Exhibit 75

FORWARD MONTANA

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 Forward Montana in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26. Forward Montana mobilizes and organizes young Montanans to shape their democracy to improve their lives and the lives of their fellow Montanans. Each year we engage 100s of volunteers and 1000s of voters in the democratic process. 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.

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.[1] 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 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),

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

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

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

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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.

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

[4] 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 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

[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/

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 76

FREEDOM FROM RELIGION *foundation*

P.O. BOX 750 · MADISON, WI 53701 · (608) 256-8900 · WWW.FFRF.ORG

March 27, 2018

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

Re: Proposed Rule Changes for Statutory Conscience Rights in Health Care, 45 C.F.R. §§ 88
[Document citation: Docket HHS-OCR-2018-0002; RIN: 0945-ZA03]

To Whom It May Concern:

We are submitting this comment on behalf of the Freedom From Religion Foundation (FFRF) and our membership. FFRF is a national nonprofit association with more than 32,000 members nationwide. FFRF's purposes are to protect the constitutional principle of separation between state and church, and to educate the public about issues relating to nontheism.

We oppose a proposed rule that purports to enhance protections for health care workers' religious-based objections to providing health care. Since 1978, FFRF has been on the forefront of combatting policies that promote discrimination under the guise of protecting religious freedom. This proposal is just such a rule.

This rule purports to fix a problem that does not exist. Health care workers already have sufficient legal protections against being forced to perform medical procedures that violate their conscience, so long as patients are given notice and have adequate access to the care they seek.

The proposed rule provides worryingly broad definitions for which practitioners, and which activities, would be protected. For instance, the term "Healthcare Program or Activity" includes any "service related to health or wellness whether directly, through payments, grants, contracts, or other instruments, through insurance, or otherwise." Based on this definition, certain patients seeking necessary medical treatment will have to contend with potential objections from every individual involved in their care in any way, from the person at a clinic's front desk who refuses to check them in to an employee of the patient's insurance company who refuses to issue payment.

The list of workers the division will "protect" is theoretically endless: the anesthesiologist who thinks that an abortion to save the life of the pregnant woman shouldn't be performed or an ambulance driver with the same objection; the

pharmacist opposed to birth control who won't process prescriptions or even refer to another pharmacist on site; the ER staffer who refuses rape victims the morning-after-pill; the nurse who doesn't want to run an IV line for a transgendered patient; the physician who refuses to treat a Muslim patient; or a medical worker to won't adhere to a patient's end-of-life directives. These are legitimate civil rights concerns for the *patients* involved, not the medical *workers*.

The newly created Conscience and Religious Freedom Division of the Office for Civil Rights would ironically work to ensure that certain civil rights violations can be carried out with impunity, so long as the violator cites a religious justification. This needlessly jeopardizes the medical needs of vulnerable patients, particularly women and LGBTQ individuals, whose rights the OCR is obligated to also protect.

When this new OCR division was first announced, FFRF pointed out that it would openly allow medical professionals—nurses, doctors, pharmacists—to refuse to treat transgender or other individual patients or take part in abortions, voluntary sterilizations or any health care they otherwise claim a religious or "moral" objection to. In fact, this proposed rule goes even further with its alarmingly broad language. It uses the guise of "religious freedom" to deny civil liberties and impose religious beliefs on others.

Certainly health care providers' religious objections can be handled without sacrificing the availability of quality care to patients in need. If anything, the existing state of the law favors religious objections to a fault, since access to abortions and other medically necessary care is often lacking. Instead of working to correct this problem, the proposed rule would make it worse by emboldening health care providers to deny care based on their religious beliefs.

Very truly,

Dan Barker & Annie Laurie Gaylor

Dan Barker and Annie Laurie Gaylor
Co-Presidents

DB:ALG:rdj

Exhibit 77

GLAD
LEGAL ADVOCATES & DEFENDERS
for the LