-bullying law, helped create 230 new gay-straight alliances (GSA's) in Colorado high schools, and trained over 10,000 educators. OCEF also led the development of the Colorado LGBTQ Health Coalition in collaboration with leading health equity experts and released three comprehensive health reports to nearly 3,000 policy makers, healthcare professionals, and LGBTQ people throughout Colorado.

Every day, too many LGBTQ people experience discrimination and other barriers to accessing the care they need. These barriers are especially pronounced for transgender individuals. The proposed regulation ignores the prevalence of discrimination and damage it causes, and it will undoubtedly lead to increased discrimination and 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 LGBTQ individuals already face.

LGBTQ people, women, and other vulnerable groups around the country already face enormous barriers to getting the care they need. 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. 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.³

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. 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.

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.american progress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

² 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.

³ Sandy E. James et al., The Report of the U.S. Transgender Survey 99 (2016), www.ustranssurvey.org/report

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. 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.⁵

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. In fact, medical staff may interpret the regulation to indicate that they can not only refuse, but decline to tell the patient where they 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 LGBTO patients' access to care services if interpreted—as the proposed rule

 $^{^{5}\} https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/$

 $^{^6}$ https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/

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 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

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.

Sincerely,

Daniel Ramos, Executive Director

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One Voice to Save Choice ("One Voice"), a 40-member volunteer interfaith coalition located in New York City and led out of Congregation Rodeph Sholom, believes a health care provider's personal beliefs should never determine the care a patient receives. In particular, Rodeph Sholom, a religious institution, along with other religious institutions constituting the coalition, have an interest in ensuring patients have access to health care in New York and that religious beliefs do not dictate patient access. That is why One Voice strongly opposes the Department of Health and Human Services' (the "Department") proposed rule ("Proposed Rule"), which seeks to permit discrimination in all aspects of health care.¹

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

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

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.

² See id. at 12.

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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 Rule].

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

Similarly, the Proposed Rule defines common phrases and words used throughout existing refusals of care laws and civil rights laws in ways that stretch their intended meaning beyond recognition. For example, the definition of "assist in the performance" greatly expands the types of services that can be refused to include merely "making arrangements for the procedure" no matter how tangential.⁶ 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.⁷

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

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 Id. at 180.

Id. at 183.

delivery of health care. The Proposed Rule attempts to combine separate definitions of "health care entity" found in different statutes and applicable in different circumstances into one broad term. Such an attempt to expand the meaning of a statutory term Congress already took the time to define not only fosters confusion, but goes directly against congressional intent. By expressly defining the term "health care entity" Congress implicitly rejected the inclusion of the other terms the Department now attempts to insert. 10

When these impermissibly broad definitions are combined with the expansive interpretations of the underlying statutes, they work together to further expand refusals of care to allow more individuals and entities to refuse to provide access to health care. For example, one way the Weldon Amendment is expanded under the Proposed Rule is through the definition of "discrimination." In particular, the Proposed Rule defines "discrimination" against a health care entity broadly to include a number of activities, including denying a grant or employment as well as an unspecified catch-all phrase "any activity reasonably regarded as discrimination." In a Proposed Rule that seeks to protect those who want to discriminate, this broad definition is nonsensical and inappropriate. Further such a vague and inappropriate definition provides no functional guidance to entities on how to comply with the applicable requirements, thereby fostering confusion.

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

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

Across the country refusals of care based on personal beliefs have been invoked in countless ways to deny patients the care they need. ¹³ One woman experiencing pregnancy complications rushed to the only hospital in her community, a religiously affiliated facility, where she was denied the miscarriage management she needed because the hospital objected to this care. ¹⁴ Another woman experiencing pregnancy loss was denied care for ten days at a religiously affiliated hospital outside Chicago, Illinois. ¹⁵ 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

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

⁹ See Rule supra note 1, at 182.

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

¹¹ See Rule supra note 1, at 180.

¹² Id.

¹³ See, e.g., supra note 3.

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

sexuality/PRPCP/bearingfaith.pdf.
15 See Julia Kaye, et al., Health Care Denied, Am. Civil. Liberties Union 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

refused to give her the procedure. ¹⁶ 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. ¹⁷ These examples exist state by state across the country.

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

Refusals of care based on personal beliefs already make it difficult for many individuals to access health care and have real consequences for those denied the care they need because of a provider or hospital's religious beliefs. When women and families are uninsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services or travel to another location, refusals bar access to necessary care. ¹⁸ 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. ¹⁹ In rural areas there may be no other sources of health and life preserving medical care. ²⁰ In developing countries where many health systems are weak, health care options and supplies are often unavailable. ²¹ When these individuals encounter refusals of care, they may have nowhere else to go.

This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals. For example, new research shows that women of color in many states disproportionately receive their care at Catholic hospitals. In nineteen states, women of color are more likely than white women to give birth in Catholic hospitals. These hospitals as well as many Catholic-affiliated hospitals must

¹⁶ 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.

¹⁷ 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.

¹⁸ 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.
¹⁹ 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.

²⁰ 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/.

²¹ 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.

²² 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.

follow the Ethical and Religious Directives (ERDs) which provides guidance on a wide range of hospital matters, including reproductive health care and can keep providers from offering the standard of care.²³ 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.²⁴ 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.²⁵

In addition, in many of the countries where the Department implements global AIDS programs, many of the patients served already face numerous barriers to care, including a broad and harmful refusal provision contained within the statute governing such programs.²⁶

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

By expanding refusals of care the Proposed Rule will exacerbate the barriers to health care services patients need. It is evident that the harm caused by this Proposed Rule will fall hardest on those most in need of care by allowing individuals and health care entities to use their personal beliefs to dictate patient care. The Department should remember, under Executive Order 13563, an agency may only propose regulations where it has made a reasoned determination that the benefits justify the costs and where the regulations are tailored "to impose the least burden on society." The Proposed Rule plainly fails on both counts. Although the Proposed Rule attempts to quantify the costs of compliance, it completely fails to address the costs and burdens to patients who may be denied care and who then may incur and experience even greater social and medical costs. 28

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

²⁴ Lori R. Freedman, When There's a Heartheat: Miscarriage Management in Catholic-Owned Hospitals, Am. J. PUB. HEALTH (2008), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.

²³ See id. at 10-13.

²⁵ 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.

²⁶ 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/.

²⁷ 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.

²⁸ See Rule supra note 1, at 94-177.

any third party. 29 Because the Proposed Rule would cause substantial harm, including to patients, it would violate the Establishment Clause. 30

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. 31 For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling32 and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.33 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.34 The Proposed Rule creates uncertainty about whether Title X grantees may ensure that the subrecipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. Such actions are particularly concerning in the context of federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for low-income populations. 35 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. 36

U.S. Const. amend. 1; 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).
 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.

³¹ 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.lths.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.

³² See, e.g., Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).

³³ See What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).

³⁴ See, e.g., Rule supra note 1, at 180-185.

³⁵ See NFPRHA supra note 34.

³⁶ See id.

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

Existing refusals of care based on personal beliefs already undermine open communication between providers and patients, interfere with providers' ability to provide care according to medical standards, and ignore the reality that many providers want to provide comprehensive care. Hospital systems across the country use religious beliefs to prevent their employees from treating patients regardless of the professional, ethical, or moral convictions of these providers. The Proposed Rule would exacerbate these problems by emboldening health care entities and institutions, including foreign and international organizations, to bind the hands of providers and attempt to limit the types of care they can provide.

The Proposed Rule threatens informed consent, a necessary principle of patient-centered decision-making intended to help balance the power dynamics between health providers and patients and ensure patient-centered decision-making. 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. By allowing providers, including hospital and health care institutions, to refuse to provide patients with information, the Proposed Rule makes it impossible for patients to have full information regarding treatment options. While the Department claims the Proposed Rule improves communication between patients and providers, in truth it will deter open, honest conversations that are vital to ensuring that a patient can control their medical circumstances. On the conversations that are vital to ensuring that a patient can control their medical circumstances.

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. 41 Individuals seeking reproductive health care,

⁴¹ For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care. Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant. Am. Diabetes Ass'n, Standards of Medical Care in Diabetes-2017, 40 Diabetes Care § 114-15, S117 (2017), available at

http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40_Supplement_LDC1/DC_40_S1_final.pdf. The American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics guidelines state that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually

³⁷ See Julia Kaye, et al., Health Care Denied, Am. CIVIL LIBERTIES UNION I, 12 (2016), https://www.aclu.org/sites/default/files/field/document/healthcaredenied.pdf.

³⁸ 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).
³⁹ See id.

⁴⁰ See Rule supra note 1, at 150-151.

regardless of their reasons for needing these services, should be treated with dignity and respect. Allowing providers to flout established medical guidelines and deny medically accurate, 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. 42 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. 43 Instead, the Proposed Rule appropriates language from civil rights statutes and regulations that were intended to improve access to health care and applies that language to situations for which it was not intended. By taking the language of civil rights laws and regulations out of context, the Proposed Rule creates a regulatory scheme that is not only nonsensical but is affirmatively harmful. For example, the notice and certification of compliance and assurance requirements simply do not make sense when applied to the laws the Proposed Rule seeks to enforce. 44 They will place a significant and burdensome requirement on health care providers and impose unique challenges for those working in other countries by taking resources away from patient care without adding any benefit.

The Department, including OCR, has an important role to play in ensuring equal opportunity to access health care and ending discriminatory practices that contribute to poor health outcomes and health disparities. 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,

suggested regardless of fetal age or potential for survival. Am. Acad. of Pediatrics & Am. Coll. of OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES FOR PERINATAL CARE 232 (7th ed. 2012).

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

⁴³ OCR's Mission and Vision, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/ocr/aboutus/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."). 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.

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 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.⁴⁸ Further, the disparity in maternal mortality is growing rather than decreasing,⁴⁹ which in part may be due to the reality that women have long been the subject of discrimination in health care and the resulting health disparities. For example, women's pain is routinely undertreated and often dismissed.⁵⁰ 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.⁵¹ Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.⁵² Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a doctor or other 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 See id.

See, e.g., Dianc 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).

⁵¹ 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).

⁵² 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-isntcaring_Lpdf. A survey examining discrimination against LGBTQ people in health care more than half of respondents reported that they have experienced at least one of the following types of discrimination in care: being refused needed care; health care professionals refusing to touch them or using excessive precautions; health care professionals using harsh or abusive language; being blamed for their health care status; or health care professionals being physically rough or abusive.

provider had refused to see them because of their actual or perceived sexual orientation or gender identity in the year before the survey. 53

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.⁵⁴

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,⁵⁵ the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.⁵⁶ With respect to religion, Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer.⁵⁷ 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.⁵⁸

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. 59 It

⁵³ 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.

⁵⁴ See supra note 46.

^{55 42} U.S.C. § 2000e-2 (1964).

⁵⁶ 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.

See id.

⁵⁸ 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.
⁵⁹ See Rule supra note 1, at 180-181.

is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

In addition, the Proposed Rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person to another facility. ⁶⁰ Under EMTALA every hospital is required to comply – even those that are religiously affiliated. ⁶¹ Because the Proposed Rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

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

One Voice is committed to ensuring that all patients in New York have access to medical care according to the standard of care. 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. 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. 62

Conclusion

The Proposed Rule will allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care. As an interfaith coalition we do not believe that one faith's core beliefs should trump all others. The Proposed Rule is discriminatory, violates multiple federal statutes and the Constitution, ignores congressional intent, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons One Voice calls on the Department to withdraw the Proposed Rule in its entirety.

^{60 42} U.S.C. § 1295dd(a)-(c) (2003).

⁶¹ 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).

Sincerely,

One Voice to Save Choice

Donna L. Bascom

Founder and Chair

Exhibit 148

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 the Oregon Foundation for Reproductive Health in response to the request for public comment on the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26. The Oregon Foundation for Reproductive Health (OFRH) is a non-profit advocacy organization located in Portland, that provides a channel for Oregon women's voices from all over the state to be heard, particularly those historically under-served. We believe that all people should have the power and resources to make healthy decisions about their bodies, sexuality, and reproduction for themselves and their families without fear of discrimination, exclusion, or harm. We will work to break down barriers to health care so that all people have the opportunity to thrive. Our mission is to improve access to comprehensive reproductive health care, such as preventing unintended pregnancy and planning healthy families, and we are committed to advancing reproductive rights and advocating for reproductive health equity in all Oregon communities.

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 or 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.

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 those 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 nonscientific 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 pregnancy⁵ based on the belief that it can cause an abortion, even though there is no scientific evidence that this is the case.

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."

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

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.

Erdely, Sabrina, Doctors' beliefs con hinder potient core, SELF magazine, June 22, 2007, accessed at http://www.nbcnews.com/id/19190916/print/1/displaymode/1098/

could mean a hospital admissions clerk could refuse to check in a patient 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.

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."

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 pregnancies⁷—have gone to hospital emergency departments and been denied prompt, medically-indicated care because of institutional religious restrictions.⁸ 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 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.⁹ Under EMTALA, every hospital is required to comply — even those that are religiously affiliated.¹⁰ 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.

⁶ 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).

⁷ 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

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

^{9 42} U.S.C. § 1295dd(a)-(c) (2003).

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 (4rd 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).

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 conduct compliance reviews of whether health care institutions are following the posting rule. 11

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. 12

The rule conflicts with other existing federal laws, including the Title VII framework for accommodation of employees' 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, ¹³ the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII. ¹⁴ 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. ¹⁵ 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.

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

¹¹ The notice requirement is spelled out in section 88.5 of the proposed rule.

¹² 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

¹⁴ 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.

¹⁵ See id.

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. 16

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 ending 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." 17

6. The proposed rule carries severe consequences for patients and will exacerbate 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. 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. Another woman experiencing pregnancy loss was denied care for 10 days at a religiously affiliated hospital outside Chicago, Illinois. In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy. 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. 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.

b. Refusals of care are especially dangerous for those already facing barriers to care

Refusals of care based on personal beliefs already make it difficult for many individuals to access health care and have real consequences for those denied the care they need because of a provider or hospital's religious beliefs. When women and families are uninsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services or travel to another

¹⁰ See The Church Amendments, 42 U.S.C. § 300a-7(c) (2018).

¹⁷ Uttley, L, et all, Miscarriage of Medicine, MergerWatch and the ACLU (2013), p. 16, https://www.aclu.org/report/miscarriage-medicine.

¹⁸ See, e.g., supra note 2.

¹⁹ See Kira Shepherd, et al., Bearing Faith The Limits of Cotholic 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. CML LIBERTIES UNION 1, 12 (2016), https://www.adu.org/sites/default/files/field_document/healthcaredenied.pdf.

²¹ See Kira Shepherd, et al., supra note 19, at 29.

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-F5.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., supra note 19, at 27.

location, refusals bar access to necessary care. ²⁴ 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. ²⁵ In rural areas there may be no other sources of health and life preserving medical care. ²⁶ When these individuals encounter refusals of care, they may have nowhere else to go.

This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals. For example, new research shows that In 19 states, women of color are more likely than white women to give birth in Catholic hospitals.²⁷ 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 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.²⁹

7. The Department is abdicating its responsibility to patients

If finalized, 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

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. For example, Black women are three to four times more likely than white women to die during or after childbirth. Lesbian, gay, bisexual and transgender individuals also encounter high rates of discrimination in health care. Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a 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. CCR must work to address these disparities, yet the proposed rule is antithetical to OCR's mission.

²⁴ 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.

²⁵ 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/50010-7824(18)30065-9/pdf; Nat'l Latina Inst. For Reproductive Health & Ctr. For Reproductive Rights, Nuestra Voz, Nuestra Salud, Nuestra Texas: the Fight for Wamen's Reproductive Health in the Ria Grande Valley 1, 7 (2013), http://www.nuestrotexas.org/pdf/NT-spread.pdf.

²⁶ 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/.
²⁷ See Kira Shepherd, et al., supra note 19, at 12.

²⁸ See id. at 10-13.

²⁹ 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.

³⁰ 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.
³¹ See, e.a., 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.

32 See Jaime M. Grant et al., Injustice at Every Turn: a Report of the National Transgender Discrimination Survey, Nat'l Gay and Lessian Task Force & Nat'l Ctr. For Transgender Equality,

http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf.

8. 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. 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.³³

Conclusion

The proposed pule 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 Oregon Foundation for Reproductive Health calls on the Department to withdraw the proposed rule in its entirety.

³³ See, e.g., Rule, Supra note 1, at 3888-89.

Exhibit 149

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our family coalition

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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, 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 Our Family Coalition in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26. Our Family Coalition has worked, since 2002, to advance equity for lesbian, gay, bisexual, transgender, and queer (LGBTQ) families with children through support, education, and advocacy – in the San Francisco Bay Area and beyond. We directly serve thousands of families annually, and provide a voice for tens of thousands more across the state.

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 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.

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

LGBTQ people, women, and other vulnerable groups around the country already face enormous barriers to getting the care they need. Accessing quality, culturally competent care and overcoming outright

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



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. 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.

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. 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 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

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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 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-Underserve d-Women/Health-Disparities-in-Rural-Women#17.

³ Sandy E. James et al., The Report of the U.S. Transgender Survey 99 (2016), <u>www.ustranssurvey.org/report</u>

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.



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.⁵

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. 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 LGBTQ patients' access 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

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https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/

https://www.american progress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/



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.

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 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

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.

Sincerely,

Renata Moreira

Executive Director, Our Family Coalition

Exhibit 150



1300 19TH STREET NW, SUITE 200 WASHINGTON, DC 20036-1624 USA

> 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

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

PAI believes that all individuals around the world have a right to quality health care and that a health care provider's personal beliefs should never determine if or the type of care an individual receives. As such, 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 and call on the Department and the Office of Civil Rights (OCR) to withdraw the Proposed Rule in its entirety.¹

The Proposed Rule seeks to drastically expand the ability of a broadly defined set of individuals and health care entities who receive federal funding to refuse to provide *any* part of a health service or program. Furthermore, the Proposed Rule unlawfully attempts to create new refusals. Such expansions exceed the Department's authority, violate the Constitution, contradict existing statutes, undermine critical programs, and interfere with the provider-patient relationship.

The Proposed Rule threatens the health and well-being of people across the United States and around the world. It ignores the reality of the lives of many people living in our own country and around the world, for whom a refusal of care means quite frankly means no access to care.

The Proposed Rule expands the reach of existing harmful refusal of care laws and create new refusals of care where none were intended.

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 will exacerbate the impacts of already harmful refusal laws by expanding the ability to refuse critical services, including abortion and other reproductive and sexual health care services. 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)." 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 including non-U.S. institutions and individuals not entitled to protection under the Constitution, to use their personal beliefs to determine a patient's access to care.

Already existing refusal of care laws are used throughout the United States to limit or deny patients the care they need. The Proposed Rule attempts to vastly expand these laws in ways that goes beyond what statutes enacted by Congress, such as the Church Amendments, intended and allow. For example, the Proposed Rule would expansively apply certain provisions of the Church Amendments to individuals working under global health programs funded by the Department. The Proposed Rule attempts to broaden these provisions to allow individuals working on such programs to refuse to perform aspects of their jobs based on a mere reference to a religious or moral belief. Moreover, by allowing global health providers and entities the ability to refuse individuals the care they need is directly in contradiction to the very purpose of many such programs to "deliver lifesaving services".

Furthermore, the Proposed Rule defines common phrases and words used throughout existing refusals of care laws and civil rights laws in ways that stretch their intended meaning beyond recognition. For example, the definition of "assist in the performance" greatly expands the types of services that can be refused to include merely "making arrangements for the procedure" no matter how tangential.⁶

The Proposed Rule's definition of "referral" also goes further, allowing refusals to provide any information, including location or funding, that could help an individual to get the care they need. This directly contradicts existing statutory language around U.S. international family planning and reproductive health programs, such as the DeConcini Amendment which states that U.S. funds may only go to projects which offer "directly or through referral to, or information

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 See Rule supra note 1, at 185.

⁵ PEPFAR. About Us. https://www.pepfar.gov/about/270968.htm

⁶ See Rule supra note 1at 180.

See Rule supra note 1 at 183.

about access to, a broad range of family planning methods and services." The Livingston-Obey Amendment explicitly prohibits discrimination against applicants for voluntary family projects if the applicant has a "religious or conscientious commitment to offer only natural family planning." However, such religiously-motivated, natural family planning-only providers are nevertheless required to refer patients to providers of other family planning methods ("shall comply with the requirements of the [DeConcini Amendment]") as a condition of eligibility for U.S. FP/RH assistance.

The Proposed Rule would make it difficult for many individuals to access care and will exacerbate already existing barriers to care and inequities, particularly overseas.

In many developing countries where the U.S. operates global heath programs, health care systems remain weak and as a result the barriers to care are high. In these areas, health care options tend to be very limited and necessary medications and other commodities are too often unavailable due to stockouts. The refusal of care in these areas, leaves individuals with nowhere to turn for the health services they need. This is particularly true in rural areas where the next available clinic or pharmacy may be unreachable for many, due to the lack of safe and adequate transportation, requiring many to travel long distances on foot. Lengthy delays or the inability to access care are not merely inconveniences, but for many can lead to life threatening or life altering consequences, particularly when it comes to accessing emergency obstetric care, post-abortion care, emergency contraception or post-exposure prophylaxis for HIV/AIDS.

Much like in the United States, the consequences of refusals are most likely to be felt by individuals who already face multiple and intersecting forms of discrimination. These individuals may include ethnic or religious minorities, women and those with disabilities, as well as those who identify as lesbian, gay, bisexual or transgender and adolescents, particularly unmarried adolescents. These vulnerable groups struggle in many parts of the world to access critically needed quality, acceptable and appropriate health services, particularly sexual and reproductive health services, that are free of discrimination and bias. The proposed rule gives a free pass to providers to deny these individuals their right to comprehensive sexual and reproductive health services.

Furthermore, many of the countries where the Department implements global AIDS programs, many of the patients served already face numerous barriers to care, many imposed by the U.S. federal government, including an excessively broad and harmful refusal provision contained within the statute governing these programs. The President's Emergency Plan for AIDS Relief

The DeConcini Amendment, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 601
The Livingston-Obey Amendment, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 602
See 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; The Way Ahead 2016-2017: Indicators 10-11: Contraceptive Stock-Outs And Availability, Family Planning 2020, http://progress.familyplanning2020.org/en/measurement-section/contraceptive-stock-outs-and-availability-indicators-10-11

authorizing statute stipulates that faith-based organizations shall not be required as a condition of eligibility for U.S. HIV/AIDS assistance to "endorse or utilize a multisectoral or comprehensive approach to combatting HIV/AIDS" or to "endorse, utilize or 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." To the extent that it may extend such refusal rights beyond an organization to individuals providing HIV/AIDS services as an employee of a non-religiously affiliated institution, the Proposed Rule would erect an addition of unconscionable barrier to patients seeking and receiving lifesaving care they need and deserve.

Other executive branch policies, such as the Trump-Pence administration's "Protecting Life in Global Health Assistance" policy restrict the ability of US funded global health providers from offering a full range of sexual and reproductive health services. 12 The proposed rule would compound the impact of these policies by strengthening barriers to care.

Expanded refusals undermines the provider-patient relationship and threatens voluntary and informed consent.

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. Many foreign faith-based organizations implementing global health programs with U.S. assistance, use religious beliefs to prevent their employees from providing a comprehensive range of health services to their patients regardless of the professional, ethical, or moral convictions of the individual providers. The Proposed Rule would exacerbate these problems by emboldening health care entities and institutions, including foreign and international organizations, to bind the hands of providers and attempt to limit the types of care they can provide.

The Proposed Rule threatens voluntary and informed consent, a necessary principle of patientcentered decision-making intended to help balance the power dynamics between health providers and patients and ensure patient-centered decision-making. ¹⁴ Informed consent requires providers disclose relevant and medically accurate information about treatment choices and alternatives so

¹¹ Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis and Malaria Authorization Act of 2008, Pub.L.No.110-293, 122 Stat. 2957 (2008)

¹² See USAID, Protecting Life in Gloval Health Assistance (May 2017), Standard Provisions for Non-U.S. Nongovernmental Organizations, Section RAA29.

https://www.usaid.gov/sites/default/files/documents/1868/303mab.pdf;

PAI, What You Need to Know About the Protecting Life in Global Health Assistance Restrictions on U.S. Global Health Assistance — An Unofficial Guide. (September 30th, 2017), https://pai.org/wp-content/uploads/2017/10/WYN2K-10.5.pdf

¹³ See Julia Kaye, et al., Health Care Denied, AM. CIVII. LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

¹⁴ 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).

that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether. 15 By allowing providers, 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. 16

This also openly contradicts other U.S. statutory language governing U.S. international family planning and reproductive health programs, such as the Tiahrt amendments that requires service providers to provide family planning acceptors (clients) "comprehensible information on the health benefits and risks" of family planning methods, as a critical piece of ensuring voluntary and informed consent.¹⁷

A longstanding provision in foreign operations appropriations legislations attempts to balance the refusal rights of faith-based organizations with the rights of patients for full information on an important contraceptive and disease prevention method. While an organization is not required to provide information on condoms, if it does, the information "must be medically accurate and shall include the public health benefits and failure rates of such use." 18

The Proposed Rule also disregards international 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. ¹⁹ Individuals seeking reproductive health care, regardless of their reasons for needing these services, should be treated with dignity and respect. Allowing providers to flout established medical guidelines and deny

¹⁵ See id.

¹⁶ See Rule supra note 1, at 150-151.

¹⁷ The Tiahrt Amendment, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 601

¹⁸ Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 602.

¹⁹ For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care. Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant. Am. DIABETES ASS'N, STANDARDS OF MEDICAL CARE IN DIABETES-2017, 40 DIABETES CARE § 114-15, S117 (2017), available at

http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf. The American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics guidelines state that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually suggested regardless of fetal age or potential for survival. Am. ACAD, OF PEDIATRICS & AM. COLL, OF OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES FOR PERINATAL CARE 232 (7th ed. 2012).

medically accurate, 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. ²⁰ No health care professional should face discrimination from their employer because they treated or provided information to a patient seeking an abortion.

Conclusion

The Proposed Rule will allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care in the U.S. and around the world. The Proposed Rule is discriminatory, violates multiple federal statutes and the Constitution, ignores congressional intent, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons PAI calls on the Department to withdraw the Proposed Rule in its entirety.

Sincerely,

PAI

²⁰ See The Church Amendments, 42 U.S.C. § 300a-7(c) (2018).

Exhibit 151



March 27, 2018

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

Mr. Roger Severino Director, Office for Civil Rights Department of Health and Human Services Hubert H. Humphrey Building, Room 509F 200 Independence Avenue S.W. Washington, DC 20201

Re: Protecting Statutory Conscience Rights in Health Care; Delegation of Authority (RIN 0945-ZA03)

Dear Director Severino:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to offer comments in response to the "Protecting Statutory Conscience Rights in Health Care" in the notice of proposed rulemaking (NPRM) published by the Department of Health and Human Services (HHS), Office for Civil Rights (OCR) in the January 26, 2018, Federal Register (83 FR 3880).

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and the exchanges established by the Affordable Care Act.

PCMA broadly supports efforts by HHS to protect individuals from discriminatory policies and practices. However, we are concerned that aspects of the NPRM are overly vague and broad, which will create significant unwarranted economic and regulatory burdens on entities like PBMs that are far removed from the actual purpose of the NPRM (which, as we understand it based on the proposed regulatory text at § 88.1 protects individuals who object to the performance of health care services on moral or ethical grounds). Below, we recommend clarifications that will help provide appropriate protections for such individuals, while also aligning with the series of existing executive orders (e.g., E.O. 13771) designed to ensure that OCR is regulating in a way that minimizes the economic burden on stakeholders.

1. Scope

<u>Issue</u>: The NPRM extends the nondiscrimination requirements applicable to governmental entities under the Weldon Amendment to private entities.

> Pharmaceutical Care Management Association 325 7th Street, NW, 9th Floor Washington, DC 20004 www.pcmanet.org



<u>Discussion</u>: We are concerned that the NPRM extends the nondiscrimination requirements applicable to governmental entities under the Weldon Amendment to private entities in excess of the HHS Secretary's authority under the plain meaning of the Amendment. As proposed, the NPRM exceeds the intent of the law with respect to health care entities. In particular, despite the clear statutory language of Weldon which extends nondiscrimination protections to health care entities *from* discrimination by a governmental agency, HHS now proposes to reinterpret the plain language of Weldon to impose duties upon these same health care entities it is intended to protect. This is a plain ultra vires interpretation. Indeed, HHS acknowledges in the preamble this clear interpretation, but then takes the significantly broader position that "nothing in the text *limits* its protection to those contexts."

As discussed further below, we note that we do not believe that the plain language of Weldon (and, therefore, this regulation) necessarily extends to entities like PBMs and other similar administrative entities such as third-party administrators (TPAs). Given that PBMs and TPAs themselves do not provide direct healthcare services – nor do they operate as health insurance plans (in that they do not bear the risk associated with insurance), it is not clear under what authority Weldon and associated nondiscrimination requirements could apply to administrative entities such as TPAs and PBMs, which are generally viewed as such.

<u>PCMA Recommendation</u>: OCR should narrow the rule to make clear that (a) the only entities that are subject to duties, requirements, or obligations as the result of the Weldon Amendment are governmental agencies and programs that are funded by an act that includes the Weldon Amendment, and (b) the Weldon Amendment does not impose any independent duties on health care entities. Moreover, OCR should clarify that, as neither health care providers nor insurers, administrative entities such as TPAs and PBMs are not "health care entities" and are not subject to the Weldon Amendment where it is applicable.

2. Definitions (§ 88.2)

a. Sub-recipient

<u>Issue</u>: OCR proposes to define sub-recipient as "any political subdivision of any State, any instrumentality of any State or political subdivision thereof, and any person or any public or private agency, institution, organization, or other entity in any State, including any successor, assign, or transferee thereof, to whom federal financial assistance (FFA) is extended through another recipient or another sub-recipient, or who otherwise receives Federal funds from the Department or a component of the Department indirectly through a recipient or another sub-recipient, but such term does not include any ultimate beneficiary."

<u>Discussion</u>: As noted above, we generally object to the application of any duty under the proposed regulation to entities such as PBMs. PBMs are considered a "downstream entity" of a health plan, bear no risk in insuring individuals enrolled in health care coverage, and provide no direct health care services. While PBMs may be appropriately classified as sub-recipients than as recipients, we believe HHS's definition of sub-recipient is expansive and over-encompassing.



Simply put, given the very clear purpose of the NPRM, PBMs do not provide the types of services that would require or necessitate the protections provided for in the NPRM. PBMs and their employees do not provide health care services – nor do PBMs pay for such services. As the administrative contractor of a health plan, PBMs manage the pharmacy benefit for many health plans, but ultimate control over this benefit rests with the health plan. As PBMs and their employees do not "perform, assist in the performance of, or undergo health care services or research activities," there can be no reasonable "objection" to any of the services provided therein.

Again, while we recognize that OCR has proposed to reduce the burden on sub-recipients (which, as proposed, would include virtually any actor participating in the health care sector) by exempting such entities from the requirements to provide written assurance and certification of compliance requirements (§ 88.4), to provide and post the notice text (§ 88.5), and to maintain primary responsibility for compliance under the rules (§ 88.6), significant burdens are still imposed on sub-recipients, as defined, under the NPRM. In particular, sub-recipients are still required to: maintain complete and accurate records evidencing compliance; to cooperate with any compliance review and investigation; and to handle the burdensome reporting requirements detailed in § 88.6(d).

<u>PCMA Recommendation</u>: OCR should narrow its definition of sub-recipient to exclude administrative entities such as TPAs and PBMs, as these entities do not provide direct health care services nor bear risk as health insurance issuers or plans. In the absence of this, OCR should explicitly clarify that entities like TPAs and PBMs that do not provide direct health care services and do not bear risk are not recipients.

3. Assurances and Certification of Compliance Requirements (§ 88.4)

Issue: OCR states that every application for FFA or Federal funds from HHS to which § 88.3 applies shall, as a condition of the approval, renewal, or extension of any FFA or Federal funds from HHS pursuant to the application, provide, contain, or be accompanied by an assurance/certification that the applicant or recipient will comply with applicable Federal health care conscience and associated antidiscrimination laws and this part.

<u>Discussion</u>: While PCMA appreciates HHS's recognition of the potential burden imposed under the NPRM by exempting sub-recipients from the requirement to provide written assurance and certifications of compliance to HHS (notwithstanding our belief that the proposed definition of sub-recipient is overly broad and vague and does not apply to entities such as TPAs and PBMs), we are not aware of any added value in having a separate written assurance requirement that provides information about the statutes when affected entities (such as health insurance issuers) already certify compliance. Imposing this unnecessary requirement on health care entities is inconsistent with the Executive Order on "Reducing Regulation and Controlling Regulatory Costs" and should be eliminated.



<u>PCMA Recommendation</u>: OCR should consider eliminating the assurance/certification of compliance requirements altogether due to its burden and lack of value. If it retains the requirement, it should clarify that the requirement for written assurances does not apply to sub-recipients.

4. Notice Requirement (§ 88.5)

<u>Issue</u>: OCR states that HHS and each recipient shall post the notice text located in Appendix A to this part in accordance with paragraph (b) of this section by April 26, 2018, or with respect to new recipients, within 90 days after becoming a recipient.

<u>Discussion</u>: As previously noted, we appreciate HHS's recognition that the notice requirement does not apply to sub-recipients. Nevertheless, the Church and Weldon Amendments *protect* health care entities from discrimination in granting funds by government agencies – but do not impose additional obligations upon them. Therefore, the notice requirement is unnecessary and inconsistent with Congress' intent in enacting these amendments.

<u>PCMA Recommendation</u>: OCR should consider eliminating the notice requirement as the Church and Weldon Amendments do not impose obligations and duties upon health care entities, but instead upon governmental entities. As such, it is inconsistent with the underlying statutory framework to require these entities to provide a notice of nondiscrimination in support of these regulations. OCR should also clarify in the final rule that the notice requirement does not apply to sub-recipients.

5. Compliance Requirements (§ 88.5)

<u>Issue</u>: OCR notes that recipients and sub-recipients must maintain records evidencing compliance with these laws and the proposed regulation and are required to cooperate with OCR in the enforcement process. If a recipient or sub-recipient is subject to an OCR compliance review, or complaint, the recipient or sub-recipient must inform any departmental funding component of such review, investigation, or complaint.

<u>Discussion</u>: The current proposal is vague and does not provide sufficient detail for stakeholders to provide meaningful input. For example, what records would be required to be maintained and for what period of time would they need to be maintained for? What if an OCR investigation showed that a sub-recipient was compliant, would it still need to inform it was subject to an investigation on departmental funding applications? Moreover, it is clear that these requirements appear duplicative of many existing processes (i.e., certification of compliance with existing laws is already made before HHS) and therefore is contrary to Executive Order 13771, "Reducing Regulation and Controlling Regulatory Costs."

<u>PCMA Recommendation</u>: Given that health care entities already certify compliance with existing statutory requirements, we believe these new requirements are duplicative, overly burdensome, and unnecessary.



6. Effective Date

Issue: The NPRM does not provide an effective date.

<u>Discussion</u>: Developing new processes, such as for recordkeeping, require system changes. Furthermore, many of the proposed provisions require clarifications not provided in the NPRM. We therefore recommend the rule not go into effect until proper implementation can be achieved.

<u>PCMA Recommendation</u>: OCR should provide adequate time and guidance to operationalize the rule.

7. Other Issues

Several issues applicable to health plans also merit clarification,

- a. Definition of "Assist in the Performance": Because the Church Amendments protect health care providers and researchers, there is no need for the rule to define "assist in the performance" to have an "articulable connection..." If OCR includes a definition, it should be limited to health care providers and researchers.
- b. Definition of Referral: The definition of "referral" should be narrowed to include referral only by health care providers or their employees. The final rule should include a specific exemption for health insurance issuer employees performing administrative functions such as answering questions from covered individuals or processing claims.

Thank you in advance for the opportunity to comment. If you have any questions, please contact me at wkrasner@pcmanet.org or Mona Mahmoud at mmahmoud@pcmanet.org.

Sincerely,

Wendy Krasner

Wendy Kreoner

Vice President, Regulatory Affairs

Exhibit 152



March 26, 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 Ave SW Washington, DC 20201

RE: Department of Health and Human Services, Office for Civil Rights RIN 0945-ZA03

To Whom It May Concern:

I am writing on behalf of People For the American Way ("PFAW") in response to the request for public comment regarding the proposed rule by the Department of Health and Human Services ("HHS") entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26, 2018. PFAW is a progressive advocacy organization established to promote and protect civil and constitutional rights, including religious liberty and freedom from discrimination. Founded in 1981 by a group of civic, educational, and religious leaders, PFAW now has hundreds of thousands of members nationwide. Over its history, PFAW has conducted extensive education, outreach, legislative and regulatory advocacy, and other activities to promote these values. PFAW strongly supports the principle that the First Amendment and appropriate federal law and regulations should be a shield for the free exercise of religion, protecting individuals of all faiths. PFAW is concerned, however, about efforts to transform this important shield into a sword to obtain accommodations that significantly harm others, which also violates the Establishment Clause.

PFAW is very concerned about the fact that every day, too many individuals, particularly women and LGBTQ people, people of color, and rural Americans, face discrimination and other barriers to accessing lifesaving health care. PFAW is concerned that the proposed regulation ignores the prevalence of discrimination and the 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. Sweeping religious exemptions that obstruct access to care are a fundamental distortion of the principle of freedom of religion. Americans deserve better.

Many people, particularly women and LGBTQ people, people of color, and rural Americans, already face significant barriers to obtaining adequate health care.

Women and LGBTQ people, people of color, rural Americans, and other vulnerable groups around the country already face enormous barriers to getting the care they need, including

refusals of care by providers based on personal beliefs. Accessing quality care and overcoming outright discrimination is an even greater challenge for those living in areas with already limited access to health care providers. The proposed regulation threatens to make access even harder, and for some people nearly impossible.

Patients living in rural and other 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 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 health care 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. 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 instance, a 2015 survey of nearly 28,000 transgender adults nationwide found that respondents reported having to travel further for transition-related care than routine care.³

If such patients are turned away or refused treatment, therefore, it is much harder—and sometimes impossible—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. For these patients, being turned away by a medical provider is not just an inconvenience; it also often means being denied care entirely with nowhere else to go.

e.e. Institute of Medicine. The

¹ 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), http://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),

https://www.lambdalegal.org/publications/when-health-care-isnt-caring; National Women's Law Center, The Patient Should Come First: Refusals to Provide Reproductive Health Care (2017).

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 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

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

The proposed regulation attempts to inappropriately broaden religious exemptions in a way that threatens to lead to dangerous denials of medically necessary care.

The proposed regulation purports, among other things, to clarify current "religious refusal clauses" related to abortion and sterilization in three existing 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 so-called 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." 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. In addition, 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 transition, 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. ⁵

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. In fact, medical staff may interpret the regulation, including the broad new definition of "referral," to indicate not only that they can refuse to provide specific care, but also can decline to even tell a patient where she or 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. The proposed 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 person.

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

Sharita Gruberg and Frank J. Bewkes, The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial (2018), https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/

⁶ Id

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. For example, the extension and broadening of this clause will impair LGBTQ patients' access 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 transition-related care, are sterilization procedures. Treatments for serious medical conditions may have the incidental effect of causing or contributing to infertility: for example, a hysterectomy, chemotherapy, 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 encourage individuals and institutions to refuse a dangerously broad range of medically needed treatments.

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

U.S. Department of Health & Human Services, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority 3923-24 (2018), https://www.federalregister.gov/documents/2018/01/26/2018-01226/protecting-statutory-conscience-rights-in-health-care-delegations-of-authority ("Rule"); U.S. Department of Health & Human Services, https://www.https://www.https://www.https://www.https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf">https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf ("NFPRHA")

⁸ e.g. Consolidated Appropriations Act of 2017 Public Law No: 115-31, 131 Stat. 135 (2017), https://www.congress.gov/bill/115th-congress/house-bill/244/text/pl?

What Requirements Must Be Met by a Family Planning Project? 42 C.F.R. § 59.5(a) (5) (2000), https://www.gpo.gov/fdsvs/grannle/CFR-2007-title42-vol1/CFR-2007-title42-vol1-sec59-5

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. 10

The proposed rule also threatens informed consent, a necessary principle of patient-centered decision-making intended to help balance the power dynamics between health care providers and patients and ensure patient-centered decision-making. ¹¹ Informed consent requires providers to 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. ¹² By allowing providers, including hospitals and other 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 HHS claims that 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. ¹³

The proposed rule conflicts with other existing federal law.

For example, the proposed rule makes no mention of Title VII, ¹⁴ the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission ("EEOC") guidance on Title VII. ¹⁵ With respect to religion, Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer. ¹⁶ 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, the EEOC

12 Id.

¹⁰ See NFPRHA

Tom Beauchamp & James Childress, Principles Of Biomedical Ethics 4th Ed (1994); Charles Lidz Et Al., Informed Consent; A Study Of Decisionmaking In Psychiatry (1984)

¹³ Rule at 3917

¹⁴ 42 U.S.C. § 2000e-2 (1964), https://www.gpo.gov/fdsvs/granule/USCODE-2010-title42/USCODE-2010-title42-chap21-subchapVI-sec2000e-2/content-detail.html

¹⁵ U.S. Equal Employment Opportunity Commission, Title VII of the Civil Rights Act of 1964 (2018), https://www.eeoc.gov/laws/statutes/fitlevii.cfm

filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard. 17

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. It is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

In addition, the proposed rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition, or if medically warranted to transfer the person to another facility. ¹⁸ Under EMTALA every hospital is required to comply—even those that are religiously affiliated. ¹⁹ Because the proposed rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

The proposed rule will make it harder for states and local governments 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, however, the proposed rule creates conflicts with

¹⁷ Reed L. Russell, EEOC Office of Legal Counsel letter responding to a request for public comment from a federal agency or department (2008), https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html
¹⁸ 42 U.S.C. § 1295dd(a)-(c) (2003)

¹⁹ In order to effectuate the law's important legislative purpose, institutions claiming a religious or moral objection to treatment must comply with EMTALA, and courts agree, e.g. Shelton v. University of Medicine and Dentistry of New Jersey ABC, 223 F.3d 220, 228 (3rd Cir. 2000); In the Matter of Baby "K", 16 F.3d 590, 597 (4rd Cir. 1994); Noesen 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).

hundreds of state and local nondiscrimination laws around the country that apply to health care. It therefore is disingenuous for HHS 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 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 HHS 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. 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. ²¹

The proposed regulation lacks safeguards to protect patients from harmful refusals of care and violates the Establishment Clause.

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 that a religious accommodation may impose on others, including patients, and prohibits granting accommodations when they would materially harm any third party. But as detailed at length above, the proposed regulation would cause significant harm by interfering with patients' access to health care and thus, conflicts with this constitutional bar.

Specifically, the Supreme Court has ruled that a religious accommodation "must be measured so that it does not override other significant interests," impose unjustified burdens on others," or have a "detrimental effect on any third party." But that is precisely what the proposed rule would do, transforming the shield of religious accommodation into a sword that would harm others, particularly patients who are dependent on receiving adequate medical care.

²² Cutter v. Wilkinson ("Cutter"), 544 U.S. 709, 722 (2005)

²⁰ Rule at 3888-89

²¹ Id

²³ Cutter, 544 U.S. at 726; Texas Monthly, Inc. v. Bullock, 480 U.S. 1, 18n.8 (1989) (accommodations may not impose "substantial burdens" on others)

²⁴ Burwell v. Hobby Lobby Stores, Inc., 134 S.Ct. 2751, 2781 n.37 (2014) (citing Cutter, 544 U.S. at 720)

Conclusion

The proposed rule goes far beyond established law, violates the Constitution, and most importantly will put the health and potentially even the lives of many patients across the country at risk. We urge you to withdraw the proposed rule.

Sincerely,

Marge Baker

Executive Vice President for Policy and Program

People For the American Way

Margery & Baker

Exhibit 153



Jodi Magee President/CEO

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March 27, 2018

The Honorable Alex Azar

Secretary of Health and Human Services

U.S. Department of Health and Human Services

200 Independence Avenue, SW

Washington, DC 20201

Re: Comments on Department of Health and Human Services, Office for Civil Rights RIN 0945-ZA03

Dear Secretary Azar:

Physicians for Reproductive Health is committed to ensuring all individuals have access to health care, regardless of their gender identity, sexual orientation, and/or the type of services being requested, including abortion, contraception or sterilization. Physicians for Reproductive Health (Physicians) is a doctor-led national advocacy organization that uses evidence-based medicine to promote sound reproductive health policies. Physicians unites the medical community and concerned supporters. Together, we work to improve access to comprehensive reproductive health care, including contraception and abortion, especially to meet the health care needs of economically disadvantaged patients. Physicians believes a health care provider's personal beliefs should never determine the care a patient receives. By allowing patient care to be compromised by religious or personal beliefs without consideration of the best medical care for the patient, this rule stands to undermine the very foundation of the doctor-patient relationship. Indeed, one of the reasons cited for the proposed rule is a case—Chamorro v. Dignity Health—we filed in California against a Catholic



hospital network regarding their refusal to allow doctors to provide patients with the standard of care in the form of postpartum tubal ligations. That is why we strongly oppose the Department of Health and Human Services' (the "Department") proposed rule ("Proposed Rule"), which seeks to permit discrimination in all aspects of health care.¹

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

By issuing the Proposed Rule and creating a new division within the Office of Civil Rights ("OCR")

– the new "Conscience and Religious Freedom Division" – the Department seeks to inappropriately use

OCR's limited resources in order to affirmatively allow institutions, insurance companies, and almost

anyone involved in patient care to use their personal beliefs to deny people the care they need. For

these reasons Physicians 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

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

2 See id. at 12.

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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 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 Unlawfully Expands Already Harmful Abortion/Sterilization Refusal of Care
 Laws

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

Furthermore, the Proposed Rule would expansively apply other provisions of the Church Amendments to, among other things, individuals working under global health programs funded by the Department, thereby allowing global health providers and entities to refuse individuals the care they need contrary to the very purpose of such programs.

Similarly, the Proposed Rule defines common phrases and words used throughout existing refusals of care laws and civil rights laws in ways that stretch their intended meaning beyond recognition. For example, the definition of "assist in the performance" greatly expands the types of services that can be

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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.



refused to include merely "making arrangements for the procedure" no matter how tangential.⁶ 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.⁷

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

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

⁶ Id. at 180.

⁷ Id. at 183.

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

⁹ See Rule supra note 1, at 182.

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

¹¹ See Rule supra note 1, at 180.

¹² Td.



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. 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. Another woman experiencing pregnancy loss was denied care for ten days at a religiously affiliated hospital outside Chicago, Illinois. In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy. 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. 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

¹³ See, e.g., supra note 3.

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

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

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

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



the following days, the hospital did not give her full information about her condition and treatment options. 18

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

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

This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals. For example, new research shows that women of color in many states disproportionately receive their care at Catholic hospitals. In nineteen

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

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

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

²² See Nurith Aizenman, Health Care Costs Push a Staggering Number of People into Extreme Poverty, NPR (Dec. 14, 2017), https://www.npr.org/sections/goatsandsoda/2017/12/14/569893722/health-care-costs-push-a-staggering-number-of-people-into-extreme-poverty; Tracking Universal Health Coverage: 2017 Global Monitoring Report, WORLD HEALTH ORG, & THE WORLD BANK (2017), http://documents.worldbank.org/curated/en/640121513095868125/pdf/122029-WP-REVISED-PUBLIC.pdf.



states, women of color are more likely than white women to give birth in Catholic hospitals.²³ These hospitals, as well as many Catholic-affiliated hospitals, must follow the Ethical and Religious Directives (ERDs) which provides guidance on a wide range of hospital matters, including reproductive health care and can keep providers from offering the standard of care.²⁴ Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals, and as a result, women were delayed care or transferred to other facilities at great risk to their health.²⁵ The reach of this type of religious refusal of care is growing with the proliferation of both the types of entities using religious beliefs to discriminate and the number of religiously affiliated entities that provide health care and related services.²⁶ In addition, in many of the countries where the Department implements global AIDS programs, many of the patients served already face numerous barriers to care, including a broad and harmful refusal provision contained within the statute governing such programs.²⁷

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

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

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

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

²⁴ See id. at 10-13.

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

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

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



completely fails to address the costs and burdens to patients who may be denied care and who then may incur and experience even greater social and medical costs.²⁹

Moreover, the Establishment Clause of the First Amendment requires the government to adequately account for just these sorts of consequences when considering whether to grant religious exemptions and, in fact, bars granting an exemption when it would detrimentally affect any third party.³⁰ Because the Proposed Rule would cause substantial harm, including to patients, it would violate the Establishment Clause.³¹

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

The Proposed Rule would seemingly allow health care entities to receive grants and contracts under HHS-funded programs or other federal health programs, such as Title X, the only domestic family planning program, while refusing to provide key services required by those programs. ³² For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling ³³ and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination. ³⁴ Under the Proposed Rule, the Department would seemingly allow entities to apply for and receive federal funds while exempting them from the core legal and programmatic duties upon which such

²⁹ See Rule supra note 1, at 94-177,

³⁰ U.S. Const. amend. I; Cutter v. Wilkinson, 554 U.S. 709, 720, 722 (2005) (to comply with the Establishment Clause, courts "must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries" and must ensure that the accommodation is "measured so that it does not override other significant interests") (citing Estate of Thornton v. Caldor, 472 U.S. 703, 710 (1985)); see also Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751, 2781 n.37 (2014); Holt v. Hobbs, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).
³¹ Respecting religious exercise may not "unduly restrict other persons, such as employees, in protecting their own 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.

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

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

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



funds are generally conditioned.³⁵ The Proposed Rule creates uncertainty about whether Title X grantees may ensure that the subrecipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. Such actions are particularly concerning in the context of federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for low-income populations.³⁶ When it comes to Title X, the Proposed Rule would not only sanction conduct at odds with pre-existing legal requirements, but could also undermine the program's fundamental objectives. Every year millions of low-income, including under-insured, and uninsured individuals, rely on Title X clinics to access services they otherwise might not be able to afford.³⁷

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

Existing refusals of care based on personal beliefs already undermine open communication between providers and patients, interfere with providers' ability to provide care according to medical standards, and ignore the reality that many providers want to provide comprehensive care. Hospital systems across the country use religious beliefs to prevent their employees from treating patients regardless of the professional, ethical, or moral convictions of these providers.³⁸ The Proposed Rule would exacerbate these problems by emboldening health care entities and institutions, including foreign and international organizations, to bind the hands of providers and attempt to limit the types of care they can provide.

The Proposed Rule threatens informed consent, a necessary principle of patient-centered decision-making intended to help balance the power dynamics between health providers and patients and ensure patient-centered decision-making.³⁹ Informed consent requires providers disclose relevant and medically accurate information about treatment choices and alternatives so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment

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.

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

³⁶ See NFPRHA supra note 34.

³⁷ See id.

³⁰ 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).



altogether.⁴⁰ By allowing providers, including hospital and health care institutions, to refuse to provide patients with information, the Proposed Rule makes it impossible for patients to have full information regarding treatment options. While the Department claims the Proposed Rule improves communication between patients and providers, in truth it will deter open, honest conversations that are vital to ensuring that a patient can control their medical circumstances.⁴¹

The Proposed Rule also disregards standards of care established by the medical community by allowing providers to opt out of providing medical care. Medical practice guidelines and standards of care establish the boundaries of medical services that patients can expect to receive and that providers should be expected to deliver. Yet, the Proposed Rule seeks to allow providers and institutions to ignore the standards of care, particularly surrounding reproductive and sexual health. Information, counseling, referral and provision of contraceptive and abortion services are part of the standard of care for a range of common medical conditions including heart disease, diabetes, epilepsy, lupus, obesity, and cancer. Individuals seeking reproductive health care, regardless of their reasons for needing these services, should be treated with dignity and respect. Allowing providers to flout established medical guidelines and deny medically accurate, 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.⁴³ No health care professional should face

4 See Rule supra note 1, at 150-151.

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

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

⁴⁰ See id.

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



discrimination from their employer because they treated or provided information to a patient seeking an abortion.

The Department is Abdicating its Responsibility to Patients

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

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

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

⁴⁵ See Rule supra note 1, at 203-214.
⁴⁶ As one of its first official acts in 1967, the Office of Equal Health Opportunity undertook the massive effort of inspecting 3,000 hospitals to ensure they were complying with Title VI's prohibition against discrimination on the basis of race, color, or national origin. 42. U.S.C. § 2000d (1964). After this auspicious start, the Office of Equal Health Opportunity which would eventually become OCR would go on to ensure that health programs and activities it regulated complied with key anti-discrimination laws including Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 (1973), Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 (1972), the Age Discrimination Act of 1976, 42 U.S.C. § 6101 (1976), and Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116 (2010), among others. Through robust enforcement of these laws, OCR has worked to reduce discrimination in health care.



segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.⁴⁷

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

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

⁴⁷ See, e.g., Serving People with Disabilities in the Most Integrated Setting: Community Living and Olmstead, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/community-living-and-olmstead/index.html, https://www.hhs.gov/civil-rights/for-individuals/special-topics/hiv/index.html, https://www.hhs.gov/civil-rights/for-individuals/special-topics/hiv/index.html, https://www.hhs.gov/civil-rights/for-individuals/special-topics/health-disparities/index.html.

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

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

⁵⁰ See id.

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

⁵³ See, e.g., When Health Care Isn't Caring, LAMBDA LEGAL 5 (2010), https://www.lambdalegal.org/sites/default/files/publications/downloads/whoic-report_when-health-care-isnt-caring_1.pdf. A survey examining discrimination against LGBTQ people in health care more than half of respondents reported that they have experienced at least one of the following types of discrimination in care: being refused needed care; health care professionals refusing to touch them or using excessive precautions; health care



lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a doctor or other 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.⁵⁴

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

The Proposed Rule Conflicts with Other Existing Federal Law

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

professionals using harsh or abusive language; being blamed for their health care status; or health care professionals being physically rough or abusive.

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

⁵⁵ See supra note 46.

^{56 42} U.S.C. § 2000e-2 (1964).

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



comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.⁵⁹

Furthermore, the language in the Proposed Rule would seem to put health care entities in the position of being forced to hire people who intend to refuse to perform essential elements of a position even though Title VII would not require such an "accommodation." For example, there is no guidance about whether it is impermissible "discrimination" for a Title X-funded health 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. ⁵⁰ It is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

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

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

⁶⁰ See Rule supra note 1, at 180-181.

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

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



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. 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.

Conclusion

The Proposed Rule will allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care. The Proposed Rule is discriminatory, violates multiple federal statutes and the Constitution, ignores congressional intent, fosters confusion, and harms patients, contrary to the Department's stated mission. For these reasons Physicians for Reproductive Health calls on the Department to withdraw the Proposed Rule in its entirety.

Sincerely,

Board of Directors, Physicians for Reproductive Health

64 See id.

⁶³ See, e.g., Rule, Supra note 1, at 3888-89.

Exhibit 154



March 27, 2018

VIA ELECTRONIC TRANSMISSION

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

Re: RIN 0945-ZA03 Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Secretary Azar and Director Severino:

Planned Parenthood Federation of America (Planned Parenthood) and Planned Parenthood Action Fund (the Action Fund) submit these comments in response to the Protecting Statutory Conscience Rights in Health Care; Delegation of Authority, released by the Department of Health and Human Services (the Department) Office for Civil Rights (OCR) and Office of the Secretary on January 19, 2018 and published in the federal register on January 26, 2018. As a trusted women's health care provider and advocate, Planned Parenthood takes every opportunity to weigh in on policy proposals that impact the communities we serve across the country.

Planned Parenthood is the nation's leading women's health care provider and advocate and a trusted, nonprofit source of primary and preventive care for women, men, and young people in communities across the United States. Each year, Planned Parenthood's more than 600 health centers provide affordable birth control, lifesaving cancer screenings, testing and treatment for sexually transmitted diseases (STDs), and other essential care to 2.4 million patients. We also provide abortion services and ensure that women have accurate information about all of their reproductive health care options. One in five women in the U.S. has visited a Planned Parenthood health center. The majority of Planned Parenthood patients have incomes at or below 150 percent of the Federal Poverty Level (FPL).

As a health care provider, Planned Parenthood knows how important it is that people have access to quality health care and information they can trust. Already, too many people in this country are denied, often without realizing it, access to medically-appropriate information and care because of a health care provider's or employer's personal beliefs. Instead of protecting

patients' access to quality care, this rule -- if finalized -- would make it easier for health care workers to refuse care, disproportionately impacting women, LGBTQ people, people with low incomes, people from rural areas, and other people already experiencing barriers to care. Importantly, the proposed rule goes beyond the reach of the statutes the Department claims to be implementing, undermining the intent of the statutes and exceeding the authority given by Congress. Further, as outlined below, the proposed rule potentially conflicts with existing civil rights statutes and state laws, and it fails to adequately account for costs.

Indeed, this proposed rule is unprecedented in its reach and harm, seeking to allow almost any worker in a health care setting to refuse services and information to a patient because of personal beliefs, which notably would include "religious, moral, ethical, or other reasons." This means that under this proposed rule, a pharmacist could refuse to fill a prescription for birth control or antidepressants, a woman could be denied life-saving treatment for cancer, or a transgender patient could be denied hormone therapy. And while the proposed rule purports to be protecting the conscience rights and "personal freedom" of health care workers "with a variety of moral, religious, and philosophical backgrounds," it selectively ignores the many workers who are prevented from following their conscience by restrictions on care imposed by their employers.

The Department has an obligation to follow parameters established by Congress and aim for equality in health care access across the country, including for women, LGBTQ people, and people living with HIV. To this end, the Department must withdraw this proposed rule.

The proposed rule would endanger patients and obstruct their access to health care.

The proposed rule reflects bad public health policy. Women -- particularly women of color and women living in rural areas -- LGBTQ people, and people living with HIV already experience barriers to care, and this proposed rule would further limit health care access and result in poor health care outcomes. The proposed rule will also interfere with the ability of patients and providers to make informed medical decisions. Notably, the proposed rule does not provide any exceptions for necessary care in the case of an emergency.

A. The proposed rule would exacerbate existing barriers to health care.

The rule would erect more barriers to reproductive health care, transition-related services, and other services, and place women, LGBTQ people, and people living with HIV at greater risk of not getting the services they need. Access to comprehensive reproductive health care, including abortion, is already limited. According to a recent report, nearly half of the women of reproductive age have to travel between 10 to 79 miles, and some women have to travel 180 miles or more, to access an abortion. Importantly, the proposed rule improperly expands upon

¹ Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3923 (Jan. 26, 2018) (to be codified at 45 C.F.R. pt. 88).

² J. Mearak, et. al., Disparities and change over time in distance women would need to travel to have an abortion in the USA; spatial analysis, The Lancet (Nov. 2017), http://www.thelancet.com/pdfs/journals/lanpub/PIIS2468-2667(17)30158-5.pdf.

existing refusal laws and policies that already harm an untold number of people, who are often denied information and care.

It is already the case that women with pregnancy complications who seek care at religiously-affiliated hospitals have been denied information or abortion care, even when that information is critical to their health. An often-cited case is that of Tamesha Means, who was rushed to Mercy Health Partners in Muskegon, Michigan after her water broke at 18 weeks of pregnancy. She was sent home twice in excruciating pain despite the fact that there was no chance that her pregnancy would survive and that continuing the pregnancy posed significant risks to her health. Due to the hospital's religious affiliation, Ms. Means was not informed that terminating her pregnancy was the safest course for her condition, and therefore her health was put at risk." Another woman, Mikki Kendall, went to an emergency room after experiencing a placental abruption. Even though her pregnancy would not survive and Ms. Kendall could have died due to the amount of blood loss, the doctor on call refused to perform an abortion and refused to contact another physician to perform the procedure. Fortunately, Ms. Kendall was able to receive the care she needed after several risky and agonizing hours." Unfortunately, many people are not even aware that they may be denied medically-appropriate care and information, even in emergency situations. For instance, nearly 40 percent of the people who regularly visit Catholic hospitals do not know of the religious affiliation, and even patients that are aware of the affiliation frequently do not know the hospital refuses to provide certain services.

Certain communities are particularly affected by denials of care. Health care refusals disproportionately impact Black women, and the expansions outlined in this proposed rule would likewise disproportionately impact Black women. For example, according to a recent report, hospitals in neighborhoods that are predominately Black are more likely to be governed by ethical and religious directives for Catholic health care services. Additionally, people living in rural areas are significantly impacted if their provider refuses to provide necessary or preventive care. Women living in in rural areas already experience provider shortages and have to travel long distances for health care, resulting in significant gaps in care and low health outcomes. By making it easier for providers to refuse care, the proposed rule would further restrict these options or cut off access to care altogether, which would compromise patient health still further.

The proposed rule also threatens access to transition-related services and HIV prevention and care -- including pre-exposure prophylaxis -- disproportionately impacting LGBTQ people and

⁶ K. Shepherd, et. al., Bearing Faith: The Limits of Catholic Health Care for Women of Color, Columbia Law School (January 2018),

https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf?mc_cid=51db21f500&mc_eid=780170d2f0.

https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co586.pdf?dmc=1&ts=20160402T0931414521.

³ ACLU, Tamesha Means v. United States of Catholic Bishops (June 30, 2015), https://www.aclu.org/cases/tamesha-means-v-united-states-conference-catholic-bishops.

Mikki Kendall, Abortion Saved my Life, Salon (May 26, 2011), https://www.salon.com/2011/05/26/abortion_saved_my_life/.

⁵ ld.

⁷ The American College of Obstetricians and Gynecologists, Health Disparities in Rural Women (2014, reaffirmed 2016).

people living with HIV. Discrimination in health care settings already prevents LGBTQ people from accessing the care they need. For instance, nearly one-third of transgender people surveyed said a doctor or health care provider refused to treat them due to their gender identity. Related, people living with HIV frequently experience stigma in the health care system. The proposed rule would increase this stigma and make it more likely that these communities are denied necessary health care.

B. The proposed rule will hinder the delivery of care.

While the Department claims that the proposed rule will "facilitat[e] open communication between providers and their patients," in fact, it would do the opposite. Specifically, the proposed rule encourages medical professionals to conceal information if they believe that information might enable a patient to seek care (even elsewhere) of which they disapprove. It also inhibits communication by increasing the risk that patients will conceal medically relevant information, such as sexual orientation, out of fear that their provider would refuse them care.

The proposed rule itself notes that mainstream medical groups have recognized the negative effects refusing care can have on patients and that these organizations have called for patient protections when refusals may compromise health. For example, the American Congress of Obstetricians and Gynecologists (ACOG) ethics opinion states that "in an emergency in which referral is not possible or might negatively affect patient's physical or mental health, providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections." The American Medical Association's (AMA) constitution and bylaws similarly note that physicians are required to be "moral agents" and "being a conscientious medical professional may well mean at times acting in ways contrary to one's personal ideals in order to adhere to a general professional obligation to serve patients' interests first." The constitution and bylaws further state that "having discretion to follow conscience with respect to specific interventions or services does not relieve the physician of the obligation to not abandon a patient." The proposed rule would exacerbate these concerns by making it harder for medical organizations and providers to preserve existing access to reproductive health care. 12

⁸ S. Mirza & C. Rooney, Discrimination Prevents LGBTQ people from Accessing Health Care, Ctr. for Amercian Progress (Jan. 18, 2018),

https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/.

ODC, HIV Among Gay and Bisexual Men, https://www.cdc.gov/hiv/group/msm/index.htm; CDC, HIV Among African-Americans, https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/cdc-hiv-aa-508.pdf.
10 83 Fed. Reg. at 3888; ACOG, The Limits of Conscientious Refusal in Reproductive Medicine (Nov. 2007, reaffirmed 2016).

https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Ethics/The-Limits-of-Conscientious-Refusal-in-Reproductive-Medicine.

¹¹ American Medical Association, Physician Exercise of Conscience: Report of the Council on Ethical and Judicial Affairs.

https://www.ama-assn.org/sites/default/files/media-browser/public/about-ama/councils/Council%20Report s/council-on-ethics-and-judicial-affairs/i14-ceja-physician-exercise-conscience.pdf.

¹² By ignoring these harms, the Department has failed in its obligation to acknowledge and consider the impact of a proposed rule on family well-being. See 83 Fed. Reg. at 3919.

C. The proposed rule does not include exceptions for medical emergencies and potentially conflicts with existing federal law.

The proposed rule could endanger women's lives because it fails to make sure that the protections of the Emergency Medical Treatment and Active Labor Act (EMTALA) apply and take precedence when a patient is facing a medical emergency. EMTALA requires virtually every hospital to provide an examination or treatment to individuals that come into the emergency room, including care for persons in active labor, and the hospital must provide an appropriate transfer if the hospital cannot stabilize the patient. The proposed rule does not address EMTALA and the potential legal conflict between that Act and the proposed rule. In particular, it is unclear if the Department or a state or local government would be considered to have engaged in prohibited "discrimination" if it penalized a hospital for failing to comply with EMTALA when a pregnant woman needs an abortion in an emergency situation. There is no dispute that some pregnant women develop serious medical complications for which the standard treatment is pregnancy termination. The proposed rule's silence on medical emergencies could create confusion among health care institutions or even allow them to refuse to comply with existing federal requirements to treat patients with medical emergencies and thereby endanger women's lives.

II. The proposed rule exceeds the authority granted under the underlying statutes.

While purporting to interpret long-standing statutes, the Department is expanding the requirements of the statutes beyond what Congress intended. The Department claims that it is seeking to clarify the scope and application of existing laws, but this rule would in fact drastically alter, not clarify, existing requirements. The Department both creates expansive definitions that did not exist before and reinterprets the provisions of the underlying laws in harmful ways.

A. The proposed rule expands the definition of various terms beyond their well-settled meanings and beyond congressional intent.

The proposed rule expands the definitions of well-settled terms used in the relevant refusal laws far beyond their commonly understood meanings, defining terms so broadly as to encompass a

¹⁴ The government can clearly take such action under Title VII. See Shelton v. Univ. of Med. & Dentistry of N.J. 223 F.3d 220, 228 (3d Cir. 2000).

¹³ 42 U.S.C. § 1395dd.

¹⁵ See *e.g.*, *Planned Parenthood v. Casey*, 505 U.S. 833, 880 (1992) ("[It is undisputed that under some circumstances each of these conditions [preeclampsia, inevitable abortion, and premature rupture of membrane] could lead to an illness with substantial and irreversible consequences.").

¹⁶ Federal abortion policy generally has recognized the need to protect women's lives. *See e.g.*, 18 U.S.C. § 1531(a) (prohibiting abortion procedure except where "necessary to save the life of a mother"); 10 U.S.C. § 1093 (banning almost all abortion services at U.S. military medical facilities, and prohibiting Department of Defense funds, which includes health insurance payments under Civilian Health and Medical Program for the Uniformed Services, from being used to perform abortions, "except where the life of the mother would be endangered if the fetus were carried to term"); Consolidated Appropriations Act, 2017, Pub. L. No. 115-131, Title V §§ 507 131 Stat. 135 (2017) (prohibiting that funds appropriated under the Act be used to pay for an abortion except where, among other narrow exceptions, "where a woman suffers from a physical disorder, physical injury, or physical illness, including a life endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed").

ridiculously wide array of activities that go well beyond congressional intent. As an initial matter, although the Department purports to be bringing the refusal laws in line with other civil rights laws, the rule proposes to define "discrimination" contrary to how it is has been long understood in those laws. Under the Department's proposed rule, "discrimination" is more broadly defined to include a large number of activities, including denying a grant, employment, benefit or other privilege, as well an unspecified catch-all phrase "any activity reasonably regarded as discrimination." It also includes any laws or policies that would have the effect of defeating or substantially impairing accomplishment of a "health program or activity." The term, "health program or activity" is then defined to include, among other things, "health studies, or any other services related to health or wellness whether directly, through payments, grants contracts, or other instruments, through insurance, or otherwise." The inclusion of any impairment of a "health program or activity," as defined, only adds to an unreasonably expansive definition of "discrimination" that could be applied to anything with a tangential connection to health or wellness. As set forth below, the rule's all-encompassing definition of "discrimination" fails to account for established anti-discrimination law that reflect a balancing of interests -- protecting against religious discrimination but recognizing it is not discriminatory to require an employee to perform functions that are essential to the position for which she applied and was hired.

The proposed rule also improperly stretches the definition of "refer" to include providing "any information ... by any method ... that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity or procedure." This means that any health care entity, including both individuals and institutions, could refuse to provide any information that could help an individual to get the care they need, including even to provide patients with a standard pamphlet. The objecting entity would be able to refuse to provide that information even if they believe that a particular health care service is only the "possible outcome of the referral." This definition would allow health care providers to deny patients full, accurate, and comprehensive information on health care options that allow people to make their own health care decisions.

The proposed rule also defines "assist in the performance of" far more broadly than its common meaning, to include participating in any program or activity with "an articulable connection" to a procedure, health service, health program, or research activity. The proposed rule specifically notes that this includes *but is not limited to* counseling, referral, training, and other arrangements. Even though the Department claims to acknowledge "the rights in the statutes are not unlimited," this definition could in effect create an unlimited right to refuse services. For example, it is unclear if an employee whose task it is to mop the floors at a hospital that provides abortion would be considered to "assist in the performance" of the abortion under this proposed rule. A definition this limitless provides no functional guidance to health care providers as to what they can ask of their employees, and the refusals permitted by health care providers and non-medical staff.

The proposed rule also broadens the health care workers that can claim "discrimination," potentially allowing a range of health care workers not directly involved in delivering care to

¹⁷ 83 Fed. Reg. at 3924.

¹⁸ Referral is defined far more narrowly elsewhere in federal law. *See, e.g.*, 42 U.S.C. § 1395nn(h)(5); 42 C.F.R. § 411.351.

^{19 83} Fed. Reg. at 3924.

²⁰ 83 Fed. Reg. at 3923.

refuse to perform their duties at a health care facility. Specifically, the proposed rule seeks to expand the definition of "health care entity," "individual," and "workforce" to include a broad range of workers and organizations, including volunteers, trainees, and contractors.²¹ The proposed rule notes that the workers included in the definitions are illustrative and not exhaustive, potentially creating the opportunity for non-medical personnel, such as receptionists or facilities staff, to refuse to perform job tasks. In particular, the notion that an individual who agrees to volunteer to perform a service for an entity has the right to then refuse to perform that service, but presumably without losing his or her status as "volunteer," is absurd. This nonsensical interpretation of the statutes exceed the Department's regulatory authority. In short, if this provision is finalized, a wide range of workers may be able to deny access to care - even if the worker's job is only tangentially related to that care.

The proposed rule also seeks to expand the health care providers and institutions that are subject to the rule's burdensome requirements. The proposed rule's broad definition of "entity" to include individuals as well as corporations, would greatly expand the individuals and institutions subject to the underlying laws' requirements.²²

In general, the proposed rule's unreasonably expansive definitions could inhibit health care providers and institutions from offering a broad range of health care services to patients, and would ultimately limit patients' access to care. This is particularly so because in addition to expanding the terms used in the refusal laws beyond any possible meaning Congress intended, the Department has also expanded the substance of the refusal laws beyond their statutory text, as is discussed below. Thus, rather than clarify statutes that are as much as forty-years old, the proposed rule has stretched the meaning of key terms. This will lead to illogical, unworkable, and unlawful results.

B. The Department broadly interprets the Church Amendments in violation of the statute.

The Department is exceeding its statutory authority by interpreting the Church Amendments far beyond what Congress intended. Each provision of the Church Amendments was enacted at a different point in time to address specific concerns. The first two provisions of the Church Amendments were enacted in 1973 during the public debate following the *Roe v. Wade* decision, and they clarify that receipt of certain federal funds does not require a health care entity to perform abortions or sterilizations or make its facilities available for abortions or sterilizations. These provisions of the Church Amendments, codified at 42 U.S.C. § 300a-7(b) and (c)(1), permit individuals to refuse to perform or assist in the performance of a sterilization or abortion in certain federally funded programs if it is contrary to their religious or moral beliefs. Sections (d) and (e) of the Amendments were passed as a part of the National Research Act, which aimed at funding biomedical and behavioral research, and ensuring that research projects involving human subjects were performed in an ethical manner. ²⁴ The Department's purported

²¹ 83 Fed. Reg. at 3923–3924.

²² 83 Fed. Reg. at 3924.

The implicated funds are the Public Health Service Act [42 U.S.C. § 201 *et seq.*], the Community Mental Health Centers Act [42 U.S.C. § 2689 *et seq.*], and the Developmental Disabilities Services and Facilities Construction Act [42 U.S.C. § 6000 *et seq.*].

²⁴ See 119 Cong. Rec. 2917 (1973).

interpretation of these provisions goes far beyond both the statutory text and Congressional intent in at least two ways.

First, section (b) of the Church Amendments states that courts, public officials, and public authorities are not authorized to require the performance of abortions or sterilizations, based on the receipt of any grant, contract, loan, or loan guarantee under the Public Health Service Act (PHSA), the Community Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act. The proposed rule goes beyond the text of the statute and interprets it to prohibit public authorities from requiring any individual or institution to perform these services if they receive a grant, contract, loan or loan guarantee under the PHSA. Therefore, while the Church Amendments only make it clear that public authorities are not allowed to require the performance or assistance in the performance of abortion or sterilization based on the receipt of certain federal funding, the proposed rule imposes a blanket prohibition on any requirements related to individuals or institutions performing or assisting in the performance of abortion and sterilization if the institution or individual receives the specified funding. Combined with the expanded definition of "assist in the performance" that impacts sections (b)(1) and (b)(2)(B), the proposed rule allows for denials of services related to abortion and sterilization by both individual providers and those ancillary to the provision of health care. It could also prevent states and the federal government from requiring a hospital to provide an abortion, even if a patient's health or life is threatened.

Second, the proposed rule interprets section (d) of the Church Amendments in a way that goes well beyond the statute and that has the potential to allow any individual employed at a vast number of health care institutions to refuse to provide care that is central to the institution. Importantly, this provision was intended to apply only to individuals who work for entities that receive grants or contracts for biomedical or behavioral research. The proposed rule incorrectly claims that paragraph (d) of the Church Amendments is not based on receiving specified funding through a specific appropriation, instrument, or authorizing statute, but applies to "[a]ny entity that carries out any part of a health service program or research activity funded in whole or in part under a program administered by" the Department.²⁵

The expansive definitions of "entity," "health service program" and "assist in the performance" only serve to exacerbate this unlawful expansion. As noted, "entity" is defined broadly in the proposed rule to include a "'person', as defined in 1 U.S.C. 1 or a State, political subdivision of any State, instrumentality of any State or political subdivision thereof, or any public agency, public institution, public organization, or other public entity in any State or political subdivision of any state." "Health service program" is discussed by the Department in the proposed rule as not only including programs where the Department provides care or health services directly, but programs administered by the Secretary that provide health services through grants, cooperative agreements or otherwise; programs where the Department reimburses another entity to provide care; and "health insurance programs where Federal funds are used to provide access to health coverage (e.g. CHIP, Medicaid, Medicare Advantage)." It also may include components of State or local governments.²⁶

Thus, under the proposed rule, virtually any individual could refuse to provide any type of health care or any job task that has a minimal connection to the provision of health care. This provision

²⁵ 83 Fed. Reg. at 3925.

²⁶ 83 Fed. Reg. at 3894.

would not only allow individuals to refuse to provide any type of care that they object to, but could also prevent states from protecting patients by requiring the provision of health care or fulfillment of other job duties by individuals in a medical facility. This could include, for instance, enforcing a state law that requires individual pharmacists to fill all the prescriptions they receive.

Nothing in the legislative history of section (d) of the Church Amendments suggests that this provision was meant to restrict the actions of this broad range of health care related individuals and organizations, nor that it was meant to apply to these individuals and institutions in the context of such a broad range of health-related programs.²⁷ The Department has clearly exceeded its statutory authority by attempting to create a catch-all provision that would allow almost any health care provider in the country to refuse to provide services based on a 40-year old law that was targeted to the receipt of specific, and limited, federal funds.

C. The Department's interpretation of the Weldon Amendment is not consistent with the plain language of the statute.

The Department has proposed a similarly broad -- and impermissible -- expansion of the Weldon Amendment. That amendment was added to the appropriations bill for the Departments of Labor, Health and Human Services, and Education in 2004 and each subsequent appropriations bill. It prohibits funds appropriated by those three agencies to be provided to a federal agency or program, or to a state or local government, if such agency, program, or government requires any institutional or individual health care entity to provide, pay for, provide coverage of, or refer for abortions. While the text of the statute is limited to state and local governments and federal agencies or programs, the rule would apply the Weldon Amendment to "any entity that receives funds through a program administered by the Secretary or under an appropriations act [HHS]." This interpretation of the Weldon Amendment would impermissibly turn private entities into "federal agencies or programs" by virtue of their receipt of HHS funding.

In addition to conflicting with the plain meaning of the statute, the Department's broad interpretation is also contrary to the legislative history of the Weldon Amendment. During final floor debates on the appropriations bill that included the first Weldon Amendment, one of its supporters explained: "The addition of conscience protection to the Hyde amendment remedies current gaps in Federal law and promotes the right of conscientious objection by forbidding federally funded government bodies to coerce the consciences of health care providers." In other words, the Weldon Amendment's reference to "federal agency or program" was intended as a restriction on government bodies only, not on private entities that receive federal funds.

Indeed, the Department of Justice (DOJ) has taken the formal position that the receipt of federal funds does not mean that an organization is a federal agency or program. In litigation, the DOJ stated: the term "federal agency or program" does not automatically include private, individual family planning clinics that receive federal funds; the Weldon Amendment does not clearly

²⁷ Indeed, section (d) of the Church Amendments does not by its terms impose any restrictions on health care providers. Rather, it is framed as an exemption to individuals from certain federal requirements that are contrary to their religious or moral beliefs. 42 U.S.C. § 300a-7(d).

²⁸ Weldon Amendment, Consolidated Appropriations Act 2017, Pub. L. 115-31, Div. H, Tit. V, Sec. 507(d).

²⁹83 Fed. Reg. at 3925.

³⁰ 150 Cong. Rec. H10095 (daily ed. Nov. 20, 2004) (statement of Rep. Smith) (emphasis added).

provide that an individual Title X clinic would constitute a "federal agency or program" covered by the statute, and "no agency responsible for the implementation or enforcement of the statute has adopted a reading to that effect." ³¹ If Congress intended for the Weldon Amendment to apply to virtually every private hospital, pharmacy, and outpatient care center in the country, and hundreds of thousands of private doctors and other health care practitioners, it surely would have said so more directly, either at the time the Weldon Amendment was enacted or in the 14 years that the amendment has been interpreted otherwise.

The unreasonably broad definitions of "discrimination" and "health care entity" also act to greatly expand the reach of the Weldon Amendment. By defining discrimination to include any adverse actions without any balancing of the interests of employers or patients, this provision could be used to attempt to strike down neutral state laws that protect access to health care. The term, "health care entity" is already defined in the Weldon Amendment, so a proposal to add certain entities via regulation clearly exceeds the authority of the Department. For example, the inclusion of "a plan sponsor, issuer, or third party administrator" expands the reach of the provision by allowing employers that provide health insurance (even if they have no connections to health care) to become "health care entities" for purposes of this protection from "discrimination."

Finally, the legislative history cited above makes it clear that the Weldon Amendment was intended to be limited to objections based on conscience, but under the proposed rule, the Department would allow refusal for *any* reason, including, for example, a financial one. All of these expansions are contrary to law and, more importantly, work to deny women access to information about and access to lawful medical services.

D. The Department similarly expands the applicability of the Coats Amendment.

The proposed rule's broad definitions of "health care entity," "refer," and "discrimination" would also expand the applicability of the Coats Amendment beyond its statutory language and intent. The Coats Amendment was adopted in 1996 in response to a new standard adopted by the Accrediting Council for Graduate Medical Education, requiring all obstetrics and gynecology residency programs to provide induced abortion training. Senator Coats offered the amendment to "prevent any government, Federal or State, from discriminating against hospitals or residents that do not perform, train, or make arrangements for abortions.

The amendment prohibits the federal government, or any state or local government that receives federal financial assistance, from discriminating against medical residency programs or individuals enrolled in those programs based on a refusal to undergo, require, or provide abortion training. ³⁴ Under the Coats Amendment, the term "health care entity" is limited to "an individual physician, a postgraduate physician training program, and a participant in a program

³¹ Brief of Respondent, NFPRHA v. Gonzales, 391 F.Supp.2d 200 (D.D.C. 2004) (No. 04-2148).

³² See 142 Cong. Rec. 5159 (March 19, 1996) (Senator Frist stating that "this amendment arose out of a controversy over accrediting standards for obstetrical and gynecological programs").

³³ 142 Cong. Rec. 4926 (March 14, 1996). *See also* 142 Cong. Rec. 5158 (March 19, 1996) (Senator Coats stating he offered the language in the bill because "it is [not] right that the Federal Government could discriminate against hospitals or ob/gyn residents simply because they choose, on a voluntary basis, not to perform abortions or receive abortion training, for whatever reason.").

³⁴ See 42 U.S.C. § 238n.

of training in the health professions."³⁵ However, the proposed rule's definition of health care entity would prohibit "discrimination" not just against those specified in the Coats Amendment, but also against other health care professionals, health care personnel, an applicant for training or study in the health professions, a hospital, a laboratory, an entity engaging in biomedical or behavioral research, a health insurance plan, a provider-sponsored organization, a health maintenance organization, a plan sponsor, issuer, third-party administrator, or any other kind of health care organization, facility or plan. Similar to the proposed rule's changes to the Weldon Amendment, the Department has taken a narrow statute that was enacted to address a specific concern and used the proposed rule to promote broader discrimination in health care.

III. The proposed rule would undermine health care access in programs that Congress intended to expand care for women with low incomes and their families.

The proposed rule would impact health care programs, both domestically and internationally, that are intended to expand access and quality of care for women, people with low incomes, people living with HIV, and others. The expanded scope of the rule would reach both the Title X Family Planning Program (Title X) and the President's Emergency Plan for AIDS Relief (PEPFAR).

A. The Department's proposal would reduce access to vital services through Title X and other programs by allowing objectors to ignore their general requirements contrary to the intent of these programs.

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. We find this 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 people with low-incomes. 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 objective of expanding access to reproductive health care to underserved communities.

Several of the Department's proposed provisions and definitions appear to exempt recipients of federal funds from following the rules that govern federal programs if they have an objection to doing so. As discussed above, the proposed rule's expansion of the Weldon Amendment turns private entities into "federal agencies or programs" and then bars them (as well as the Department) from "discriminating" against a "health care entity" based on its refusal to provide "referrals" for abortion. "Discrimination" includes, among other things, denying federal awards or sub-awards to objectors. Timilarly, the proposed rule provides that the Department cannot require recipients of grants provided under the Public Health Service Act to "assist in the performance of an abortion." Such "assistance" includes an unreasonably broad range of conduct, including "counseling, referral, training, and other arrangements." Also, the proposed rule provides that entities receiving Public Health Service Act grants cannot be required to

^{35 42} USC § 238n(c)(2).

³⁶ 83 Fed. Reg. at 3925.

³⁷ 83 Fed. Reg. at 3923–3924.

^{38 83} Fed. Reg. at 3925.

provide personnel for "the performance or assistance in the performance of any . . . abortion;" the overbroad definition of "assistance" again applies here.

Federal agencies routinely provide financial assistance to eligible entities in the form of grants, contracts, or other agreements in exchange for the performance of a prescribed set of services or activities. The Department's approach would seem to give objectors a virtually unlimited right to ignore these generally applicable requirements and may even force the Department to fund entities that refuse to advance the fundamental goals of the programs in which they seek to participate. Nowhere in the proposed rule does the Department acknowledge that its exemptions in these areas would allow conduct that conflicts with pre-existing legal requirements. Nor does it consider how overriding these rules could undermine important health care objectives that are central to the effective administration of federally supported health programs.

The proposed rule's defects come into clear focus in the context of Title X, the nation's program for birth control and reproductive health. Title X of the Public Health Service Act empowers the Department to make grants to public and not-for-profit entities for the purpose of providing confidential family planning and related preventive services. Title X gives priority to services for people with low incomes and, depending on their income and insurance status, patients may be eligible for free or discounted Title X services. In 2016, Title X-funded providers served over 4 million people. This total includes a disproportionate share of individuals from groups that face longstanding racial and ethnic inequities; for example, 32 percent of Title X patients identified as Hispanic or Latino, and 21 percent identified as Black in 2016. Title X-funded projects offer a range of reproductive health care and information, including counseling and services related to a broad range of contraceptive methods, HIV/STI services, cancer screenings, and other care.

The Department's proposal appears to sanction conduct that would interfere with Title X's legal requirements. For example, although Title X funds are barred from going toward abortion, the program's regulations expressly require providers to offer non-directive options counseling to patients, including abortion counseling and referrals upon request. Even before its codification in regulation, longstanding Departmental interpretations held that non-directive options counseling was a basic and necessary Title X service. The centrality of non-directive options counseling in Title X is reinforced every year through legislative mandates in annual appropriations measures. These prescriptions reflect well-settled principles of medical ethics: patients are entitled to prompt, accurate, and complete information to enable them to make informed decisions about their health. And, especially when an entity does not offer a desired

^{39 83} Fed. Reg. at 3925.

^{40 42} U.S.C. §§ 300 - 300a-8.

^{41 42} U.S.C. § 300a-4(c).

⁴² Christina Fowler, et al., RTI International, Family Planning Annual Report: 2016 national summary (2017), available at https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf.
⁴³ Id.

⁴⁴ 42 U.S.C. § 300a-6 (prohibiting funding for abortion); 42 C.F.R. § 59.5(a)(5) (requiring non-directive options counseling and referral).

⁴⁵ See Comptroller General of the United States, "Restrictions on Abortion and Lobbying Activities In Family Planning Programs Need Clarification" (Sept. 1982), available at http://www.gao.gov/assets/140/138760.pdf.

⁴⁶ See, e.g., Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, 131 Stat 135 (2017).

service such as abortion, health professionals have a responsibility to provide the information and referrals needed to ensure that such services are provided to patients in a timely and competent manner. Yet, under the proposal, entities that object to "assist[ing] in the performance of abortion" could claim a right to refuse to offer non-directive options counseling and referrals to Title X patients.

On top of interfering with counseling and referrals under Title X, the proposed rule could also override other program requirements. For instance, Title X requires projects to provide medical services, including "a broad range of acceptable and effective medically approved family planning methods." This unquestionably includes long-acting reversible contraceptive methods such as intrauterine devices (IUDs). The central place of IUDs, which are exceptionally effective, in the family planning repertoire is cemented by the Centers for Disease Control and Prevention's (CDC) Quality Family Planning recommendations. These recommendations provide, for example, that "[c]ontraceptive services should include consideration of a full range of FDA-approved contraceptive methods," and a "broad range of methods, including long-acting reversible contraception (i.e., intrauterine devices [IUDs] and implants), should be discussed with all women and adolescents." Despite these national clinical standards of care, some individuals are opposed to contraception or certain forms of contraception, and under the proposed impermissible expansion of Church (d) discussed above, any individual working for an entity participating in Title X could claim a right to refuse to provide information or services related to contraception for Title X patients.

If allowed by the Department, such exemptions not only would overtake pre-existing legal rules, but could also thwart the critical health care objectives that federal programs are meant to advance. For example, Congress's purpose in passing Title X was, in part, "to assist in making comprehensive voluntary family planning services readily available to all persons desiring such services," and "to enable public and nonprofit private entities to plan and develop comprehensive programs of family planning services." Permitting health care entities to withhold vital counseling, referrals, and services is hardly conducive to the "comprehensive" approach that was contemplated by Congress. In practical terms, such policies could cut off access to basic, preventive health care and information for the low-income and uninsured people who turn to Title X-funded providers.

Since the inception of these important public health programs, entities that do not want to provide the required services are free to decline to participate. All recipients of federal funds, however, should be bound by the same, general requirements and serve the same priorities in order to serve program beneficiaries and faithfully adhere to Congress's aims.

B. The proposed rule would severely undermine the purpose and effectiveness of U.S. funded health programs around the world.

The Department's global health programs include those focused on combating HIV/AIDS and malaria, improving maternal and child health, and enhancing global health security. In addition

^{47 42} C.F.R. § 59.5(a)(1).

⁴⁸ Centers for Disease Control and Prevention, *Providing Quality Family Planning Services:*Recommendations of CDC and the U.S. Office of Population Affairs, 7, 8, (2014), available at https://www.cdc.gov/mmwr/pdf/rr/m6304.pdf.

⁴⁹ Act of Dec. 24, 1970, Pub. L. No. 91-572, § 2, 84 Stat. 1504 (1970).

to funds directly appropriated to the Department for global health, considerable funding is transferred to the Department by the State Department and USAID to administer global AIDS programs under PEPFAR.

We strongly oppose the statutory prohibition on the use of foreign aid funding for abortion as a method of family planning, known as the Helms Amendment, both as it is written and the broader manner in which it is applied, and the broad and harmful refusal provision contained within the statute governing PEPFAR, which are both cited in the proposed regulation. The Helms Amendment effectively coerces women into continuing unwanted pregnancies because the health care they are able to access is provided with U.S. funding. The outcome of this harmful policy is increased unwanted pregnancies and maternal morbidity and mortality.

PEPFAR's statutory refusal provision, which applies only to organizations, already puts beneficiaries at risk and undermines the overall program. For example, this restriction allows PEPFAR-participating organizations to refuse to provide condoms (or any other service to which they object) or even information about condoms to people served by the program -- despite the fact that the purpose of the program is to combat HIV/AIDS and condom provision is proven to be an essential component of effective HIV prevention programs. Organizations may even refuse to coordinate their activities or have any other relationship with programs that provide the services or information to which they object, creating a serious barrier to ensuring that the full range of HIV prevention, care, and treatment activities are available in any one community or to any individual client.

The proposed rule would go even further than the statutory refusal provision and under the guise of paragraph (d) of the Church Amendments allow any individual working under global health funds from the Department (whether the funds are from direct appropriations or transferred from another agency and then administered by the Department) to refuse to perform or assist in any part of a health service program. As explained above, this expansion of Church (d) is contrary to Congress' intent in enacting this provision. The result is to magnify the harm of PEPFAR's refusal provision by appearing to allow individuals to refuse to treat any patient if doing so would violate his or religious beliefs or moral convictions, without concern for the needs of the patient and regardless of what type of health service the patient needs -- whether it be contraception, a blood transfusion, a vaccination, condoms to prevent HIV transmission, sexually transmitted infection screenings and treatment, or even information about health care options. The proposed rule would impact a limitless array of health services.

Moreover, individuals could potentially use this broad interpretation of section (d) of the Church Amendments to pick and choose which patients to assist, making LGBTQ individuals, adolescent girls and young women, and other marginalized populations particularly vulnerable to discrimination in the provision of services. This is particularly egregious in the context of HIV/AIDS programs where these communities face elevated risk in many parts of the world. In developing countries where health systems are especially weak, there is a shortage of available health care options and supplies, and individuals often travel long distances to obtain the services that they need; it is particularly critical that individual health care providers do not deny patients the information and services that they need. Such action undermines the purpose of the programs and the rights of those they intend to serve.

⁵⁰ 83 Fed. Reg. at 3926–3927.

Furthermore, the proposed rule does not refer or defer to any but a small set of federal provisions governing U.S. foreign policy and foreign assistance, or to the agencies entrusted to set this policy. This could create confusion or even conflict with existing laws and policies, which may differ, for example, across PEPFAR implementing agencies and departments.

Finally, we are deeply concerned that the proposed rule defines recipient and subrecipient as including foreign and international organizations, including agencies of the United Nations. There are likely unique and severe compliance and certification burdens on international recipients and subrecipients, including, but not limited to with regard to translation and conflict with local law and policy. The proposed rule may directly conflict with the laws and policies of other countries where global health programs operate, putting those implementing the global health programs in an untenable position. For example, some countries may require health care providers to provide necessary care in emergency situations or information or referral for all legal health services - requirements that would be in direct conflict with this proposed regulation. The application of these requirements to UN agencies, such as the World Health Organization (WHO) with whom the Department works on issues like measles and polio, may be wholly unworkable given their missions and structures and could completely jeopardize the ability of these agencies to partner with the Department.

V. The proposed rule would cause chaos and confusion as it is inconsistent with federal and state laws designed to prohibit discrimination and increase people's access to care.

The Department claims that it is creating a regulatory scheme that is "comparable to the regulatory schemes implementing other civil rights laws." First, the proposal does not warrant the broad enforcement authority delegated to the newly created division within OCR. The proposed rule and underlying statutes are not civil rights laws, and the proposed rule seeks to grant OCR the authority to take enforcement actions. Further, the proposed rule is not consistent with civil rights laws as it fails to provide covered entities due process protections afforded under Title VI of the Civil Rights Act (Title VI). Finally, the proposed rule would create confusion as to the interaction with existing federal and state laws. In particular, the proposed rule does not explain how it interacts with Title VII of the Civil Rights Act (Title VII) and it undermines states' ability to require care.

A. The proposed rule provides expanded enforcement authority to OCR, while at the same time lacking necessary due process protections, such as those provided by Title VI.

While the proposed rule purports to model itself after "the general principles . . . enshrined in Title VI of the Civil Rights Act (Title VI)," it includes draconian enforcement provisions that are wildly out of sync with those in Title VI. Title VI requires a four step process before a federal agency may deny or terminate a recipient's federal funds: 1) the recipient must be notified that it has been found not in compliance with the statutes and that it can voluntarily comply; 2) the recipient must be afforded an opportunity for a hearing on the record and the agency must make an express finding of failure to comply; 3) the Secretary or head of the agency must approve the decision to suspend or terminate funds; and 4) the Secretary of the agency must file a report with the House and Senate legislative committees with jurisdiction over the applicable programs that explains the grounds for the agency's decision, and the agency may not terminate funds

until 30 days after the report is filed. ⁵¹ The proposed rule affords no such procedural due process for those accused, investigated, or those found in violation of the underlying requirements. In particular, if the proposed rule were to become law as is, then a recipient could have its financial assistance withheld in whole or in part, have its case referred to DOJ, or face a range of other unspecified actions – all without the opportunity to explain or defend its actions.

Additionally, Title VI clearly requires that an agency must engage in a concerted effort to obtain voluntary compliance *before* it may begin enforcement proceedings against an entity found to be in violation. Specifically, federal law states that "effective enforcement of Title VI requires that agencies take prompt action to achieve voluntary compliance in all instances in which noncompliance is found." The proposed rule loosely states that "OCR will inform relevant parties and the matter will be resolved informally wherever possible," and notes that while attempting to obtain this informal compliance, OCR can simultaneous engage in a range of enforcement actions. This is not consistent with Title VI as it does not require the Department to attempt to achieve voluntary compliance from an entity *before* enforcement actions are taken.

Further, no guidance is given about the actions that would trigger each enforcement mechanism. For instance, would failure to meet the rule's requirement to post a notice result in millions of dollars of funds being withheld? Can failure to certify intention to comply with the rule result in a referral to DOJ? This proposed rule seems to allow OCR unlimited discretion to choose its enforcement mechanism -- including withdrawal of all federal funding and/or a referral to DOJ within any assurance that the Department's actions are proportionate to the violation. The Supreme Court has found government overreach when Congress authorized the Department to utilize federal financial assistance to control recipients' actions. Specifically, in National Federation of Independent Business v. Sebelius, the Supreme Court held that Congress exceeded its authority when it authorized the Department to withhold federal financial assistance from a state's Medicaid program if the state failed to expand the program's eligibility. The Court explained if the Department withheld all federal funding from a state for failing to comply with conditions attached to the funding, then States would not have a "genuine choice whether to accept the offer" for funding. Such financial inducement was found to be akin to a "gun to the head." Therefore, the Department does not have unbridled authority to withhold federal financial assistance, and the Department's actions must be proportionate to the violation.

The enforcement actions contemplated under the proposed rule resulting from a formal or informal complaint are all the more problematic given that the entity may ultimately not be found in violation of the proposed rule's requirements. Covered entities subject to a "compliance review or investigation" must inform any Department funding component of such review, investigation, or complaint, and for five years, the entity must disclose on applications for new or renewed federal financial assistance or Department funding that it has been the subject of a

^{51 42} U.S.C. § 2000d-1.

^{52 42} U.S.C. § 2000d-1.

^{53 28} C.F.R. § 42.411(a).

^{54 83} Fed. Reg. at 3930.

⁵⁵ National Federation of Independent Business v. Sebelius, 567 U.S. 519, 588 (2012).

⁵⁶ Id. at 584.

⁵⁷ Id. at 582.

review, investigation, or complaint. This disclosure must be done even if the compliance reviews or investigations are found frivolous or do not lead to a finding of violation. The Department can conduct compliance reviews "whether or not a formal complaint has been filed." The Department is also "explicitly authorized to investigate 'whistleblower' complaints, or complaints made on behalf of others, whether or not the particular complainant is a person or entity protected by" the refusal laws.

The Department's sweeping enforcement authority, coupled with the lack of specific guidance to covered entities about what the proposed rule would require, places an unwarranted burden upon covered entities. The proposed rule is not consistent with Title VI - in particular, the rule does not offer due process and affords the Department complete discretion to impose penalties disproportionate to actions or alleged actions.

B. The proposed rule upsets the balance for religious objection long enshrined in law by Title VII.

For more than 50 years, Title VII has provided protections against religious discrimination. In defining "discrimination" in a way that can be understood as both different from and far broader than it has long been understood, the Department has both exceeded its authority and caused confusion. In particular, the proposed rule does not clearly state that "discrimination" has the same limits as it does in the context of religious discrimination under Title VII and in particular that the "reasonable accommodation/undue hardship" framework for assessing if there has been "discrimination" also applies under the proposed rule. On its face, it is unclear if the proposed rule adopts Title VII's reasonable accommodation/undue hardship standard, or rather, creates a per se rule that allows employees' beliefs to take precedence over the needs and interests of health care providers and their patients under any circumstance.

Under Title VII and the case law interpreting it: [A]n employer, once on notice, [must] reasonably accommodate an employee whose sincerely held religious belief, practice or observance conflicts with a work requirement, unless providing the accommodation would create an undue hardship, ... [meaning] that the proposed accommodation in a particular case poses a "more than de minimis" cost or burden. Court cases that have addressed the issue of religious refusal have found that there are limits to what employers must do to accommodate refusals, and specifically that it is legal and appropriate for employers to prioritize maintaining patient access to care. Additionally, years of case law interpreting religious accommodation

^{58 83} Fed. Reg. at 3929-3930.

^{59 42} U.S.C. § 2000e(j).

⁵⁰ U.S. Equal Employment Opportunities Comm'n, Section 12: Religious Discrimination, Compliance Manual 46 (2008), available at http://eeoc.gov/policy/docs/religion.html [hereinafter EEOC Compliance Manual] (emphasis added).

⁵¹ See, e.g., Walden v. Centers for Disease Control & Prevention, 669 F.3d 1277 (11th Cir. 2012) (The plaintiff was employed as a counselor through CDC's employment assistance program, but refused to counsel people in same-sex relationships. After she was laid off, the court held that CDC "reasonably accommodated Ms. Walden when it encouraged her to obtain new employment with the company and offered her assistance in obtaining a new position"); Bruff v. N. Miss. Health Servs., 244 F.3d 495, 501 (5th Cir. 2001) (the accommodation requested by plaintiff—a counselor who refused to counsel individuals on certain topics that conflicted with her religious beliefs—constituted an undue hardship

provisions of Title VII has made clear that an accommodation should not place an unfair load on co-workers. Finally, case law has made it clear that "Title VII does not require an employer to reasonably accommodate an employee's religious beliefs if such accommodation would violate a federal statute." The proposed rule fails to give any consideration to this binding precedent or suggest why "discrimination" should be given any different meaning in the context of the refusal laws.

By requiring a balancing of interests between the employee, the employer, and the employer's clients, Title VII ensures that accommodating the religious beliefs of an employee in the health care field does not harm patients by denying them health care and/or health care information. Title VII also avoids placing employers in the untenable position of having employees on staff who will not fulfill core job functions. The Department has ignored that balancing, undermining its stated goal to "ensure knowledge, compliance, and enforcement of the Federal health care conscience and associated antidiscrimination laws." In so doing, the Department should bear in mind that a decision not to incorporate the Title VII reasonable accommodation/undue hardship balancing would lead to absurd and disastrous results. For example, a health care provider could be forced to hire employees who refuse to be involved in medical services that form the core of the medical care it offers. The Department should also bear in mind Executive Order 13563's injunction, which as the Department notes requires it to "avoid creating redundant, inconsistent, or overlapping requirements applicable to already highly-regulated industries and sectors."

The ability of health care employers to continue providing medically appropriate services and information would be significantly compromised if they are forced to operate under a rule which could be understood to compel them to hire, retain, and/or not transfer employees who refuse to provide medically necessary health services and information to patients -- or face a possible penalty of loss of all federal funding.

C. The proposed rule limits states' authority to increase health care access for their citizens.

This rule would undermine states' ability to protect and expand health care access. States have an important role to play when addressing the harm from denials of health care. State laws that require institutions to provide information, referrals, prescriptions, or care in the event of a life or health risk are vital safeguards for individuals who might be impacted by religious refusals. The expansion of the Weldon and Church Amendments through new definitions and a

because it would have required her co-workers to assume her counseling duties whenever she refused to do so, resulting in a disproportionate workload on co-workers); see also Haliye v. Celestica Corp., 717 F. Supp. 2d 873, 880 (D. Minn. 2010) ("when an employee has a religious objection to performing one or more of her job duties, the employer may have to offer very little in the way of an accommodation—perhaps nothing more than a limited opportunity to apply for another position within the organization") (citing Bruff).

⁶² See, e.g., Tagore v. United States, 735 F.3d 324, 330 (5th Cir. 2013) ("more than de minimis adjustments could require coworkers unfairly to perform extra work to accommodate the plaintiff"); Harrell v. Donahue, 638 F.3d 975, 980 (8th Cir. 2011) ("an accommodation creates an undue hardship if it causes more than a de minimis impact on co-workers").

⁶³ Yeager v. First Energy Generation Corp., 777 F.3d 362, 363 (6th Cir. 2015).

⁶⁴ 83 Fed. Reg. at 3887.

reinterpretation of existing law could render useless any existing or future state laws that protect patients and consumers.

The Department makes it clear that there are certain types of state laws that they seek to eliminate by reinterpreting the federal refusal laws. For example, the Department clearly wants to undermine state laws that require coverage of abortion. To do so, the Department not only reverses their position on the application of the Weldon amendment, but actually changes the existing (and statutory) definition of "health care entity" so as to include plan sponsors and third party administrators. This will mean more individuals are covered under the statute. The Department has previously rejected this interpretation noting "by its plain terms, the Weldon Amendment's protections extend only to health care entities and not individuals who are patients of, or institutions, or individuals that are insured by such entities."

The Department also highlights state laws that require crisis pregnancy centers to provide information or referrals, as well as state laws and previous lawsuits that seek to require the provision of health care by an institution when a patient's health or life is at risk. The Department clearly wishes to contort the federal refusal laws to address state laws that it finds objectionable. If Congress had wanted to prohibit federal, state, and local governments from ever requiring health care entities to provide, pay for, cover, or refer for abortions, it could easily have done so. The Department now reinterprets these laws to attempt to limit the reach of state laws that protect patients from harmful denials of health care, including laws that simply require referrals to another provider.

The proposed rule invites those who oppose access to reproductive health to make OCR complaints by allowing any individual to file a complaint, whether or not they are the subject of any potential violation. This may have a chilling effect on states' willingness to enforce their own laws. The uncertainty regarding whether enforcement of state laws is "discrimination," especially as to health care entities that refuse to provide medical services or insurance coverage for reasons other than moral or religious reasons, would inhibit states' ability to increase access and provide for the well-being of their citizens. The negative effects of such confusion and uncertainty in our public health care system would certainly fall disproportionately on the millions of people in this country who already experiences barriers to health care access and worse health outcomes, including but not limited to women, LGBTQ people, and people living with HIV.

VI. The proposed rule fails to properly account for the enormous costs it would impose on providers, patients, and the public.

The Department purports to have conducted an economic analysis for the proposed rule, as required by Executive Order 12866 as well as the Regulatory Flexibility Act, but that analysis is deficient in at least two respects.⁶⁶ First, and critically, the Department's analysis ignores entirely the cost to patients of reduced access to health care, fewer health care options, less

⁶⁵ Letter from Jocelyn Samuels, Director, Office for Civil Rights to Catherine Short, Life Legal Defense Foundation et. al. re: OCR Transaction Numbers: 14-193604, 15-193782, & 15-195665 (June 21, 2016), http://www.adfmedia.org/files/CDMHCInvestigationClosureLetter.pdf.

⁶⁶ That Act requires an analysis of a rule's effects on small businesses, including non-profits. The proposed rule's analysis at 83 Fed. Reg. 3918 is inadequate because as explained below it radically underestimates costs. And while the proposed rule notes that some entities are exempted from some requirements based on cost concerns, it fails to explain why those exemptions (which at any rate would not mitigate the costs described below) were so limited.

comprehensive medical information, impeded ability for patients to make their own health care choices, and interference with provider-patient relationships. Also contrary to Executive Order 12866, it fails to account for how these costs are distributed, e.g. whether they will fall disproportionately on women, rural residents, individuals with low incomes, people of color, LGBTQ people, and people living with HIV. It fails to account for the public health costs associated with reduced patient access to medical information, contraception, abortion, and other reproductive health care, or delays in accessing care due to refusals. Thus, it clearly fails multiple requirements under Executive Order 12866, including the requirement that the Department analyze "any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs."

Second, the Department's estimate of costs that the rule imposes on health care providers is far too low. Given the new burdensome notice and attestation policies, it is unrealistic to think that health care providers -- who as of 2015, employed more than 12 million employees -- would be able to adjust all of their policies, train all of their hiring managers, and ensure and document compliance with the proposed rules, for less than \$1000 the first year and less than \$900 in subsequent years. Moreover, the Department's cost analysis ignores entirely the enormous cost imposed on health care providers if they were required to employ people unwilling to fulfill job functions necessary to deliver care.

Therefore, the Department's estimate that the proposed rule would cost over \$812 million dollars within the first five years is inadequate. ⁶⁹ But even if it would *only* cost the amount estimated by the Department (which it would not), that sum could be far better used to *provide* health care to individuals and correct inequities in the health care system. While the Department claims the rule is required to "vindicate" the religious or moral conscience of health care providers, significant portions of the proposed rule have nothing to do with the Department's purported motivation. Rather, certain sections give license to HMOs, health insurance plans, or any other kind of health care organization to refuse to pay for, or provide coverage of necessary abortion services for any reason—even financial. These provisions do not protect anyone's conscience, they simply undercut providers' ability to deliver care and consumers' ability to obtain and pay for medical services. The limited resources of the Department and health care providers should be better spent.

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We strongly urge the Department to withdraw this rule. In 2011, the Department withdrew a

⁶⁷ The Department claims that the rule provides non-quantifiable benefits, such as more diverse and inclusive workforce, improved provider patient relationships; and equity, fairness, and non-discrimination. This proposed rule would in fact lead to the exact opposite of these intended benefits. While the Department claims to be protecting the psychological, emotional, and financial well-being of health care workers who refuse to provide care, the proposed rule does not mention the psychological, emotional, or financial harms to patients of well-being associated with being denied access to care.

⁶⁸ Kaiser Family Foundation, State Facts: Total Health Care Employment (May 2015), https://www.kff.org/other/state-indicator/total-health-care-employment/?currentTimeframe=0&sortModel=%7B%22colld%22:%22Location%22,%22sort%22:%22asc%22%7D.

⁶⁹ The economic analysis estimates the cost at \$312 million dollars in year one alone and over \$125 million annually in years two through five. And those estimates are based on "uncertain" assumptions that the costs would decrease after five years. 83 Fed. Reg. at 3902.

⁷⁰ 83 Fed. Reg. at 3925.

similar rule that was enacted in 2008 noting that the 2008 rule attempting to clarify existing laws had "instead led to greater confusion." This rule has the potential to cause even more confusion and, more egregiously, to reduce access to critical health care even more severely than the 2008 rule. It would jeopardize many people's health and lives. Planned Parenthood strongly urges the Department to follow the law and withdraw this dangerous rule.

Respectfully,

Dana Singiser

Washington, DC 20005

Vice President of Public Policy and Government Relations
Planned Parenthood Action Fund
Planned Parenthood Federation of America
1110 Vermont Avenue NW, Suite 300

Exhibit 155



March 27, 2018

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

RE: Conscience NPRM, RIN 0945-ZA03 "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority"

Dear Secretary Azar,

Power to Decide, the campaign to prevent unplanned pregnancy is a private, nonpartisan, non-profit organization that works to ensure all people—no matter who they are, where they live, or what their economic status might be-have the power to decide if, when, and under what circumstances to get pregnant. We believe that all young people should have the opportunity to pursue the future they want, realize their full possibility, and follow their intentions. Power to Decide provides objective, evidence-based information about sexual health and contraceptive options, and we work to guarantee equitable access to and information about the full range of contraceptive methods.

Power to Decide is committed to ensuring all individuals have access to the full range of birth control methods no matter who they are, where they live or what their economic status may be. That is why we strongly oppose the Department of Health and Human Services' (the "Department") Proposed Rule creating a new division within the Office of Civil Rights ("OCR")—the new "Conscience and Religious Freedom Division." 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 to which they object, the Proposed Rule would undermine critical HHS programs like the Title X Family Planning Program; interfere with the provider-patient relationship; and threaten the health and well-being of people across the country. By proposing this new 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. HHS's core mission is to enhance the health and well-being of all Americans. Enabling health care providers to refuse to provide health services and support based on their beliefs rather than the health needs of their patients runs counter to HHS' mission and violates a person's power to decide what health services and support is right for them. For these reasons Power to Decide calls on the Department and OCR to withdraw the Proposed Rule in its entirety.

The Proposed Rule Will Exacerbate Already Existing Inequities

More than 19 million women in need of publicly funded family planning live in contraceptive deserts, where they lack reasonable access to a publicly funded clinic in their county that offers the full range of contraceptive methods. I Deep in the heart of those deserts, more than 3 million women in need live in counties without a single public clinic that offers the full range of contraceptive methods.2 When women who face these barriers to access find themselves further disenfranchised by providers who refuse them both information about and access to the full range of birth control methods we only further exacerbate these contraceptive access gaps. These barriers already disproportionately impact low-income women and women of color.3 This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals of care such as birth control. 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.4 What happens when these women request immediate post-partum long acting contraception, a clinical best practice for women seeking to space or prevent future pregnancies?5 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 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. 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. 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

³ 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.

S American College of Obstetricians and Gynecologists, Committee Opinion, Number 670, August 2016, https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Immediate-Postpartum-Long-Acting-Reversible-Contraception

Power to Decide: https://powertodecide.org/what-we-do/access/access-birth-control

² Ibid.

⁴ 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.

⁶ 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.

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

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. When it comes to Title X, the Proposed Rule would not only sanction conduct at odds with pre-existing requirements, but could also undermine the program's fundamental objectives. Every year, more than 4 million low-income people, including under-insured, and uninsured individuals, rely on Title X clinics to access services they otherwise might not be able to afford.

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. 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 on the full range of contraceptive methods. It is nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions.

The Proposed Rule Will Undermine the Provider-Patient Relationship

Birth control is basic healthcare. In fact, 85 percent of Americans agree it's essential.8 Yet the Proposed Rule will further interfere with providers' ability to provide care according to medical standards, and ignore the reality that many providers want to provide comprehensive care. It would exacerbate gaps in accessing needed care by emboldening health care entities and institutions to bind the hands of providers and attempt to limit the types of care they can provide. In doing so, 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 patientcentered decision-making.9 Informed consent requires providers to 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, such as the full range of birth control methods. 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 choose the best option for her.

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 contraception and sexual health. Information, counseling, referral and provision of contraceptive services are part of the standard of care for sexually active

⁸ Power to Decide: https://powertodecide.org/what-we-do/information/resource-library/survey-says-thanks-birth-control-november-2017

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 Ibid.

women of reproductive age. Allowing providers to flout established medical guidelines and deny medically accurate, 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 contraception. No health care professional should face discrimination from their employer because they treated or provided information to a patient seeking contraception.

The Department is Abdicating its Responsibility to Protect the Civil Rights of Patients

The Proposed Rule exceeds OCR's authority by abandoning OCR's mission to address health disparities and discrimination that harms patients. I 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. 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. 12 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. Nevertheless, there is still work to be done, and the Proposed Rule seeks to divert limited resources away from ending discrimination. For example, rates of unplanned pregnancy remain higher for women of color.13 And Black women, for are three to four times more likely than white women to die during or after childbirth.14 Further, the disparity in maternal mortality is growing rather than decreasing. 15 Helping all women to plan and space pregnancies can help to ensure healthier pregnancies and babies. But if resources are diverted from OCR's mission to reduce disparities, we're likely to see these problems continue and even get worse. OCR must work to address these disparities, yet the Proposed Rule seeks to prioritize the expansion of existing religious refusal laws

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.").
¹² 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.

http://www.cdc.gov/teenpregnancy/prevent-teen-pregnancy/social-determinants-disparitiesteen-pregnancy.htm and http://www.nejm.org/doi/full/10.1056/NEJMsa1506575

¹⁴ 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.

¹⁵ Ibid

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.

Conclusion

The Proposed Rule will allow religious beliefs to dictate patient care, thereby expanding already harmful refusals of care. It will lead to further gaps in information about and access to contraception. The Proposed Rule is discriminatory, ignores congressional intent, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons, Power to Decide calls on the Department to withdraw the Proposed Rule in its entirety. If you have questions about these comments, please contact Rachel Fey, Director of Public Policy, at (202) 478-8529 or regovernodecide.org. Thank you.

Sincerely,

Ginny Ehrlich Chief Executive

Chief Executive Officer

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Exhibit 156

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 PROMO Fund in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26. PROMO Fund is Missouri's statewide LGBT equality organization. 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 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.

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

LGBTQ people, women, and other vulnerable groups around the country already face enormous barriers to getting the care they need. Accessing quality, culturally competent care and overcoming outright discrimination is even a greater challenge for those living in areas with

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.

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.² 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.³

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. 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 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.

² 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.

³ Sandy E. James et al., The Report of the U.S. Transgender Survey 99 (2016), www.ustranssurvey.org/report

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 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.⁵

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.⁶ 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 LGBTQ patients' access 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

⁵ https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/

 $^{^6\} https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/$

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 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

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.

Exhibit 157

March 27, 2018

U.S. Department of Health and Human Services Office for Civil Rights RIN 0945-ZA03 Docket HHS-OCR-2018-0002

Public Health Law Watchⁱ (PHLW) and the Public Health Law Centerⁱⁱ appreciate the opportunity to make comments on the proposed Department of Health and Human Services (HHS) revisions to 45 CFR Part 88, "Protecting Statutory Conscience Rights; Delegations of Authority." PHLW is a project of the George Consortium, a nationwide network of public health law scholars, experts, and practitioners. The Public Health Law Center is nonprofit affiliate of the Mitchell Hamline School of Law, iii and a leading center of expertise in the use of law to prevent chronic disease. The Center's team of lawyers, law students, policy analysts and graduate students helps health leaders nationwide create communities where everyone can be healthy, with a focus on promoting healthy eating, encouraging physical activity, reducing the use of tobacco products, supporting health equity, and addressing cross-cutting legal issues that affect the nation's health. Based on our combined expertise in public health law and policy, we offer the following comments on five main issues: (1) the lack of evidence that these rule revisions are necessary; (2) the absence of consideration for patients who face refusal of care; (3) the potentially dangerous expansion of existing definitions around "conscience protections;" (4) the potential harm these rules will cause for the LGBTO population; and (5) the detriment these proposals would cause to reproductive health and rights.

First, we question the need for these regulatory revisions. As laid out in the Supplementary Information accompanying the proposed regulations, federal law already contains a plethora of provisions that protect individuals who invoke a religious objection to providing certain types of care, including abortion and assisted suicide. Yet, that information contained scant evidence that a pervasive discriminatory environment towards individuals and institutions who invoke these protections actually exists. Rather, while the evidence provided describes an uptick in "conscience" complaints since the election of President Trump in late 2016, a total of only 44 complaints have been made since 2008. That represents less than 0.2% of the estimated 25,000 complaints^{iv} that the HHS Office of Civil Rights (OCR) receives every year. Most of the remaining claimed support in the accompanying information is based solely on anecdotal commentary rather quantifiable data. Expanding these existing protections also risks directly conflicting with numerous professional standards, including the American Medical Association acknowledgement that conscience protections are not unlimited and that physicians "are expected to provide care in emergencies, honor patients' informed decisions to refuse lifesustaining treatment, and respect basic civil liberties and not discriminate against individuals in deciding whether to enter into a professional relationship with a new patient." The current version of 45 CFR Part 88 is fully adequate to properly address existing and potential complaints about conscience protection violations. HHS can also fully institute its stated goals of ensuring

"knowledge, compliance, and enforcement" of existing conscience protections via administrative means that do not require revising and expanding the current regulations.

Second, we are concerned that the regulations contain no protections for patients who face denial of care when health care providers and entities invoke these "conscience protections." By leaving patient consideration out, these regulations not only devalue those patients as individuals, but also potentially put their lives at risk. We have no way to know exactly how many times such "conscience protections" have been invoked or the extent of harm caused, but we do know that providers have, vi for example, refused to inseminate a woman because of her sexual orientation, refused to help a profusely bleeding pregnant woman because the fetus would not survive the procedure necessary to save her life, and refused to transport a pregnant woman by ambulance to a clinic that provided abortions. As the American Academy of Family Physicians has emphasized, vii "There is a distinct difference between declining to participate in a procedure versus denying access to care to an individual patient. The former is a protected right, the latter is an unacceptable shirking of our basic responsibility to care for our patients and contrary to the key underpinnings of the Code of Medical Ethics." Even if OCR prioritizes "conscience protections" of the health care providers and entities, the regulations also need to adequately protect the health and lives of the patients affected when such conscience protections are invoked. Further, the regulations are focused solely on health care providers and entities that refuse to provide certain types of care, yet fail to protect health care workersviii who view providing services like abortion as moral imperatives and yet face constant barriers and little consideration for their views.

Third, though the regulations are intended to enforce the "conscience protection" provisions in federal law, several of the proposed definitions in section 88.2 are so wide as to significantly expand existing law. We are particularly alarmed about the broad proposed definition of the term "referral or refer for." While some of the existing provisions include a right for health care workers not to provide a "referral" for a service they have a religious or moral objection to, this definition of referral includes "the provision of any information...by any method... that could provide any assistance in a person obtaining....a particular health care service, activity, or procedure[.]" (emphasis added). This expansive definition conceivably allows a health care provider to not only refuse to provide a direct referral for care, but also to present the health care services he or she is willing to perform as the only medical options available to the patient. This could deprive a patient of the ability to make a decision with informed consent and leave them unaware that they can seek alternative and appropriate care from another provider. Again, these regulations provide no recourse to a patient harmed by this situation; rather, the regulations consider only the provider.

Compounding the concern about the broad definition of "refer," the terms "workforce" and "assist" also have definitions that include activities, omissions, and persons far beyond the scope of those already protected under federal law. "Workforce" includes not only health care entity employees and contractors but also includes unpaid volunteers. "Assist in the performance" means "to participate in any program or activity with an articulable connection to a…"

procedure, activity, or program. This explicitly includes, but is not limited to, "counseling, referral, training, and other arrangements...." These exceptionally broad definitions expand the scope of those who can invoke "conscience protections" beyond those originally envisioned in many of the federal provisions at issue. By allowing such a broad population of individuals to invoke "conscience protections" in such a wide range of situations, the care of patients is further diminished. This particularly puts at risk the health of patients in areas with few existing resources; low-income U.S. residents are already more likely to live in areas with <u>fewer physicians and fewer hospitals</u> and to have <u>significantly poorer health</u> overall. Residents in rural and farm communities also face <u>similar barriers to access</u> and <u>health disparities</u>. The regulations should ensure adherence to the federal laws so that they apply narrowly and therefore minimize the impact on patient care.

Fourth, we are deeply concerned that these regulations particularly imperil care of the LGBTO population. Health care already has a long history of anti-LGBTQ discrimination, xiii such as classification of homosexuality as a psychiatric disorder and "treatment" that included electroshocks and "conversion" therapy. Partially as a result of this harm, LGBTQ populations have <u>numerous health disparities</u>, xiv including higher rates of HIV, suicidal ideation and attempts, and violence victimization. They face frequent discrimination in health care contexts and these regulations would only enhance that discrimination by allowing a health care worker to raise a "moral objection" to, for example, homosexuality in general or to same-sex marriage. The objection could conceivably even be invoked to refuse treatment to children who have same-sex parents. Within the LGBTQ community, the transgender population is particularly at risk under these regulations. Absolutely no evidence exists that health care providers are being forced, for example, "to perform gender-affirming surgeries against their will...but what is happening every day, is transgender patients are being denied every kind of medical care you can think of."xv A full 22% of transgender people in America already avoid doctors and medical care due to fear of discrimination^{xvi} and 31% have no access to regular health care at all. Those numbers are already alarming in the context of public health; these regulations risk leading to even wider denial of care, which would only increase that crisis.

Finally, the health care services explicitly targeted most often by these regulations (and by existing federal law) are those involving reproduction. In fact, the regulations often seem to be directly intended to "undermine existing legal and ethical protections for patients' access to sexual and reproductive health information and services, and other critical care." Many of the existing federal provisions explicitly allow providers and entities to invoke conscience protections in relation to directly providing abortions. But conscience protections have also been invoked to refuse access to emergency contraception for rape victims viii and to refuse to perform medically necessary procedures to save a woman's life. The United States already has the worst rate of maternal deaths in the developed world, and this issue is further compounded by significant disparities: black mothers die at a rate 3-4 times more often than white mothers. To allow health care providers to invoke conscience protections to lifesaving reproductive health care even as a woman dies will escalate already unacceptably high rates. Further, these regulations also target – according to the supplementary information provided - laws requiring

insurance coverage of reproductive health services, public notice requirements for "crisis pregnancy centers," and attempts to require hospitals and healthcare professionals to provide abortion care when a woman's life is endangered. **XXXIII* These provisions go well beyond what the federal law currently covers, dangerously encroaching not only on a constitutionally protected right to reproductive health care but also on the very lives of women as patients.

While protecting religious convictions has indeed been a long-respected – though never unlimited - right in the United States, HHS's proposed regulations prioritize expansion provider protections without adequate consideration for how they endanger the health and lives of already vulnerable patient populations. We urge HHS **not** to adopt these proposed regulations.

Sincerely,

PHLW and PHLC

Public Health Law Watch A project of the George Consortium Publichealthlawwatch.org

Public Health Law Center Publichealthlawcenter.org

ProtectingStatutoryConscienceRights-032018.pdf

i https://www.publichealthlawwatch.org/

ii http://www.publichealthlawcenter.org/

iii https://mitchellhamline.edu/

 $^{^{}iv}\ https://www.npr.org/sections/health-shots/2018/03/20/591833000/civil-rights-chief-at-hhs-defends-the-right-to-refuse-care-on-religious-grounds$

^v https://www.ama-assn.org/delivering-care/physician-exercise-conscience

vi http://via.library.depaul.edu/cgi/viewcontent.cgi?article=1199&context=law-review

vii https://www.aafp.org/dam/AAFP/documents/advocacy/prevention/women/LT-HHS-

viii https://www.nytimes.com/2018/01/26/opinion/protecting-conscientious-providers-of-health-care.html

ix https://newsinteractive.post-gazette.com/longform/stories/poorhealth/1/

x https://www.irp.wisc.edu/publications/factsheets/pdfs/PoorInPoorHealth.pdf

xi https://www.ruralhealthinfo.org/topics/healthcare-access#services

xii https://www.ruralhealthinfo.org/topics/rural-health-disparities

xiii http://www.lgbthealtheducation.org/wp-content/uploads/LGBTHealthDisparitiesMar2016.pdf

xiv https://www.apa.org/advocacy/health-disparities/lgbt-health.pdf

xv https://www.npr.org/sections/health-shots/2018/03/20/591833000/civil-rights-chief-at-hhs-defends-the-right-to-refuse-care-on-religious-grounds

xvi https://www.npr.org/documents/2017/nov/npr-discrimination-lgbtq-final.pdf

xvii https://www.guttmacher.org/article/2018/03/how-administrations-proposed-conscience-rule-undermines-reproductive-health-and

xviii https://www.teenvogue.com/story/hospitals-didnt-give-rape-victims-emergency-contraception

 $^{^{}xix}$ https://www.theguardian.com/us-news/2016/feb/18/michigan-catholic-hospital-women-miscarriage-abortion-mercy-health-partners

xxx https://www.npr.org/2017/05/12/528098789/u-s-has-the-worst-rate-of-maternal-deaths-in-the-developed-world xxxi https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irvings-story-

explains-why xxii https://www.ahcmedia.com/articles/142319-proposed-conscience-rule-could-interfere-with-patient-care

Exhibit 158

THE PUBLIC RIGHTS/PRIVATE CONSCIENCE PROJECT COLUMBIA LAW SCHOOL 435 WEST 116™ STREET NEW YORK, NY 10027

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March 27, 2018

VIA ELECTRONIC SUBMISSION
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

To Whom It May Concern:

We submit the following comments on the Proposed Rule "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" ("the rule"). The Public Rights/Private Conscience Project (PRPCP) brings legal, policy, and academic expertise to bear on the multiple contexts in which fundamental religious liberty rights are at stake and can be in tension with or undermine other fundamental rights to equality and liberty. As such, we write to condemn the rule not only because it fails to ensure that patients have access to necessary health care, but also because, by preferring particular religious beliefs over others, it violates rather than protects religious liberty.

Under the proposed rule, health care providers with moral or religious objections to abortion, sterilization, and certain other services would never be obligated to provide such care, regardless of the policies of the institution where they work, the religious or moral beliefs of their patient, or the standards of care of the medical profession generally. In contrast, medical professionals whose religious or moral beliefs require them to provide patients with the full range of reproductive health services may be prohibited by their employer from acting on this belief. For example, the rule would permit a Catholic hospital to forbid doctors from providing abortion care within the facility, even if such prohibition would violate a doctor's conscience. Such imbalanced regulations belie the agency's purported interest in protecting "religious liberty" generally, revealing its actual aim to be in protecting *only* religious adherents who oppose comprehensive reproductive health care. By giving a preference to certain religious beliefs over others, the regulation clearly conflicts with religious liberty law and policy that requires, at a minimum, even-handed accommodation of religious beliefs.

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For an in-depth discussion of the conscience rights of pro-choice medical providers and asymmetrical religious refusal laws, see Elizabeth Sepper, Taking Conscience Seriously, 98 Virginia L. Rev. 1501 (2012).

A. People of Faith Hold a Wide Range of Views on Sexual and Reproductive Health Care

PRPCP endorses the comments submitted by numerous organizations, including the National Women's Law Center, demonstrating that the proposed rule poses significant harms to patients by failing to protect their access to necessary medical care, particularly during medical emergencies. However, we are also concerned that the proposed rule fails to protect the very right it claims to defend—freedom of conscience. The proposed rule provides blatantly lopsided, and therefore legally suspect, right to religious exemptions. Communities and people of faith hold a wide spectrum of views regarding the health services implicated by the rule, including abortion, sterilization, contraception, LGBTQ+ health care, and end of life care. By rigorously shielding those who seek to deny health care, regardless of the impact such refusals have on others, while simultaneously failing to ensure any religious or moral right to provide care, the proposed rule in fact advances not religious freedom but only particular religious views. The First Amendment clearly prohibits government agencies from favoring particular religious views over others.

As acknowledged by the Supreme Court in Roe v. Wade, religious denominations, communities, and individuals hold a wide range of views on both the morality and the legality of abortion.² So to do religious practitioners vary considerably in their religious and moral opinions regarding sterilization, contraception, and LGBTQ+ health care. A number of mainstream faiths, including the Presbyterian Church,³ Reform⁴ and Conservative⁵ Judaism, the United Church of Christ,⁶ and

² Roe v. Wade, 410 U.S. 113, 160-61 (1973) ("It should be sufficient to note briefly the wide divergence of thinking on this most sensitive and difficult question. There has always been strong support for the view that life does not begin until live birth. This was the belief of the Stoics. It appears to be the predominant, though not the unanimous, attitude of the Jewish faith."). See also id. at 116 (acknowledging "the vigorous opposing views, even among physicians, and of the deep and seemingly absolute convictions that the subject inspires. One's philosophy, one's experiences, one's exposure to the raw edges of human existence, one's religious training, one's attitudes toward life and family and their values, and the moral standards one establishes and seeks to observe, are all likely to influence and to color one's thinking and conclusions about abortion.").

³ PRESBYTERIAN CHURCH (U.S.A.) OFFICE OF THE GENERAL ASSEMBLY, Report of the Special Committee on Problem Pregnancies and Abortion 11 (1992), http://www.pcusa.org/site_media/media/uploads/oga/pdf/problempregnancies.pdf ("We do not wish to see laws enacted that would attach criminal penalties to those who seek abortions or to appropriately qualified and licensed persons who perform abortions in medically approved facilities")

⁴ CENTRAL CONFERENCE OF AMERICAN RABBIS, Resolution Adopted by the CCAR On Abortion and the Hyde Amendment, (1984) https://www.ccarnet.org/ccar-resolutions/abortion-1984/ (stating that "the Central Conference of American Rabbis has gone on record in 1967, 1975, and 1980 in affirming the right of a woman or individual family to terminate a pregnancy."); UNION FOR REFORM JUDAISM, Reproductive Rights (last visited Mar. 13, 2018) https://urj.org/what-we-believe/resolutions/reproductive-rights.

THE RABBINICAL ASSEMBLY, Resolution on Reproductive Freedom, (June 15, 2011), https://www.rabbinicalassembly.org/resolution-reproductive-freedom ("the Rabbinical Assembly urges its members to support full access for all women to the entire spectrum of reproductive healthcare, and to oppose all efforts by federal, state, local or private entities or individuals to limit such access.").

⁶ UNITED CHURCH OF CHRIST, General Synod Statements and Resolutions Regarding Freedom of Choice (last visited Mar. 13, 2018), http://d3n8a8pro7vhmx.cloudfront.net/unitedchurchofchrist/legacy_url/2038/GS-Resolutions-Freedon-of-Choice.pdf?1418425637 ("for 20 years, Synods of the United Church of Christ have affirmed a woman's right to choose with respect to abortion.").

the Unitarian Universalist Association, ⁷ support a legal right to abortion in most or all circumstances. Other faiths, such Buddhism, Orthodox Judaism, and the National Baptist Convention, take no official stance on abortion rights.⁸

A number of denominations take more complex positions. For example, the Evangelical Lutheran Church in America (ELCA) opposes "legislation that would outlaw abortion in all circumstances" or "prevent access to information about all options available to women faced with unintended pregnancies." At the same time, it supports "legislation that prohibits abortions that are performed after the fetus is determined to be viable, except when the mother's life is threatened or when lethal abnormalities indicate the prospective newborn will die very soon." ELCA "neither supports nor opposes" legislation that falls between these two categories. Statements of the United Methodist Church have expressed a "reluctance to affirm absolute perspectives either supporting or opposing abortion which do not account for the individual woman's sacred worth and agency." While the Episcopal Church has stated that abortion should be "used only in extreme situations," it has opposed certain legal efforts to restrict abortion rights, such as parental notification laws. While these churches have expressed some uncertainty over the issue of abortion, all have openly supported contraceptive use. 14

Moreover, several religious denominations hold that the right to reproductive health care is an essential aspect of religious freedom. In a resolution adopted in 1984, the Central Conference of American Rabbis, an association of Reform rabbis, stated that "freedom of choice in the issue of abortion is directly related to the First Amendment's guarantee of religious freedom." In a 2011

UNITARIAN UNIVERSALIST ASSOCIATION, Right to Choose 1987 General Resolution (1987) ("the 1987 General Assembly of the Unitarian Universalist Association reaffirms its historic position, supporting the right to choose contraception and abortion as legitimate aspects of the right to privacy.").

⁸ David Masci, Where Major Religious Groups Stand on Abortion, PEW RESEARCH CENTER (June 21, 2016), http://www.pewresearch.org/fact-tank/2016/06/21/where-major-religious-groups-stand-on-abortion/.

EVANGELICAL LUTHERAN CHURCH IN AMERICA, A Social Statement on Abortion (1991), http://download.elca.org/ELCA%20Resource%20Repository/AbortionSS.pdf?_ga=2,200020200,771729105,152089 4009-874109350,1520894009.

¹⁰ Id.

^{11 14}

¹² UNITED METHODIST CHURCH, The United Methodist Church and the complex topic of abortion (Nov. 3, 2015), http://www.umc.org/what-we-believe/the-united-methodist-church-and-the-complex-topic-of-abortion.

¹⁵ The Episcopal Church, Oppose Certain Legislation Requiring Parental Consent for Termination of Pregnancy, (1991) https://episcopalarchives.org/cgi-bin/acts/acts_resolution.pl?resolution=1991-C037; see also https://www.episcopalchurch.org/library/article/religious-leaders-support-maintaining-status-quo-abortion-health-care-reform.

¹⁴ EVANGELICAL LUTHERAN CHURCH IN AMERICA, A Social Statement on Abortion, supra note 9 (We recognize the need for contraceptives to be available, for voluntary sterilization to be considered, and for research and development of new forms of contraception); UNITED METHODIST CHURCH, Social Principles: The Nurturing Community (last visited Mar. 13, 2018) http://www.umc.org/what-we-believe/the-nurturing-community ("The Church shall encourage ministries to reduce unintended pregnancies such as...advocacy in regard to contraception"); THE EPISCOPAL CHURCH, Episcopal Church Official Voices Support for Abortion-Prevention Bill (July 24, 2009) https://www.episcopalchurch.org/library/article/episcopal-church-official-voices-support-abortion-prevention-bill (statement supporting legislation that "restores and expands family planning programs for low-income women.").

¹⁵ CENTRAL CONFERENCE OF AMERICAN RABBIS, Resolution Adopted by the CCAR On Abortion and the Hyde Amendment, supra note 4.

Resolution on Reproductive Freedom, The Rabbinical Assembly, an international association of Conservative rabbis, stated that to "deny a woman and her family full access to the complete spectrum of reproductive healthcare, including contraception, abortion-inducing devices, and abortions, among others, on religious grounds is to deprive these women of their Constitutional right to religious freedom." ¹⁶

In 1971, the Eighth General Synod of the United Church of Christ issued a resolution stating that "The theological...views on when human life begins are so numerous and varied that that one particular view should not be forced on society through its legal system." The sixteenth General Synod in 1987 further stated that "women and men must make decisions about unplanned or unwanted pregnancies that involve their physical, emotional, and spiritual wellbeing." The Unitarian Universalist Association, in a 1987 general resolution, found that any legislative attempt to restrict abortion access is "an infringement of the principle of separation of church and state in that it tries to enact private morality into public law." Acknowledging the spectrum of views on abortion held by its members, the ELCA has stated that "[f]or some, the question of pregnancy and abortion is not a matter for governmental interference, but a matter of religious liberty and freedom of conscience protected by the First Amendment."

The Presbyterian Church has issued several lengthy documents on abortion rights over the past forty years, acknowledging that its membership holds varying views on this issue. In 1983 document "Covenant and Creation: Theological Reflections on Contraception and Abortion," the Church affirmed "Christian freedom and responsibility (Christian conscience) in the process of deciding whether to abort," and supported "national policy that embodies that conviction, carefully guarding the separation of church and state with respect for the freedom of the individual's conscience." ²¹ A subsequent report on abortion affirmed "the ability and responsibility of women, guided by the Scriptures and the Holy Spirit, in the context of their communities of faith, to make good moral choices in regard to problem pregnancies." ²² Similarly, the United Methodist Church has stated that "Governmental laws and regulations do not provide all the guidance required by the informed Christian conscience. Therefore, a decision concerning abortion should be made only after thoughtful and prayerful consideration

¹⁹ Unitarian Universalist Association, *1987 General Resolution* (1987),

https://www.uua.org/action/statements/right-choose.

¹⁶ THE RABBINICAL ASSEMBLY, Resolution on Reproductive Freedom, supra note 5.

¹⁷ UNITED CHURCH OF CHRIST, General Synod Statements and Resolutions Regarding Freedom of Choice, supra note 6.

¹⁸ *Id*.

²⁰ EVANGELICAL LUTHERAN CHURCH IN AMERICA, A Social Statement on Abortion, supra note 9.

²¹ THE 195TH GENERAL ASSEMBLY, The Covenant of Life and The Caring Community & Covenant and Creation: Theological Reflections on Contraception and Abortion, 104-05 (1983) available at

https://www.presbyterianmission.org/wp-content/uploads/8-covenant-of-life-and-covenant-and-creation-1993.pdf.

²² Office of the General Assembly of the Presbyterian Church (U.S.A.), Report of the Special Committee on Problem Pregnancies and Abortion, 10-11 (1992) available at

http://www.pcusa.org/site_media/media/uploads/oga/pdf/problem-pregnancies.pdf. The denomination's website similarly states that "[h]umans are empowered by the spirit prayerfully to make significant moral choices, including the choice to continue or end a pregnancy." PRESBYTERIAN CHURCH (U.S.A.), *Abortion Issues* (last visited Mar. 23, 2018), https://www.presbyterianmission.org/what-we-believe/social-issues/abortion-issues/.

by the parties involved, with medical, family, pastoral, and other appropriate counsel." The Episcopal Church in 1994 expressed its "deep conviction that any proposed legislation on the part of national or state governments regarding abortions must take special care to see that the individual conscience is respected, and that the responsibility of individuals to reach informed decisions in this matter is acknowledged and honored." ²⁴

The views about abortion held by smaller religious organizations and individuals are even more varied. Many individual houses of worship or faith leaders believe the provision of reproductive health care is a moral good. For example, clergy members including a Baptist pastor, Hindu priest, and Jewish rabbi have participated in ceremonies to bless abortion clinics. ²⁵ Faith organizations including Catholics for Choice, Presbyterians Affirming Reproductive Options, Religious Coalition for Reproductive Choice, the Religious Institute, and National Council of Jewish Women advocate for comprehensive access to contraception and abortion. Before *Roe v. Wade* legalized abortion across the country in 1973, the Clergy Consultation Service, a network made up of an estimated 2,000 faith leaders nationwide, assisted hundreds of thousands of people access abortion care. ²⁶ According to recent data from the Pew Research Center, 57% of U.S. adults say that abortion should be legal; this includes many people of faith including 83% of Jews, 82% of Buddhists, 79% of Episcopalians, 68% of Hindus, 65% of Presbyterians, 65% of Evangelical Lutherans, and 55% of Muslims. ²⁷ Many members of religious denominations that oppose abortion nevertheless support the right to abortion access, including nearly half (48%) of Catholics, nearly a third (30%) of Southern Baptists, and over a quarter (27%) of Mormons. ²⁸

Perhaps most importantly for the purpose of this rule, some medical providers' religious faith and moral convictions motivate them not only to support the right to abortion, but to actively provide their patients with comprehensive reproductive health care. In his recent book *Life's Work: A Moral Argument for Choice*, abortion provider Dr. Willie Parker detailed his personal and spiritual journey from refusing to provide abortions to becoming a dedicated abortion provider and advocate. He writes of his moment of conversion on this issue, inspired by the biblical story of the Good Samaritan:

"It was like a punch, all at once, in my spiritual gut. The Scripture came alive and it spoke to me. For the Samaritan, the person in need was the fallen traveler. For me, it was a pregnant woman. The earth spun, and with it, this question turned on its head. It

28 Id.

²³ UNITED METHODIST CHURCH, Social Principles: The Nurturing Community (last visited Mar. 23, 2018), http://www.umc.org/what-we-believe/the-nurturing-community#abortion.

²⁴ THE ARCHIVES OF THE EPISCOPAL CHURCH, Reaffirm General Convention Statement on Childbirth and Abortion (1994), https://episcopalarchives.org/cgi-bin/acts/acts/resolution.pl?resolution=1994-A054.

²⁵ Julic Zauzmer, Clergy Gather to Bless One of the Only U.S. Clinics Performing Late-Term Abortions, THE WASHINGTON POST (Jan. 29, 2018), https://www.washingtonpost.com/news/acts-of-faith/wp/2018/01/29/clergy-gather-to-bless-an-abortion-clinic-which-provides-rare-late-term-abortions-in-bethesda/?utm_term=.760670a044d7.
²⁶ JOSHUA D. WOLFF, MINISTERS OF A HIGHER LAW: THE STORY OF THE CLERGY CONSULTATION SERVICE ON

ABORTION 110 (1998) available at http://classic.judson.org/images/Ministers_of_a_Higher_Law_Chapter_4.pdf.

David Masci, American Religious Groups Vary Widely in Their Views of Abortion, PEW RESEARCH CENTER (Jan. 22, 1018), http://www.pewresearch.org/fact-tank/2018/01/22/american-religious-groups-vary-widely-in-their-views-of-abortion/.

became not: Is it right for me, as a Christian, to perform abortions? But rather: Is it right for me, as a Christian, to refuse them? "29

Nor is Dr. Parker the only abortion provider to speak publicly about how his religious faith motivates his medical practice. Dr. George Tiller, who was murdered by an anti-abortion activist while serving as an usher in his Lutheran Church, referred to his work providing abortion care as a "ministry." Two members of Dr. Tiller's staff echoed this view, stating respectively, "I felt I was doing the Lord's work," and "God put me here to do this work." Dr. LeRory Carhart, an abortion provider and observant Methodist, stated in an interview, "I think what I'm doing is because of God, not in spite of God." Dr. Sara Imershein has described providing abortion care as a "mitzvah" and said that "No one should be able to step in the way of what I consider to be my moral obligation." One article on a Jewish website stated that Imershein and four other Jewish abortion providers contacted by the writer all "described the resonance between their Judaism... and their decision to provide abortion care." Dr. Curtis Boyd, a Unitarian, first became an abortion provider when he was asked by a minister and member of the Clergy Consultation Service to perform the procedure illegally prior to *Roe v Wade*. Dr. Boyd explained, "Finally, my work had the larger meaning Γ'd sought. My religious ideals became immediate and personal."

²⁹ DR. WILLIE PARKER, LIFE'S WORK: A MORAL ARGUMENT FOR CHOICE 36 (2017).

³⁰ Revolution Interview with Dr. Susan Robinson: "Chasing the Abortion", REVOLUTION NEWSPAPER (May 16, 2014), http://revcom.us/movement-for-revolution/stop-patriarchy/a/335/chasing-the-abortion-interview-with-dr-susan-robinson-en.html ("What I'd like people to know about Dr. Tiller was that he believed intensely that he was making the world better one woman at a time, and that he regarded his practice of medicine as a ministry to women. So he had a very deep conviction that this was not only the right thing to do, but a life-saving thing to do."). See also, Carol Joffe, Working with Dr. Tiller: His Staff Recalls a Tradition of Compassionate Care at Women's Health Care Services of Wichita, REWIRE (Aug. 15, 2011), https://rewire.news/article/2011/08/15/working-tiller-staff-recollections-women-health-care-services-wichita/ ("As noted earlier, Dr. Tiller was a highly spiritual person, and he periodically referred to the clinic's work as a 'ministry.'").

³¹ Joffe, supra note 30.

Tiffany Arnold, An Interview with Dr. LeRoy Carhart, GERMANTOWN PATCH (Aug. 16, 2011), https://patch.com/maryland/germantown/an-interview-with-dr-leroy-carhart. In an interview, Dr. Carhart explained his religious views on abortion as consistent with his overall obligations as a health care provider, stating "I think it's no different than with someone who has had a heart attack: If we were to save their life are we going against God's will because if medicine didn't intervene, the patient was going to die? Is that what God wants, for a person to die?...It's the same thing with a flawed pregnancy. People wouldn't think God created a flawed pregnancy to punish or test the parents. I think that it's just like any other medical condition, something that happens. God has provided us with a way to educate people to help take care of it. I think that because a certain, small group of people don't believe in it doesn't mean that it's not the right thing to do." Id. In another article, Dr. Carhart noted that while "he believes in God 'very strongly," he stopped going to church "when his pastor told him he was risking his safety by predictably appearing in the pews every week." Zauzmer, supra note 25.

³³ A Hebrew word meaning a "commandment," or, colloquially, a good deed.

³⁴ Steph Herold, What It's Like for Jewish Moms Who Are Abortion Providers, KVELLER (May 15, 2017), https://www.kveller.com/what-its-like-for-jewish-moms-who-are-abortion-providers/.

³⁶ Dr. Curtis Boyd, How the First Legal Abortion Clinic in Texas Came to Be, THE HUFFINGTON POST (Nov. 3, 2016), https://www.huffingtonpost.com/entry/how-the-first-legal-abortion-clinic-in-texas-came-to-us-581a08dde4b0bd7151a2535c.

Many abortion providers have described their work as a moral duty. For example, Dr. Leah Torres has called it her "moral and ethical obligation" to provide abortion care. ³⁷ Dr. David Gunn, who was also murdered by anti-abortion extremists, travelled 1,000 miles and worked six days a week providing abortion care because, according to his son, he believed "people would suffer without care if he refused." ³⁸ Dr. Warren Hern has described his decision to provide abortion care even at great personal risk in deep-seated moral terms, stating that "women need my help" and that "If women are not free to make decisions about their own lives and health, they are not free. And if women are not free, none of us are free." ³⁹ As a corollary, some providers have argued that limitations on their patient's right to access abortion, or their right to provide abortion care, are *immoral*. Dr. Susan Robinson explained her belief that "it's deeply immoral for people to feel that it's appropriate to impose their religious views on other people, 'cause [abortion] is essentially a religious issue." ⁴⁰ Dr. Parker, describing the decision of a chief administrator at the clinic where he worked to ban abortion care, wrote "it wasn't acceptable to deny [patients] a safe and legal procedure. It wasn't right."

Even doctors who do not feel morally obligated to perform abortions under most circumstances may feel obliged to do so when the life or health of a patient is at risk, in cases of severe fetal anomaly, or in other extenuating circumstances. In one study, an overwhelming 91% of OB/GYNs surveyed—including some who generally refused to assist with abortion services—said that they would help a patient obtain an abortion if she had been recently diagnosed with breast cancer and required chemotherapy and radiation. ⁴² Other studies and articles have described conflicts between physicians who wish to provide emergency care to patients, including evacuation of the uterus during a miscarriage with complications, and religious rules prohibiting such care in faith-based medical facilities. ⁴³

People and communities of faith hold a complex array of views on abortion and other reproductive health care. While some medical providers' moral and religious beliefs lead them to

³⁷ Leah Torres, The Danger of Utah's Abortion Law, CNN (Mar. 31, 2016).

https://www.cnn.com/2016/03/31/opinions/utah-abortion-law-torres/index.html.

³⁸ Letter by David Gunn, Jr., published by LADY PARTS JUSTICE LEAGUE (Mar. 10, 2018).

https://ladypartsjusticeleague.com/remembering-dr-david-gunn-abortion-providers-appreciation-day/.

Warren M. Hern, An Abortion Doctor Speaks Out About Decades of Threats and Violence, STAT NEWS (Dec. 4, 2015), https://www.statnews.com/2015/12/04/abortion-doctor-violence/.

⁴⁰ Revolution Interview with Dr. Susan Robinson, supra note 30.

⁴¹ Willie Parker, supra note 29 at 31.

Lisa H Harris, Alexandra Cooper, Kenneth A Rasinski, Farr A Curlin & Anne Drapkin Lyerly, Obstetrician— Gynecologists' Objections to and Willingness to Help Patients Obtain an Abortion 118 OBSTETRICS & GYNECOLOGY 905 (2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4185126/ (correction unrelated to results made in 118 OBSTETRICS & GYNECOLOGY 1424 (2011).

⁴³ Lori R. Freeman & Debra B. Stulberg, Conflicts in Care for Obstetric Complications in Catholic Hospitals, 4 AJOB PRIMARY RESEARCH 1 (2013) available at

https://www.aclu.org/sites/default/files/assets/conflicts_in_care.pdf; Angel M. Foster, Amanda Dennis, Fiona Smith, Do Religious Restrictions Influence Ectopic Pregnancy Management? A National Qualitative Study, IBIS REPRODUCTIVE HEALTH, 21 WOMEN'S HEALTH ISSUES 24, 24 (2011),

https://www.ncbi.nlm.nih.gov/pubmed/21353977; Amy Littlefield, Catholic Rules Forced This Doctor to Watch Her Patient Sicken—Now, She's Speaking Out, REWIRE (Sep. 7, 2017),

https://rewire.news/article/2017/09/07/catholic-niles-forced-doctor-watch-patient-sicken-now-shes-speaking/.

abstain from providing such care, other providers feel morally required to provide it—especially when their patient's life or health is at risk. As is clear from the examples given above, support for abortion rights is neither a new nor an unusual religious belief. To the contrary, the fact that many health care providers feel a strong faith-based commitment to respecting the reproductive decisions made by women was the reason that the U.S. Catholic Conference and the National Right to Life Committee opposed the passage of the Religious Freedom Restoration Act when it was pending in Congress in 1992; these organizations were concerned that RFRA could be used by people of faith to support access to abortion.⁴⁴

B. The HHS Regulation Provides Far Stronger Protections for Certain Religious Beliefs Regarding Abortion

The proposed HHS rule would enact sweeping protections for medical providers, health care facilities, insurance plans, and even employers who believe that abortion and other health care services are morally wrong. In contrast, it provides extremely limited protections to those whose religious or moral beliefs lead them to offer their patients the full range of sexual and reproductive health care.

The proposed rule greatly expands the scope of existing religious refusal laws by allowing providers to refuse not just care that is *directly related* to the provision of an abortion, sterilization, or other procedure but to refuse "to participate in any program or activity with an articulable connection to" the service to which a provider objects. It would expand the definition of a "health care entity" who is permitted to refuse care to include not only medical providers, health facilities, and insurance plans but "a plan sponsor, issuer, or third-party administrator, or any other kind of health care organization, facility, or plan," and even "components of State or local governments."

The definition of a heath care referral under the proposed rule is also extremely broad. The rule would allow a health care entity to refuse to provide "any information... pertaining to a health care service, activity, or procedure... 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 making the referral sincerely understands that particular health care service, activity, or procedure to be a purpose or possible outcome of the referral." This definition is so all-encompassing that it would appear to include even basic

See e.g., The Religious Freedom Restoration Act: Hearing on S. 2969 Before the Comm. on the Judiciary of the United States Senate, 102nd Cong. 2, 129-35 (Sept. 18, 1992) (Statement of Mark Chopko, General Counsel, United States Catholic Conference) ("The Conference has legitimate concerns that S. 2969 will be utilized to attempt to promote the destruction of innocent unborn human lives") available at

http://www.justice.gov/sites/default/files/jmd/legacy/2014/02/13/hear-j-102-82-1992.pdf. See id. (Statement of James Bopp, Jr., General Counsel, National Right to Life Committee, titled "Why The Religious Freedom Restoration Act Much Expressly Exclude a Right to Abortion.").

⁴⁵ 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) (emphasis added).
⁴⁶ Id. (emphasis added).

diagnostic information about a patient's health or pregnancy if the medical provider believes abortion to be a "possible outcome" of providing the diagnosis. By potentially limiting access even to accurate medical *information*, the rule may limit a patient's ability to make health care decisions based on her own moral and religious views.

Thus, under the proposed rule, an enormous number of people—including non-medical providers, such as employers—may permissibly refuse to undertake nearly any act that could be remotely linked to a health service to which they morally or religiously object, regardless of the beliefs or medical needs of their patients. Furthermore, a religiously-affiliated health care entity that believed the *denial* of health care to be immoral could not mandate that its employees offer all medically appropriate care to patients; regardless of an employer's religious or moral beliefs to the contrary, medical providers under the rule have an absolute right to refuse services.

Meanwhile, providers whose religious or moral beliefs lead them to provide abortion, sterilization, contraception, and LGBTQ+ health care may be prohibited from acting on their sincerely-held beliefs by their employer. The Church Amendments prohibit employers from refusing to hire medical providers because they "performed or assisted in the performance of a lawful sterilization procedure or abortion... or because of [their] religious beliefs or moral convictions respecting sterilization procedures or abortions." However while the Amendments do not allow employers to punish medical providers because of their acts or beliefs related to abortion outside the scope of their employment, employers may still forbid heath care providers from acting on their religious and moral commitment to provide patients with all medical options. The proposed rule therefore fails to protect all religious beliefs about abortion, sterilization, and other medical care equally.

C. The Government Should Not Favor Particular Religious Beliefs

Constitutional principles and federal laws and policies prohibit the government from favoring particular religious beliefs over others. "A proper respect for both the Free Exercise and the Establishment Clauses compels the State to pursue a course of 'neutrality' toward religion... favoring neither one religion over others nor religious adherents collectively over nonadherents." This neutrality principle has been at the core of First Amendment religious liberty jurisprudence. In the landmark decision *Sherbert v. Verner*, the Supreme Court held that Sabbatarians should be entitled to unemployment insurance benefits despite their refusal to work on Saturdays; the opinion explained that this conclusion "reflects nothing more than the governmental obligation of neutrality in the face of religious differences." The Court specifically noted that its ruling in the case did nothing "to abridge any other person's religious liberties." In contrast, in striking down a religious exemption in *Estate of Thorton v. Caldor*, Justice O'Connor's concurrence stressed that the law impermissibly "single[d] out Sabbath

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

Board of Education of Kiryas Joel Village School District v. Grumet, 512 U.S. 687, 696 (1994) (internal citations omitted).

Sherbert v. Verner, 374 U.S. 398, 409 (1963).

So Id.

observers for special and, as the Court concludes, absolute protection without according similar accommodation to ethical and religious beliefs and practices of other private employees."51

In Board of Education of Kiryas Joel Village School District v. Grumet, the Court held that a law creating a separate school district for a Hasidic Jewish community improperly "single[d] out a particular religious sect for special treatment, and whatever the limits of permissible legislative accommodations may be...it is clear that neutrality as among religions must be honored." Even language in Corp. of Presiding Bishop v. Amos, in which the Court upheld an exemption allowing religiously-affiliated employers to practice co-religionist hiring discrimination, supports the precept that accommodations may not preference a particular religious belief. In that opinion, the Court noted that while "[t]here is ample room under the Establishment Clause for benevolent neutrality which will permit religious exercise to exist without sponsorship and without interference... At some point, accommodation may devolve into 'an unlawful fostering of religion." The Court was also careful to note that the religious exemption at issue was "neutral on its face"—allowing religious organizations of all faiths and creeds to prefer co-religionists.

The HHS regulation singles out particular religious beliefs about sexual and reproductive health care for special protection while failing to extend the same protection to those with other religious views. Thus, rather than merely accommodating religious liberty in general, it openly prefers anti-choice religious beliefs. To be clear, this comment does not take a particular position on the appropriate balance of rights in the event of a religious conflict between a medical facility and its employee, except to say the following: first, that any rule on this matter must ensure the ability of patients to make informed decisions about their health based on their own values and conscience, and; second, that a rule which favors particular religious views on abortion—allowing religious institutions that oppose reproductive health care to impose their views on employees while forbidding the reverse— is improper.

⁵¹ Estate of Thorton v. Caldor, 472 U.S. 703, 711 (1985) (O'Connor, J., concurring).

⁵² Board of Education of Kiryas Joel, 512 U.S. at 706-07.

⁵³ Corporation of Presiding Bishop v. Amos, 483 U.S. 334-35, (1987) (emphasis added). See also Walz v. Tax Commission, 397 U.S. 664, 670 (1970). In this relatively early Establishment Clause case, Justice Burger upheld a state statute exempting religious organizations from certain taxes by noting the general principle underlying the Establishment Clause: "Mr. Justice Black, writing for the Court's majority, said the First Amendment 'means at least this: Neither a state nor the Federal Government can pass laws which aid one religion, aid all religions, or prefer one religion over another." Everson v. Board of Education, 330 U.S. 1, 15 (1947).").

Exhibit 159



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 (Submitted electronically)

To Whom it May Concern:

We are writing on behalf of Raising Women's Voices for the Health Care We Need (Raising Women's Voices) in response to the request for public comment on the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26.

Raising Women's Voices is a national initiative with 30 regional coordinator organizations in 29 states working to ensure that the health care needs of women and our families are addressed in federal and state health policies. We have a special mission of engaging women who are not often invited into health policy discussions: women of color, low-income women, immigrant women, young women, women with disabilities, and members of the LGBTQ community.

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 we believe the American health system must do to achieve "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 pregnancy⁵ 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."

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.

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.

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 pregnancies⁸ -- 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

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).

^{*} 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

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

The 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

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

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.

^{11 42} U.S.C. § 1295dd(a)-(c) (2003).

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

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.

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 ending 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

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 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. 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 access health care and have real consequences for those denied the care they need because of a provider or hospital's religious beliefs. When women and families are uninsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services or travel to another location, refusals bar access to necessary care. 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.

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..

²² See, e.g., supra note 2.

²⁶ See The Patient Should Come First: Refusals to Provide Reproductive Health Care, NAT'L WOMEN'S L. CTR. (2017), https://nwlcciw49tixgw5lbab.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-saidno/2015/09/13/bd2038ca-57ef-11e5-8bb1-b488d231bba2 story.html?utm term=.8c022b364b75.

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

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/.

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.

³¹ See Kira Shepherd, et al., supra note 23, at 12.

³² See id. at 10-13.

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

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." 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. Because the proposed rule would cause substantial harm, including to patients, it would violate the Establishment Clause. Value 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. The proposed rule would cause substantial harm, including to patients, it

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

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. Black women are three to four times more likely than white women to die during or after childbirth. 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. Voung Black women said they felt they were shamed by

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/health-disparities/index.html.

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.
 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. Individuals with HIV – a recognized disability under the 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. 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

9. The proposed rule will make it harder for states to protect their residents

https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/CERD Shadow US 6.30.14 Web.p df [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.

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. 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. 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.

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 counseling⁵⁹ 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 and the

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.

Constitution, ignores congressional intent, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons, Raising Women's Voices calls on the Department to withdraw the proposed rule in its entirety.

If you have any questions regarding these comments, please contact Lois Uttley, co-founder of Raising Women's Voices and Women's Health Program Director for Community Catalyst, at luttley@communitycatalyst.org.

Respectfully submitted,

Raising Women's Voices for the Health Care We Need

Exhibit 160



RABBI JONAH DOV PESNER, Director ISABEL P. (LTZ) DUNST, Chair, Commission on Social Action of Reform Judoism

> Arthur and Sara Jo Kobacker Building 2027 Massachusetts Avenue, NW, at Krise Kaplan Way, Washington, DK 20036

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To:

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

From:

Barbara Weinstein
Director, Commission on Social Action of Reform Judaism
Associate Director, Religious Action Center of Reform Judaism
2027 Massachusetts Avenue NW
Washington, D.C. 20036

Re: RIN 0945-ZA03

DT: March 27, 2018

I write on behalf of the Union for Reform Judaism, whose more than 900 congregations across North America encompass 1.5 million Reform Jews, and the Central Conference of American Rabbis, whose membership includes more than 2,000 Reform rabbis, in response to the proposed rule from the U.S. Department of Health and Human Services, RIN 0945-ZA03, titled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority."

As people of faith, we are deeply concerned about this proposed rule. It creates a framework that distorts essential protections for religious freedom to justify discrimination. Accordingly, we ask the Department to withdraw it.

This rule would create a blanket exemption to allow hospitals, insurance companies, health care providers, and support staff to refuse patients care or even referrals for care. We reject the use of religion to deny essential health care services to people without ensuring that such individuals receive the care they need. Inspired by our faith, we feel a moral imperative to ensure that patients receive the health care they request without delay and to oppose the Administration's proposal that could allow religion to be used to deny patients' access to critical health care.







By making it easier to use moral and religious objections to discriminate and hamper access to critical medical care and services, this rule will disproportionately burden women and LGBTQ individuals. We are particularly concerned that the rule will negatively impact reproductive health care, including access to abortion and contraceptive care, as well as necessary transition-related care for transgender individuals. Moreover, since the rule governs all entities or individuals that benefit from federally funded health care programs or activities, this rule will allow taxpayer dollars to subsidize discriminatory behavior and certain religious viewpoints.

Specifically, we raise the following concerns about the proposed rule:

• The rule creates an unacceptable blanket exemption for religious or moral objections without regard for other interests: Religious freedom is a fundamental American value. Yet this essential freedom has always been understood to have boundaries. We support religious accommodations that are carefully crafted to maintain the freedom to exercise faith without infringing on other important rights and freedoms. In fact, the First Amendment requires that when creating a religious exemption, the government must account for the burdens an exemption would impose on others. This understanding of religious freedom also reflects a tenet of our faith tradition: We should treat others fairly, as we would like to be treated.

This proposed rule, however, appears to allow religious and moral conviction claims to trump any and all other interests. The rule gives complete deference to a hospital's or provider's religious objection to providing or referring for a certain medical service, ignoring the government's significant interests in maintaining broad access to health care, an individual's ability to obtain certain medical services, and our nation's longstanding commitment to extant civil rights protections. This rule instead creates what amounts to a blanket exemption, casting aside other important rights and ignoring the need to carefully craft accommodations.

For instance, Title VII of the Civil Rights Act of 1964 requires employers to reasonably accommodate employees' or applicants' sincerely held religious beliefs, observances, and practices, unless doing so would impose an "undue hardship" on an employer. When a health care worker requests an accommodation, Title VII ensures that employers consider how to balance an accommodation with obligations to serve patients, protect coworkers, ensure public safety, and abide by other legal requirements. The proposed rule, however, establishes an entirely different and conflicting standard.

• The scope of the proposed rule is sweeping and would permit a wide range of individuals and entities to refuse to provide a broad spectrum of services: The proposed rule would greatly expand the individuals and entities that may invoke religious beliefs or moral convictions to refuse to provide, directly or indirectly, essential services and care. The proposed rule not only applies to medical professionals like doctors and nurses, but also extends to support staff, volunteers, trainees, contractors, and others who work at a health care entity. The set of entities that may receive an exemption is also broad: it includes organizations offering insurance plans and "plan sponsors," an expansion which might ultimately protect businesses unrelated to the provision of health care.



In addition, the proposed rule also extends to referrals for care. Depending on location or circumstance, this may functionally block people from obtaining vitally needed services. This rule creates a vast scope for objections or objectors that will endanger many individuals' ability to access the care or services they need.

Many health care providers are called by their faith to uphold a duty to their patients. The
proposed rule ignores that many providers' religious and moral convictions prompt them to
prioritize their patients' health. Providers should be able to give patients sound information
about treatment choices so patients can make informed decisions about their care. And
providers should be able to deliver health care, including abortion and transition-related care.

As advocates for religious freedom, we are alarmed by the proposed rule. Categorical exemptions like these distort and degrade religious freedom, endangering the wide support carefully crafted religious accommodations have long enjoyed in our country.

As Reform Jews, we live by the value that we are all created b'tzelem Elohim, in the image of God. We must build a world in which we celebrate each person's sacredness just as we celebrate that of the Divine. Our commitment to protecting the civil rights and equality of all stems from this prophetic mandate.

This rule takes great liberties in reinterpreting extant civil rights law and religious exemptions. We urge you to rescind this proposed rule.

Sincerely,

Barbara Weinstein

Director, Commission on Social Action of Reform Judaism Associate Director, Religious Action Center of Reform Judaism

Exhibit 161



March 26, 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

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

To Whom it May Concern:

SAGE is writing to oppose the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care," published January 26, which would endanger the health and welfare of LGBT older adults by providing a license to discriminate based on moral or religious grounds. Medical decisions should be based on a patient's health-related needs, not a provider's personal belief or moral disapproval of an aspect of a patient's life.

This proposed rule and other religious exemptions pose a unique risk for LGBT older people. As SAGE, The Public Rights/Private Conscience Project at the Center for Gender and Sexuality Law at Columbia Law School, and The Movement Advancement Project (MAP) outline in our December 2017 report, "Dignity Denied: Religious Exemptions and LGBT Elder Services," religious exemption laws and policies disproportionately impact an already at-risk population. Because of the challenges outlined below, including higher rates of social isolation and poverty, LGBT older adults are more dependent on the aging network than their heterosexual and cis-gender peers. At the same time, data shows that the aging network is dominated by religiously affiliated providers. In fact, the report cites a study showing that, "85% of nonprofit continuing care retirement communities were religiously affiliated." And it cites another study showing that, "14% of hospitals in the United States were religiously affiliated accounting for 17% of all hospital beds." If nothing else, these stark statistics emphasize why providing these religiously-affiliated institutions and others with a license to discriminate leaves the lives of LGBT older adults in the balance.

¹Dignity Denied: Religious Exemptions and LGBT Elder Services. 2017. Available at https://sageusa.org/files/Older-Adults-Religious-Exemptions.pdf



As the country's oldest and largest organization dedicated to improving the lives of LGBT older adults, SAGE is compelled to speak out against continued threats to this population. SAGE and its 28 affiliates in 21 states offers supportive services and consumer resources to LGBT older adults and their caregivers, advocates for public policy changes that address the needs of LGBT older people, and provides training for agencies and organizations that serve LGBT older adults. SAGE – in collaboration with 18 leading organizations nationwide – operates the National Resource Center on LGBT Aging (NRC), which is the country's first and only technical assistance resource center aimed at improving the quality of services and supports offered to LGBT older adults. SAGECare is SAGE's training and consulting program and the country's only national LGBT aging cultural competency credentialing program. The NRC and SAGECare provide training, technical assistance, and educational resources to aging providers, LGBT organizations, and LGBT older adults. To date, the NRC and SAGECare have trained over 29,000 professionals across the United States and the District of Columbia, and SAGECare has awarded a SAGECare Credential to 297 providers.

Data, research, and the experience of SAGE, its affiliates, and its partners across the country confirm that LGBT older adults face a number of barriers to successful aging that place them at greater need for care by our nation's health and aging professionals. First, LGBT older adults face higher rates of social isolation and have thinner support networks than their non-LGBT peers. They are up to twice as likely to live alone, half as likely to have close relatives to call for help, and four times less likely to have children to assist them.² They are also much more likely to be disconnected from families of origin.³ Second, LGBT older adults face higher poverty rates than their non-LGBT peers. Nearly sixteen percent of single gay men over 65 live in poverty, compared to just 9.7 percent of single heterosexual men their age. Further, six percent of lesbian couples age 65 and older have incomes below the poverty line, compared to 3.5 percent for heterosexual married couples in the same age group.⁴ Third, and most importantly for this rulemaking, LGBT older adults face pronounced health disparities compared to their non-LGBT peers. HIV impacts the LGBT community disproportionately,⁵ and it is affecting an increasing number of older adults.⁶

The National Institutes of Health (NIH) and National Institute on Aging (NIA)-funded *Aging and Health Report* outlines a number of other disparities, including: lesbian, gay and bisexual (LGB) older adults face higher rates of disability and mental health challenges; older bisexual and gay men face higher rates of physical health challenges; bisexual and lesbian older women have higher obesity rates and higher rates of cardiovascular disease; and transgender older adults face greater risk of suicidal ideation,

² LGBT Movement Advancement Project & Services and Advocacy for Gay, Lesbian, Bisexual and Transgender Elders (MAP & SAGE), *Improving the Lives of LGBT Older Adults*. 2010. Available at http://www.lgbtmap.org/file/improving-the-lives-of-lgbt-older-adults.pdf

³ LGBT Movement Advancement Project & Services and Advocacy for Gay, Lesbian, Bisexual and Transgender Elders (MAP & SAGE), *Improving the Lives of LGBT Older Adults*. 2010. Available at http://www.lgbtmap.org/file/improving-the-lives-of-lgbt-older-adults.pdf

⁴ M.V. Lee Badgett, et al., Williams Inst., New Patterns of Poverty in the Lesbian, Gay and Bisexual Community. 2013. Available at https://williamsinstitute.law.ucla.edu/research/census-lgbt-demographics-studies/lgbt-poverty-update-iune-2013/

⁵ Centers for Disease Control and Prevention: HIV Among Gay and Bisexual Men. 2016. Available at https://www.cdc.gov/hiv/group/msm/

⁶ Centers for Disease Control and Prevention: *HIV Among People Aged 50 and Over*. 2017. *Available at* https://www.cdc.gov/hiv/group/age/olderamericans/



disability, and depression compared to their peers. Lastly, despite their need to rely on providers for services because of their truncated support networks, LGBT older adults lack access to LGBT-culturally competent care and services.

One segment of the LGBT population on which this proposed rule would have a disproportional adverse impact is transgender older adults. Transgender older adults are even more likely than other LGBT older adults to have greatest social and economic need (as defined in the Older Americans Act), while they are least likely to receive the services and supports they need to live independently. Transgender older adults are even more likely than other LGBT older adults to: suffer from "physical and mental disabilities;" face cultural, social or geographic isolation;" and have "an income level at or below the poverty line." At the same time, the shortage of providers competent in transgender care and transgender older peoples' reluctance to seek care, for fear of discrimination, exacerbate their already acute needs. As a result, transgender older adults are at a particularly high risk of not receiving the services and supports that they need to live independently.8 Anything this proposed rule would do to inhibit access to services and supports - particularly healthcare - would only intensify the health disparities and other challenges transgender older adults already face.

We know that moral and religious exemptions or refusals can make it harder for LGBT patients and other vulnerable populations to receive the health care they need. Of course, we believe religious freedom is important, but this freedom is already protected by existing law, and this rule expands exemptions for health care refusals far beyond what existing law allows. The proposed rule does not take into account the impact that expanding religious or moral refusals can have on patients' health, especially LGB and transgender older adults, who already face barriers to accessing health care. This rule could encourage healthcare institutions or individual health care workers to refuse to provide basic care for LGBT older adults, and transgender older adults in particular, simply because they disapprove of being transgender.

Every day, too many LGBT 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

⁷ Fredriksen-Goldsen KI, Kim HJ, Emlet CA, et al.: The Aging and Health Report: Disparities and Resilience Among Lesbian, Gay, Bisexual, and Transgender Older Adults. 2011. Seattle, WA: Institute for Multigenerational Health, University of Washington.

⁸ Soon Kyu Choi and Ilan H. Meyer, Williams Inst., LGBT Aging: A Review of Research Findings, Needs, and Policy Implications (2016), available at http://williamsinstitute.law.ucla.edu/wp-content/uploads/LGBT-Aging-White-Paper.pdf; SAGE, Out and Visible: The Experiences and Attitudes of Lesbian, Gay, Bisexual and Transgender Older Adults, Ages 45-75 (2014), available at www.sageusa.org/files/LGBT OAMarketResearch Rpt.pdf; LGBT Movement Advancement Project & SAGE, Improving the Lives of LGBT Older Adults (2010), available at www.lgbtmap.org/file/improving-the-lives-of-lgbt-older-adults.pdf; Richard Wright et al., Same-Sex Legal Marriage and Psychological Well-Being: Findings from the California Health Interview Survey, 103 Am. J. Pub. Health (2013); Movement Advancement Project & SAGE, Understanding Issues Facing LGBT Older Adults (2016), available at www.lgbtmap.org/file/understanding-issues-facing-lgbtolder-adults.pdf; Sandy E. James et al., Nat'l Ctr. for Transgender Equal., The Report of the 2015 U.S. Transgender Survey (2016), available at http://www.transequality.org/sites/default/files/docs/usts/USTS%20Full%20Report%20-%20FINAL%201.6.17.pdf; Williams Inst., Best Practices for Asking Questions to Identify Transgender and Other Gender Minorities on Population-Based Surveys (2014), available at http://williamsinstitute.law.ucla.edu/wp-content/uploads/geniuss-report-sep-2014.pdf; Carina Storrs, Gender Transitioning for Seniors Has

Unique Challenges, CNN (June 3, 2015), available at http://www.cnn.com/2015/06/03/health/senior-gender-transition/index.html; Justice in Aging, LGBT Older Adults in Long-Term Care Facilities: Stories from the Field (2015), available at

http://www.justiceinaging.org.customers.tigertech.net/wp-content/uploads/2015/06/Stories-from-the-Field.pdf



value freedom of religion, but sweeping exemptions that obstruct access to care are a fundamental distortion of that principle. Americans deserve better.

Sincerely,

Aaron Tax Director of Advocacy 1200 18th Street NW #700 Washington, DC 20036

Exhibit 162

City and County of San Francisco Mark Farrell Mayor

San Francisco Department of Public Health

Barbara A. Garcia, MPA Director of Health

Secretary Alex Azar
The U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Department of Health and Human Services Proposed Rule, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," Docket ID No. HHS-OCR-2018-0002 (RIN 0945-ZA03)

Dear Secretary Azar,

Thank you for the opportunity to submit comments on "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," Department of Health and Human Services (HHS) proposed rule RIN0945-ZA03, Docket ID No. HHS-OCR-2018-0002. The San Francisco Department of Public Health (SFDPH) strongly opposes this proposed rule and requests that it be withdrawn. In support of our position, we offer the information below based on our experience as a safety net provider of direct health services to thousands of insured and uninsured residents of San Francisco, including those most socially and medically vulnerable.

SFDPH, through the San Francisco Health Network (SFHN), provides San Francisco's only complete care system and includes primary care, dental care, emergency and trauma treatment, medical and surgical specialties, diagnostic testing, skilled nursing and rehabilitation, behavioral health services and jail health services. The mission of SFDPH is to protect and promote the health of all San Franciscans. SFDPH is dedicated to reducing health disparities and providing inclusive care to all patients. SFDPH provides this care though its top-rated programs, fifteen primary care community clinics, and hospitals, including Zuckerberg San Francisco General Hospital and Trauma Center (ZSFG). For example, Zuckerberg San Francisco General alone delivers over one thousand babies a year, has been at the forefront of HIV/AIDS care from the beginning of the AIDS crisis, and provides gender-confirmation surgeries to transgender patients.

Zuckerberg San Francisco General cares for approximately one in eight San Franciscans a year, regardless of their ability to pay. As the City's safety net hospital, Zuckerberg San Francisco General provides the highest-quality services, including to many patients covered through Medi-Cal (California's Medicare program). It provides life-saving emergency care as the only level one trauma center in San Francisco, serving a region of more than 1.5 million people. With the busiest emergency room in San Francisco, Zuckerberg San Francisco General receives one-third of all ambulances in the City, and treats nearly four

The mission of the San Francisco Department of Public Health is to protect and promote the health of all San Franciscans.

We shall ~ Assess and research the health of the community ~ Develop and enforce health policy ~ Prevent disease and injury ~

~ Educate the public and train health care providers ~ Provide quality, comprehensive, culturally-proficient health services ~ Ensure equal access to all ~

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thousand patients with traumatic injuries, annually. Many of Zuckerberg San Francisco General's programs focus on providing life-saving care in emergency situations.

As a safety net provider, SFDPH is extremely concerned by the proposed rule. HHS recently created the Division of Conscience and Religious Freedom with the purpose of protecting health care workers who refuse to treat patients on the basis of religious and moral objections. This new division and the proposed rule threaten the health of our patients, and are likely to have a particular negative impact on low-income people, women, and the LGBTQ community.

The proposed rule compromises patient care, undermines the oaths sworn to by medical and healthcare professionals, is unnecessary, and is practically unworkable.

First, the proposed rule provides no benefits and imposes only burdens on patients. It fails to take into account the very real costs it imposes on patients' rights to access care, and to do so without being subjected to discrimination. Prioritizing religious freedom over the provision of care allows discrimination and threatens the lives of patients, including women and the LGBTQ community. The proposed rule would undermine San Francisco's long-standing efforts to advance women's health and reproductive rights, prevent domestic violence, address sexual assault and human trafficking, and promote the health and well-being of women and the LGBTQ community through access to health promotion and health care services. The proposed rule threatens patients' constitutional right to access reproductive healthcare services, including abortions. This proposed rule would also exacerbate already enormous deficiencies in health care access among transgender and gender non-conforming individuals. Nearly a quarter of transgender people already report avoiding seeking medical care for fear of being mistreated.¹ This rule could further dissuade transgender people from seeking even the most routine services. The breadth of the rule is such that it is impossible to fully predict how the rule could impact patients—even access to basic care that on its face has no discernable connection to religious observance, such as dental care, could be threatened. Further, it would disproportionately place low-income San Franciscans at risk and threaten San Francisco's ability to provide necessary healthcare services to its residents most in need. The proposed rule completely fails to take into account the very real costs it imposes on patients' rights to access care, and to do so without being subjected to discrimination.

Second, the proposed rule elevates a right of conscience above all other ethical considerations. The proposed rule is in direct violation of the Hippocratic Oath, in which doctors swear to do no harm and to treat the ill to the best of their ability. Its definition of "refer" is so broad that it could potentially prevent SFDPH from ensuring that if one health care provider were unwilling to give certain care, another provider would be able to provide it without delay. When a patient seeks care from one of SFHN's clinics or hospitals, both the patient and SFDPH need to know that the patient is receiving all medically-necessary care.

Third, existing laws and regulations ensure that patients receive the essential health services they need, while adequately protecting the rights of conscience of healthcare workers. Patients have the right to access high-quality, inclusive and comprehensive care without encountering discrimination, and current

¹ Sandy E. James et al., The Report of the U.S. Transgender Survey 98 (2016), www.ustranssurvey.org/report.

law ensures that access while also allowing accommodations for healthcare workers' religious beliefs. SFDPH is not aware of any employee request for a religious accommodation that it has been unable to provide under existing laws and regulations. Current law is perfectly adequate, and there is no need for the proposed rule.

Lastly, the proposed rule is unworkable in many other respects. In addition to ignoring the needs of patients, the proposed rule fails to account for how a health care organization could legally administer it. The proposed rule ignores competing obligations imposed on SFHN by other statutes such as the Emergency Medical Treatment and Active Labor Act and California's Unruh Civil Rights Act. It also ignores SFDPH's contractual obligations to its employees; the proposed rule could create problems with the fair administration of labor contracts between employees asserting conscience rights and those who do not.

The rule also appears to create administrative obstacles to providing employees with religious accommodations. The current draft lacks a requirement that workers seeking to assert a right of conscience inform their organization of their request, and therefore could deny the organization an opportunity to provide the worker with an accommodation. Moreover, the proposed definition of "discrimination" is so broad that even if a worker did request an accommodation, the very act of providing one could be considered discriminatory. If an employee failed to request an accommodation in advance of being presented with a patient who has an immediate need for care, the proposed rule creates a very real risk that the patient could be denied legally required or medically necessary care. Patient care is SFDPH's first and primary priority, but it is worth noting that in addition to harming a patient, such a situation could also potentially expose SFDPH to liability for violations of other laws and for malpractice.

For these reasons, we respectfully request HHS withdraw the Proposed Rule from consideration.

Sincerely,

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Barbara A. Garcia

Director of Health

San Francisco Department of Public Health

Exhibit 163

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 209F 200 Independence Avenue SW Washington, DC 20201

Introduction

On behalf of the Sargent Shriver National Center on Poverty Law (Shriver Center), we respectfully submit these comments to the federal Department of Health and Human Services ("Department") and its Office for Civil Rights ("OCR") to express our strong opposition on behalf of our clients to the proposed regulation entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority."

Shriver Center advocates for quality comprehensive, accessible, and affordable health care coverage and services for all populations experiencing poverty. Shriver Center advocates against racial inequity and inequality and works to reduce health care disparities for communities of color. In particular, we have a special focus and expertise in Medicaid policy as well as policy implementing the Affordable Care Act Marketplace, which provides subsidized health care coverage to Illinois residents with household income under 400% of the poverty level. We provide training and technical assistance to thousands of enrollment professionals in Illinois who assist consumers to enroll in health care programs including Medicaid and the Marketplace and to access financial assistance and health care services. We are also a co-leader of Protect Our Care Illinois, a membership coalition of healthcare advocates, providers, and consumers, joining efforts to promote and preserve access to high quality affordable healthcare for Illinois residents and families. The regulations as proposed would significantly burden our clients and restrict their access to care causing poorer health outcomes. Our specific concerns are outlined below.

In general, 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.

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").

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 special health care needs, 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 causing 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 the care they need. For these reasons, Shriver Center 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

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.

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 significant 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. Women of color experience health care disparities such as high rates of cervical cancer and are disproportionately impacted by HIV. 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 religious refusals will only 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.

a. The proposed rule will block access to care for low-income women, including immigrant women and African American women

Broadly-defined and widely-implemented refusal clauses undermine access to basic health services for all, but will be particularly harmful to low-income women. The burdens on low-income women can be insurmountable when women and families are uninsured, ⁷ underinsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services nor travel to another location. This is especially true for immigrant women. In comparison to their U.S. born

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.

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 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. KAISER FAMILY FOUND., *Women's Health Insurance Coverage* 3 (Oct. 31, 2017), http://files.kff.org/attachment/fact-sheet-womenshealth-insurance-coverage.

peers, immigrant women are more likely to be uninsured.⁸ Notably, immigrant, Latina women have far higher rates of being uninsured than Latina women born in the United States (48 percent versus 21 percent, respectively).⁹

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. 10 Young Black women noted that they were shamed by providers when seeking sexual health information and contraceptive care in part, due to their age, and in some instances, sexual orientation. 11

New research also shows that women of color in many states disproportionately receive their care at Catholic hospitals, subjecting them to treatment that does not comply with the standards of care. 12 In nineteen states, women of color are more likely than white women to give birth in Catholic hospitals. 13 In New Jersey, for example, women of color make up 50 percent of women of reproductive age in the state, yet have twice the number of births at Catholic hospitals compared to their white counterparts. 14 These hospitals as well as many Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provides guidance on wide range of hospital matters. including reproductive health care. In practice, the ERDs prohibit the provision of emergency contraception, sterilization, abortion, fertility services, and some treatments for ectopic pregnancies. 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, risking their health. 15 The proposed rule will give health care providers a license, such as Catholic hospitals, to opt out of evidence-based care that the medical community endorses. If this rule were to be implemented, more women, particularly women of color, will be put in situations where they will have to decide between receiving compromised care or seeking another provider to receive quality, comprehensive reproductive health services. For many, this choice does not exist.

⁸ Athena Tapales et al., The Sexual and Reproductive Health of Foreign-Born Women in the United States, Contraception 8 (2018), http://www.contraceptionjournal.org/article/S0010-7824(18)30065-9/pdf.
⁹ Id. at 8, 16.

¹⁰ 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

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.

¹¹ Reproductive Injustice, supra note 10, at 16-17.

¹² Kira Shepherd, et al., Bearing Faith The Limits of Catholic Health Care for Women of Color, Pub. RIGHTS PRIVATE CONSCIENCE PROJECT (2018), available at

https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
¹³ *Id* at 12.

¹⁴ Id at 9.

¹⁵ Lori R. Freedman et al., 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/.

b. The proposed rule will negatively impact rural communities

The ability to refuse care to patients will leave many individuals in rural communities with no health care options. Medically underserved areas already exist in every state, 16 with over 75 percent of chief executive officers of rural hospitals reporting physician shortages. 17 Many rural communities experience a wide array of mental health, dental health, and primary care health professional shortages, leaving individuals in rural communities with less access to care that is close, affordable, and high quality, than their urban counterparts. 18 Among the many geographic and spatial barriers that exist, individuals in rural areas often must have a driver's license and own a private car to access care, as they must travel further distances for regular checkups, often on poorer quality roads, and have less access to reliable public transportation. 19 This scarcity of accessible services leaves survivors of intimate partner violence (IPV) in rural areas with fewer shelter beds close to their homes, with an average of just 3.3 IPV shelter beds per rural county as compared to 13.8 in urban counties. 20 Among respondents of one survey, more than 25 percent of survivors of IPV in rural areas have to travel over 40 miles to the nearest support service, compared to less than one percent of women in urban areas.21

Illinois has a large number of counties in rural areas of the state, many of which are designated as health care shortage areas. Patients in these rural counties already have to travel by car very long distances to find providers, hospitals and specialists who can treat them – sometimes even traveling to providers in other neighboring states including Indiana, Missouri and Iowa. Many of our clients who are low income do not have the resources to travel these distances and public transportation is basically non-existent. This proposed rule will only exacerbate an already difficult situation. Patients in rural counties in Illinois cannot afford to lose any providers or have providers refuse to treat them.

Some individuals in rural areas, such as people with disabilities, people with Hepatitis C, and people of color, have intersecting identities that further exacerbate existing barriers to care in rural areas. Racial and ethnic minority communities often live in concentrated parts of rural America, in communities experiencing rural poverty, lack of insurance, and

21 Id.

¹⁶ Health Res. & Serv. Admin, *Quick Maps – Medically Underserved Areas/Populations*, U.S. DEP'T OF HEALTH & HUM. SERV., https://datawarehouse.hrsa.gov/Tools/MapToolQuick.aspx?mapName=MUA, (last visited Mar. 21, 2018).

¹⁷ M. MacDowell et al., A National View of Rural Health Workforce Issues in the USA, 10 RURAL REMOTE HEALTH (2010), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3760483/.

Carol Jones et al., Health Status and Health Care Access of Farm and Rural Populations, ECON.
 RESEARCH SERV. (2009), available at https://www.ers.usda.gov/publications/pub-details/?pubid=44427.
 Thomas A. Arcury et al., The Effects of Geography and Spatial Behavior on Health Care Utilization among the Residents of a Rural Region, 40 HEALTH SERV. RESEARCH (2005) available at

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1361130/.

²⁰ Corinne Peek-Asa et al., *Rural Disparity in Domestic Violence Prevalence and Access to Resources*,

20 J. of Women's Health (Nov. 2011) available at
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3216064/.

health professional shortage areas.²² People with disabilities experience difficulties finding competent physicians in rural areas who can provide experienced and specialized care for their specific needs, in buildings that are barrier free.²³ Individuals with Hepatitis C infection find few providers in rural areas with the specialized knowledge to manage the emerging treatment options, drug toxicities and side effects.²⁴ All of these barriers will worsen if providers are allowed to refuse care to particular patients.

Meanwhile, immigrant, Latina women and their families often face cultural and linguistic barriers to care, especially in rural areas.²⁵ These women often lack access to transportation and may have to travel great distances to get the care they need.²⁶ In rural areas there may simply be no other sources of health and life preserving medical care. When these women encounter health care refusals, they have nowhere else to go.

c. 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." 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

²² Janice C. Probst et al., Person and Place: The Compounding Effects of Race/Ethnicity and Rurality on Health, Am. J. Pub. HEALTH (2011), available at http://aiph.aphapublications.org/doi/full/10.2105/AJPH.94.10.1695.

²³ Lisa Î. lezzoni et al., Rural Residents with Disabilities Confront Substantial Barriers to Obtaining Primary Care, 41 HEALTH SERV. RESEARCH (2006), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1797079/.

²⁴ Sanjeev Arora et al., Expanding access to hepatitis C virus treatment – Extension for Community Healthcare Outcomes (ECHO) Project: Disruptive Innovation in Specialty Care, 52 HEPATOLOGY (2010), available at http://onlinelibrary.wiley.com/doi/10.1002/hep.23802/full.

²⁵ Michelle M. Casey et al., Providing Health Care to Latino Immigrants: Community-Based Efforts in the Rural Midwest, Am. J. Pub. HEALTH (2011), available at http://ajph.aphapublications.org/doi/full/10.2105/AJPH.94.10.1709.

NAT'L LATINA INST. FOR REPROD. HEALTH & CTR. FOR REPROD. RIGHTS, NUESTRA VOZ, NUESTRA SALUD, NUESTRO TEXAS: THE FIGHT FOR WOMEN'S REPRODUCTIVE HEALTH IN THE RIO GRANDE VALLEY, 7 (2013), available at http://www.nuestrotexas.org/pdf/NT-spread.pdf.

²⁷ 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).

physical and mental health care services.²⁸ In a recent study published in *Health Affairs*, researchers examined the intersection of gender identity, sexual orientation, race, and economic factors in health care access.²⁹ 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.³⁰

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.³¹ Numerous federal courts have found that federal sex discrimination statutes reach these forms of gender-based discrimination.³² In 2012, the Equal Employment Opportunity Commission (EEOC) likewise held that "intentional discrimination against a transgender individual because that person is transgender is,

²⁸ 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.

²⁹ 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.

³¹ 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. III. 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. III. 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).

³² 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).

by definition, discrimination based on sex and such discrimination therefore violates Title VII.*33

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.³⁴ 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.³⁵ 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."³⁶

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.

ii. <u>Discrimination Based Upon Sexual Orientation</u>

³³ Macy v. Holder, E.E.O.C. App. No. 0120120821, 2012 WL 1435995, *12 (Apr. 20, 2012).

³⁴ 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.

³⁵ 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].

³⁶ 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/.

Many LGBTQ people lack insurance and providers are not competent in health care issues and obstacles that the LGBTQ community experiences. 37 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.38

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.39 Almost ten percent of LGB respondents reported that they had been denied necessary health care expressly because of their sexual orientation. 40 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.41
- Lesbian and bisexual women report poorer overall physical health than heterosexual women. 42
- 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.43
- · 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.44

³⁷ 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.

³⁸ Mirza, supra note 34. 39 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-careisnt-caring.pdf.

⁴⁰ Id.

⁴¹ 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-healthamong-sexual-minorities/. 42 Id.

⁴³ Id.

⁴⁴ 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.

Bisexual people face significant health disparities, including increased risk of mental health issues and some types of cancer.⁴⁵

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 immediate family or them [identifying as LGBTQ]".46 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.⁴⁷

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.⁴⁸ 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. 49 The American College of Obstetricians and Gynecologists warns that failure to provide gender-affirming treatment can lead to serious health consequences for transgender individuals. 50 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

⁴⁵ 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. ⁴⁶ Human Rights Watch, supra note 28.

⁴⁷ Mirza, supra note 34.

⁴⁸ 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-lgbtqfriendly-practice#Meet a Standard of Practice (last visited Jan. 26, 2018, 12:56 PM).

⁴⁹ 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.

⁵⁰ 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.

cardiovascular disease.⁵¹ The LGBTQ community is significantly at risk for sexual violence.⁵² Eighteen percent of lesbian, gay, bisexual students have reported being forced to have sex.⁵³ Transgender women, particularly women of color, face high rates of HIV.⁵⁴

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.

d. The proposed rule will hurt people living with disabilities

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. Individuals with HIV – a recognized disability under the 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. 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

⁵¹ Kates, supra note 37, at 4.

⁵² 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.

⁵³ Health Risks Among Sexual Minority Youth, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/healthyyouth/disparities/smy.htm (last updated May 24, 2017).

⁵⁴ More than 1 in 4 transgender women are HIV positive. Kates, supra note 37, at 6.

⁵⁵ 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).
⁵⁶ 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.

moral or religious objection is extremely alarming and could seriously compromise the health, autonomy, and well-being of people with disabilities.

Many people with disabilities live or spend much of their day in provider-controlled settings where they often receive supports and services. They may rely on a case manager to coordinate necessary services, a transportation provider to get them to community appointments, or a personal care attendant to help them take medications and manage their daily activities. Under this broad new proposed language, any of these providers could believe they are entitled to object to providing a service covered under the regulation and not even tell the individual where they could obtain that service, how to find an alternative provider, or even whether the service is available to them. A case manager might refuse to set up a routine appointment with a gynecologist because contraceptives might be discussed. A personal home health aide could refuse to help someone take a contraceptive. An interpreter for a deaf individual could refuse to mediate a conversation with a doctor about abortion. In these cases, a denial based on someone's personal moral objection can potentially impact every facet of life for a person with disabilities — including visitation rights, autonomy, and access to the community.

Finally, due to limited provider networks in some areas and to the important role that case managers and personal care attendants play in coordinating care, it may be more difficult for people with disabilities and older adults to find an alternate providers who can help them. For example, home care agencies and home-based hospice agencies in rural areas are facing significant financial difficulties staying open. Seven percent of all zip codes in the United States to not have any hospice services available to them. ⁵⁷ Finding providers competent to treat people with certain disabilities can increase the challenge. Add in the possibility of a case manager or personal care attendant who objects to helping and the barrier to accessing these services can be insurmountable. Moreover, people with disabilities who identify as LGBTQ or who belong to a historically disadvantaged racial or ethnic group may be both more likely to encounter service refusals and also face greater challenges to receive (or even know about) accommodations.

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.⁵⁸ 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

⁵⁷ Julie A. Nelson & Barbara Stover Gingerich, *Rural Health: Access to Care and Services*, 22 Home HEALTH CARE MGMT. PRAC. (2010), *available at* http://globalag.igc.org/ruralaging/us/2010/access.pdf.
⁵⁸ Tom Beauchamp & James Childress, Principles of Biomedical Ethics (4th ed. 1994); Charles Lidz ET AL., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY (1984).

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. ⁵⁹ 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. ⁶⁰ In order to ensure that patient decisions are based on free will, informed 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." The American Nursing Association similarly requires that patient autonomy and self-determination are core ethical tenets of nursing. "Patients have the moral and

⁵⁹ BEAUCHAMP & CHILDRESS, *supra* note 58; Robert Zussman, *Sociological perspectives on medical ethics* and decision-making, 23 ANN. Rev. Soc. 171-89 (1997).

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 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).

61 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.

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." 62 Similarly, pharmacists are called to respect the autonomy and dignity of each patient. 63

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. ⁶⁴ 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.' [citation omitted] 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."65

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 established medical principles. 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." In addition, the proposed rule undermines principles of quality care. Health care should be safe, effective, patient-centered, timely, efficient, and equitable. Pacifically, 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.

⁶² 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.

⁶³ Code of Ethics for Pharmacists, Am. Pharmacists Ass'n (1994).

⁶⁴ 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.

⁶⁵ Brownfield v. Daniel Freeman Marina Hospital, 256 Cal. Rptr. 240 (Ct. App. 1989).

⁶⁶ Amy G. Bryant & Jonas J. Schwartz, Why Crisis Pregnancy Centers Are Legal but Unethical, 20 Am. MED. Ass'n J. ETHICS 269, 272 (2018).

⁶⁷ 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.

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 suffering from 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 2016.⁶⁹ The latest 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.⁷⁰

The clear, evidence-based treatment standard for opioid use disorder (OUD) is medication-assisted treatment (MAT).⁷¹ 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."⁷² Buprenorphine and

⁶⁹ Holly Hedegaard M.D., et al. *Drug Overdose Deaths in the United States, 1999-2016*, NAT'L CTR. FOR HEALTH STATISTICS1-8 (2017).

⁷⁰ Vital Signs, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vitalsigns/opioid-overdoses/.

⁷¹ 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.

⁷² World Health Organization, 19th WHO Model List of Essential Medicines (April 2015), http://www.who.int/medicines/publications/essentialmedicines/EML2015 8-May-15.pdf

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.⁷³ 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.⁷⁴ 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.⁷⁵ 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 harm and do not increase drug use.⁷⁶ 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.⁷⁷

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." 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

⁷³ 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].

⁷⁴ See James M. Chamberlain & Bruce L. Klein, *A Comprehensive Review of Naloxone for the Emergency Physician*, 12 AM. J. EMERGENCY MED. 650 (1994).

⁷⁵ 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.

⁷⁶ 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.

⁷⁷ 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.

⁷⁸ Lopez, supra note 75.

"completely cured."⁷⁹ 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.⁸⁰ 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.⁸¹

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. ⁸² 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. ⁸³ 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. ⁸⁴ The current Secretary of the Department has noted that expanding access to MAT is necessary to save lives and that it will be "impossible" to quell the opioid epidemic without increasing the number of providers offering the evidence-based standard of care. ⁸⁵ 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

Azar, supra note 84.

⁷⁹ 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.

⁸⁰ 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.

⁸¹ 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
⁸² 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

^{83 42} C.F.R. §8.610.

⁸⁴ 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.

conditions including heart disease, diabetes, epilepsy, lupus, obesity, and cancer. Many of these conditions disproportionately affect women of color. 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. 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. Meanwhile, the number of Catholic hospitals in the United States has increased by 22 percent since 2001, and now own one in six hospital beds across the country. The increase of Catholic hospitals poses a danger for women seeking reliable access to medical services, many of whom do not understand the full range of services that may be denied them. One public opinion survey found that, among the less than one-third of women who understood that a Catholic hospital might limit care, only 43 percent expected limited access to contraception, and a mere 6 percent expected limited access to the morning-after pill.

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, Eiliping.adults.are more likely to be

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.

⁸⁶ 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),

⁸⁷ 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/.

⁸⁸ 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/.

⁸⁹ Julia Kaye et al., Health Care Denied: Patients and Physicians Speak Out About Catholic Hospitals and the Threat to Women's Health and Lives, Am. CIVIL LIBERTIES UNION 22 (2017), available at https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

⁹⁰ Nadia Sawicki, Mandating Disclosure Of Conscience-Based Limitations On Medical Practice, 42 Am. J. of Law & Med. 85-128 (2016) available at http://journals.sagepub.com/doi/pdf/10.1177/0098858816644717.

a. Pregnancy prevention

The importance of the ability of women to make decisions for themselves to prevent or postpone pregnancy is well-established within the medical guidelines across a range of practice areas. Millions of women live with chronic conditions such as cardiovascular disease, diabetes, lupus, and epilepsy, which if not properly controlled, can lead to health risks to the pregnant woman or even death during pregnancy. Denying these women access to contraceptive information and services violates medical standards that recommend pregnancy prevention for these medical conditions. For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care. Precommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant.

Moreover, women who experience poverty are disproportionately impacted by unintended pregnancy. In 2011, 45% of pregnancies in the U.S. were unintended – meaning that they were either unwanted or mistimed. Dow-income women have higher rates of unintended pregnancy as they are least likely to have the resources to obtain reliable methods of family planning, and yet, they are most likely to be impacted negatively by unintended pregnancy. The Institute of Medicine has documented negative health effects of unwanted pregnancy for mothers and children. Unwanted pregnancy is associated with maternal morbidity and risky health behaviors as well as low-birth weight babies and insufficient prenatal care.

b. 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. 96

⁹³ Unintended Pregnancy in the United States, Guttmacher Inst. (Sept. 2016), https://www.guttmacher.org/fact-sheet/unintended-pregnancy-united-states.

⁹¹ Am. Diabetes Ass'n, Standards of Medical Care in Diabetes-2017, 40 Diabetes Care S115, S117 (2017), available at:

http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement 1.DC1/DC 40 S1 final

⁹² Id. at S114.

⁹⁴ Lawrence B. Finer & Stanley K. Henshaw, Disparities in rates of unintended pregnancy in the United States, 1994 and 2001, 38 Perspectives on Sexual & Reprod. Health 90-6 (2006).

⁹⁵ Institute of Medicine Committee on Unintended Pregnancy, The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families (Sarah S. Brown & Leon Eisenberg eds.,1995).
⁹⁶ 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.

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.⁹⁷

c. Ending a Pregnancy

While there are numerous reasons for why a person would seek to end a pregnancy, there are many medical conditions in which ending a pregnancy is recommended as treatment. These conditions include: preeclampsia and eclampsia, certain forms of cardiovascular disease, and complications for chronic conditions. Significant racial disparities exist in rates of and complications associated with preeclampsia. For example, the rate of preeclampsia is 61% higher for Black women than for white women, and 50% higher than women overall. The American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics guidelines state that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually suggested regardless of fetal age or potential for survival. ACOG and American Heart Association recommend that a pregnancy be avoided or ended for certain conditions such as severe pulmonary hypertension. Many medications can cause significant fetal impairments, and therefore the Federal Food and Drug Administration and professional medical associations recommend that women use contraceptives to ensure that they do not become pregnant while taking these

⁹⁷ 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.

Sajid Shahul et al., Racial Disparities in Comorbidities, Complication, and Maternal and Fetal
 Outcomes in Women With Preeclampsia/eclampsia, 34 HYPERTENSION PREGNANCY (Dec. 4, 2015), http://www.tandfonline.com/doi/abs/10.3109/10641955.2015.1090581?journalCode=ihip20.
 Richard Franki, Preeclampsia/eclampsia rate highest in black women, OB.GYN. News (Apr. 29., 2017),

^{**} Richard Franki, *Preeciampsia/eciampsia rate highest in black women*, OB.GYN. NEWS (Apr. 29., 2017), http://www.mdedge.com/obgynnews/article/136887/obstetrics/preeclampsia/eclampsia-rate-highest-black-women.

 $^{^{100}}$ American Academy of Pediatrics & American College of Obstetricians and Gynecologists, Guidelines for perinatal care 232 (7th ed. 2012).

¹⁰¹ Mary M. Canobbio et al., *Management of Pregnancy in Patients With Complex Congenital Heart Disease*, 135 CIRCULATION e1-e39 (2017); Debabrata Mukherjee, *Pregnancy in Patients With Complex Congenital Heart Disease*, Am. Coll. Cardiology (Jan. 24, 2017), http://www.acc.org/latest-incardiology/ten-points-to-remember/2017/01/24/14/40/management-of-pregnancy-in-patients-with-complex-chd.

medications.¹⁰² In addition, some medical guidelines counsel patients to end a pregnancy if they are taking certain medications for thyroid disease.¹⁰³

d. Emergency contraception

The proposed rule will magnify the harm in circumstances where women are already denied the standard of care. Catholic hospitals have a record of providing substandard care or refusing care altogether to women for a range of medical conditions and crises that implicate reproductive health. For example, in a 2005 study of Catholic hospital emergency rooms by Ibis Reproductive Health for Catholics for Choice, it was found that 55 percent would not dispense emergency contraception under any circumstances. The three percent of the hospitals limited EC to victims of sexual assault.

These hospitals violated the standards of care established by medical providers regarding treatment of sexual assault. Medical guidelines state that survivors of sexual assault should be provided emergency contraception subject to informed consent and that it should be immediately available where survivors are treated. At the bare minimum, survivors should be given comprehensive information regarding emergency contraception. The standard st

e. Artificial Reproductive Technology (ART)

Refusals to provide the standard of care to LGBTQ individuals because of their sexual orientation or gender identity can impact access to care across a broad spectrum of health concerns, which includes primary and specialty care settings. One example of refusals that impacts LGBTQ patients, as well as non-LGBTQ patients, is refusals to educate about, provide, or cover ART procedures for religious reasons. For individuals with cancer, the standard of care includes education and informed consent around

¹⁰² ELEANOR BIMLA SCHWARZ M.D. M.S., et al., *Documentation of Contraception and Pregnancy When Prescribing Potentially Teratogenic Medications for Reproductive-Age Women*, 147 Annals of Internal Medicine. (Sept. 18, 2007).

 ¹⁰³ For example, the American College of Obstetricians and Gynecologists specifically recommends that if a woman taking Iodine 131 becomes pregnant, her physician should caution her to consider the serious risks to the fetus, and consider termination. American College of Obstetricians and Gynecologists, ACOG Practice Bulletin No. 37: Thyroid disease in pregnancy 100 Obstetricians and Gynecology 387-96 (2002).
 104 Teresa Harrison, Availability of Emergency Contraception: A Survey of Hospital Emergency Department Staff, 46 Annals Emergency Med. 105-10 (Aug. 2005), http://www.annemergmed.com/article/S0196-0644(05)00083-1/pdf
 105 Id. at 105.

¹⁰⁶ Committee Opinion 592: Sexual Assault, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (Apr. 2014), https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co592.pdf?dmc=1&ts=20170213T2116487879; Management of the Patient with the Complaint of Sexual Assault, AM. COLL. EMERGENCY MED. (Apr. 2014), https://www.acep.org/Clinical---Practice-Management/Management-of-the-Patient-with-the-Complaint-of-Sexual-Assault/#sm.00000bexmo6ofmepmultb97nfbh3r.

¹⁰⁷ Access to Emergency Contraception H-75.985, AMA (2014), https://policysearch.ama-assn.org/policyfinder/detail/emergency%20contraception%20sexual%20assault?uri=%2FAMADoc%2FH OD.xml-0-5214.xml.

fertility preservation, according to the American Society for Clinical Oncology and the Oncology Nursing Society. 108 Refusals to educate patients about or to provide ART occur for two reasons: refusal based on religious beliefs about ART itself and refusals to provide ART to LGBTQ individuals because of their LGBTQ identity. In both situations, refusals to educate patients about ART and fertility preservation, and to facilitate ART when requested, are against the standard of care.

The lack of clarity in the rule could lead a hospital or an individual provider to refuse to provide ART to same-sex couples based on religious belief. For some couples, this discrimination would increase the cost and emotional toll of family building. In some parts of the country, however, these refusals would be a complete barrier to parenthood. More broadly, these refusals deny patients the human right and dignity to be able to decide to have children, and cause psychological harm to patients who are already vulnerable because of their health status or their experience of health disparities.

f. 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. 109 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 proposed rule violates the Establishment Clause

The Establishment Clause of the First Amendment bars the government from granting religious and moral exemptions that would harm any third party. 110 It requires the

¹⁰⁸ Alison W. Loren et al., *Fertility Preservation for Patients With Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update*, 31 J. CLINICAL ONCOLOGY 2500-10 (July 1, 2013); Ethics Committee of the American Society for Reproductive Medicine, *Fertility preservation and reproduction in patients facing gonadotoxic therapies: a committee opinion*, 100 AM. Soc'y Reprod. Med. 1224-31 (Nov. 2013), http://www.allianceforfertilitypreservation.org/_assets/pdf/ASRMGuidelines2014.pdf; Joanne Frankel Kelvin, *Fertility Preservation Before Cancer Treatment: Options, Strategies, and Resources*, 20 CLINICAL J. ONCOLOGY NURSING 44-51 (Feb. 2016).

¹⁰⁹ 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. ¹¹⁰ E.g., Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751, 2781 n.37 (2014); Cutter v. Wilkinson, 544 U.S.709, 720, 726 (2005); Texas Monthly, Inc. v. Bullock, 489 U.S. 1, 18 n.8 (1989).

Department to "take adequate account of the burdens" that an exemption "may impose on non-beneficiaries" and must ensure that any exemption is "measured so that it does not override other significant interests."

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The Supreme Court acknowledged the limitations imposed by the Establishment Clause in *Burwell v. Hobby Lobby Stores, Inc.*, declaring the effect on employees of an accommodation provided to employers under the Religious Freedom Restoration Act (RFRA) "would be precisely zero." Justice Kennedy emphasized that an accommodation must not "unduly restrict other persons, such as employees, in protecting their own interests." The proposed exemptions clearly impose burdens on and harm others and thus, violate the clear mandate of the Establishment Clause.

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

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." 114 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. 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. 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.

If this balance is not maintained, the language in the proposed rule could force health care providers to hire people who intend to refuse to perform essential elements of a

¹¹¹ Cutter, 544 U.S. at 720, 722; see also Estate of Thornton v. Caldor, Inc., 472 U.S. 703, 709-10 (1985).

¹¹² Hobby Lobby, 134 S. Ct. 2751, 2760 (2014).

¹¹³ Id. at 2786-87 (Kennedy, J., concurring).

^{114 83} Fed. Reg. 3894.

^{115 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.
116 Id.

position. For example, the proposed rule lacks clarity about whether a Title X-funded health center's decision not to hire a counselor or clinician who objected to provide non-directive options counseling as an essential job function of their position would be deemed discrimination under the rule. Furthermore, the proposed rule does not provide guidance on whether it is impermissible "discrimination" for a Title X-funded state or local health department to transfer such a counselor or clinician to a unit where pregnancy counseling is not done.

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 muddles 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. 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 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." The uncertainty regarding how the proposed rule will interact with non-discrimination laws is extremely concerning.

b. Assist in the performance

The definition of "assist in the performance" greatly expands the types of services that can be refused beyond any reasonable stretch of the imagination. The proposed rule defines "assistance" to include participation "in any activity with an *articulable connection* to a procedure, health service or health service program, or research activity."¹¹⁹ In addition, the Department includes activities such as "making

¹¹⁷ 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).

¹¹⁸ Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751, slip op. at 46 (2014). ¹¹⁹ 83 Fed. Reg. 3892.

arrangements for the procedure."¹²⁰ If workers in very tangential positions, such as schedulers, are able to refuse to do their jobs based on personal beliefs, the ability of any health system or entity to plan, to properly staff, and to deliver quality care will be undermined. Employers and medical staff may be stymied in their ability to establish protocols, policies and procedures under these vague and broad definitions. The proposed rule creates the potential for a wide range of workers to interfere with and interrupt the delivery of health care in accordance with the standard of care.

The regulations also leave unclear whether a worker can assert his or her moral belief in refusing to treat patients on the basis of their identity or deny care for reasons outside of religious or moral beliefs. Even though women living with disabilities report engaging in sexual activities at the same rate as women who do not live with disabilities, they often do not receive the reproductive health care they need for multiple reasons, including lack of accessible provider offices and misconceptions about their reproductive health needs. Biased counseling can contribute to unwanted health outcomes and exacerbate health disparities. The proposed rule is especially alarming as it does not articulate a definition of moral beliefs. The prejudices of a health care professional could easily inform their beliefs and consequently, serve as the basis of denying care to an individual based on characteristics alone. The proposed rule will foster discriminatory health care settings and interactions between patients and providers that are informed by bias instead of medically accurate, evidence-based, patient-centered care.

Moreover, in the preamble, the proposed rule states that the exemptions that Weldon provides is not limited to refusals of abortion care on the basis of religious or moral beliefs. Due to this, health care professionals may think they can deny abortion care and other health services just because they do not want to provide the service. The preamble uses language such as "those who choose not to provide" or "Would rather not" as justification for a refusal. This is more concerning because the proposed rule contains no mechanism to ensure that patients receive the care they need if their provider refuses to furnish a service. The onus will be on the patient to question whether her hospital, medical doctor, or health care professional has religious, moral, or other beliefs that would lead them to deny services or if services were denied, the basis for refusal. This is likely to occur as the proposed rule does not have any provisions that

¹²⁰ Id

¹²¹ RM Haynes et al., Contraceptive Use at Last Intercourse Among Reproductive-Aged Women with Disabilities: An Analysis of Population-Based Data from Seven States, Contraception (2017), https://www.ncbi.nlm.nih.gov/pubmed/29253580; See generally Alex Zielinski, Why Reproductive Health Can Be A Special Struggle for Women with Disabilities, ThinkProgress, Oct. 1, 2015, https://thinkprogress.org/why-reproductive-health-can-be-a-special-struggle-for-women-with-disabilities-73ececea23c4/.

¹²² In one study in Massachusetts, women living with intellectual and developmental disabilities, including those who were Black and Latina, faced increased risks of preterm delivery and very low and low birth weight babies. M. Mitra et al., *Pregnancy Outcomes Among Women with Intellectual and Developmental Disabilities*, AM. J. PREV. MED. (2015), https://www.ncbi.nlm.nih.gov/pubmed/25547927.

¹²³ 83 Fed. Reg. 3890-91.

stipulate that patients must be given notice that they may be refused certain health care services on the basis of religious or moral beliefs.

c. Referral

The definition of "referral" similarly goes beyond any understanding of the term, allowing refusals to provide any information based on which an individual could get the care they need. Any information distributed by any method, including online or print, regarding any service, procedure, or activity could be refused by an entity if the information given would lead to a service, activity, or procedure that the entity or health care entity objects. Under this definition, could a medical doctor refuse to provide a website describing the medical conditions which contraception treats? Or could an entity refuse to provide a list of LGBTQ-friendly providers? In addition, the Department states that the underlying statutes of the proposed rule permits entities to deny help to anyone who is likely to make a referral for an abortion or for other services. 124 The breadth and vagueness of this definition will possibly lead providers to refrain from providing information vital to patients out of anxiety and confusion of what the proposed rule permits them to do.

d. Health Care Entity

The proposed rule's definition of "health care entity" conflicts with Federal religious refusal laws such as the Coats and Weldon Amendments, thus fostering confusion regarding which entities are required to comply with the proposed rule and existing Federal religious refusals. Specifically, under the Coats and Weldon Amendments a "health care entity" is defined to encompass a limited and specific range of individuals and entities involved in health care delivery. Under the proposed rule, a plan sponsor "not primarily engaged in the business of health care" would be deemed a "health care entity." This definition would mean that an employer acting as a third party administrator or sponsor could count as a "health care entity" and deny coverage. In 2016, OCR found that religiously affiliated employers were not health care entities under the Weldon amendment. 126

Moreover, the Department states that their definition of "health care entity" is "not an exhaustive list" for concern that the Department would "inadvertently omit[ting] certain types of health care professionals or health care personnel." Additionally, the proposed rule incorporates entities as defined in 1 USC 1 which includes corporations, firms, societies, etc. States and public agencies and institutions are also deemed to be entities. The Department's inclusion of entities who are primarily not engaged in the health care delivery system highlights the true purpose of the proposed rule, to

¹²⁴ *Id*. at 3895.

¹²⁵ Id. at 3893.

¹²⁶ Office for Civil Rights, Decision Re: OCR Transaction Numbers: 14-193604, 15-193782 & 15-195665, 4 (Jun. 21, 2016) (letter on file with NHeLP-DC office).

¹²⁷ 83 Fed. Reg. 3893.

¹²⁸ *Id*.

¹²⁹ *Id*.

permit a greater number of entities to interfere in the provider-patient relationship and deter a patient from making the best decision based on their circumstances, preferences, and beliefs.

Conclusion

For the reasons listed above, Shriver Center opposes the proposed rule as it expands religious refusals to the detriment of our clients' 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 a 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 cause further harm to the communities that we represent who already lack equal access to care and endure discrimination resulting in healthcare disparities.

Thank you for your attention to our comments. If you have questions, please contact Stephanie Altman, stephaniealtman@povertylaw.org.

Exhibit 164

March 27, 2018

VIA ELECTRONIC SUBMISSION

Secretary Alex Azar
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

RE: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority; RIN 0945-ZA03 or Docket HHS-OCR-2018-0002

Dear Secretary Azar:

On behalf of SisterLove, Inc.--an Atlanta-based sexual and reproductive justice advocacy organization dedicated to eradicating the impact of HIV, AIDS, and reproductive oppression upon all women and femmes of color and their families--we write to provide detailed comments below in response to the Department of Health and Human Services, Office for Civil Rights, Proposed Rule "Protecting Statutory Conscience Rights in Health Care."

We at SisterLove face the crushing burden of addressing the many health inequities that disproportionately impact our communities. Affordable access to quality healthcare is paramount to our mission. Our community-based model allows us to interact with many folks living with and disproportionately affected by HIV and AIDs. Their experiences with barriers to preventative care and treatment inform our position on the Department's proposed rule.

Because of the intersectional nature of our service provision model, we are dedicated to providing services to our communities in a manner that is respectful and upholds the autonomous decision-making power of every individual. Using this person-centered approach, we know our communities cannot face any more barriers to medical care. Thus, we register our opposition to the Department's expansion of the ability of healthcare providers to discriminate against patients under the guise of "conscience rights."

We demand the Department revoke this proposed rule because it will further harm millions of people who need meaningful access to preventive services such as counseling for sexual health and reproductive care, contraceptive care, sterilization, IVF and other fertility services, and abortion.

Many of the populations we serve have limited access to sexual and reproductive healthcare, and the government cannot condone further marginalizing these populations through further condoning exemptions for healthcare providers with bias of conscience. Black women are three to four times more likely to die from pregnancy complications than white women, and HIV-related and pregnancy-related complications remain within the 10 leading causes of death for Black women aged 20-54 and 15-34 years, respectively. Women and girls who live in rural areas, almost 4 million of

¹ Prather, C, Fuller, TR, Marshall, KJ, Jeffries IV, WL, The Impact of Racism on the Sexual and Reproductive Health of African American Women, J Womens Health. 2016 Jul; 25(7): 664-671 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4939479/>.

whom are estimated to be women of color, also experience worse maternal and child health outcomes than those in urban areas because there is a shortage of family planning services, OB/GYN care, and HIV and AIDs related care.² These shortages and disproportionate outcomes are the result of systemic racism and segregation, meaning Black people do not have access to facilities and providers that white people typically do. Furthermore, the rate of unintended pregnancy is highest among young low-income women, who are disproportionately women of color, highlighting the need for reproductive health care that includes education, counseling, contraception, and abortion.³

As the Department notes, federal laws and the Constitution already protect healthcare providers from acting against their religion or conscience. Though the Department claims it is clearing up "confusion" around the applicability of the laws, in actuality it encourages more providers to discriminate against patients and ignore patient needs under the guise of religious or conscience objections. The Department cites a small number of lawsuits and a very small number of people who commented on previous versions of a similar administrative rule to justify its promulgation of the current proposed rule. The concerns of a small few of doctors, nurses, medical students, and other healthcare providers do not merit this rule.

In line with this administration's ongoing persecution of reproductive rights, the Department, through this proposed rule, seeks to bolster discrimination against people seeking reproductive healthcare that includes abortion, sterilization, and contraception under the guise of conscience or religious objections. Rather than encouraging healthcare providers to center their patients and their patients' needs, the Department plays into the false rhetoric that "freedom of religion" and "freedom of conscience" are under attack. Rather than encouraging healthcare providers to refer patients to those who can perform services to which they object, the Department allows providers to continue to withhold needed information and services from their patients. Rather than support under-served communities, including low-income folks, people of color, LGBTQ+ folks, people with disabilities, and undocumented folks, the Department continues this administration's catering to those who disguise their racism, ableism, homophobia, transphobia, and xenophobia with religion and "conscience." Because we will not be marginalized any further, we demand the Department rescind this proposed rule.

Sincerely,

Sequoia Ayala, Esq. Policy and Advocacy Program Manager, SisterLove. Inc.

Carolyn Calhoun, Esq. Policy Counsel, SisterLove, Inc.

² Bennett, KJ, Lopes Jr., JE, Spencer, K, Van Hecke, S. National Rural Health Association Policy Brief: Rural Women's Health, 2013 https://www.ruralhealthweb.org/getattachment/Advocate/Policy-Documents/RuralWomensHealth-(1).pdf.aspx.

³ Guttmacher Institute, September 2016 Fact Sheet: Unintended Pregnancy in the United States https://www.guttmacher.org/fact-sheet/unintended-pregnancy-united-states.

Exhibit 165



March 16, 2018

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 the Southern Arizona Gender Alliance (SAGA), in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26. SAGA is a non-profit in Southern Arizona, providing support and services for of over 1,000 members, who like all people depend on the unbiased care and the concern of their health care professionals.

Every day too many LGBTQ people face discrimination and other barriers to accessing lifesaving care. These barriers are especially pronounced for our members 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.

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

LGBTQ people, women, and other vulnerable groups around the country already face enormous barriers to getting the care they need. Accessing quality, culturally competent care and

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

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.² 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.³

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. 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 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,

(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.american progress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

² 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.

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

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.

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.⁵

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. 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 LGBTQ patients' access 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

⁵ https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/

 $^{^6}$ https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/

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 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

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.

Thank you,

Miki Odawa, President Board of Directors

Southern Arizona Gender Alliance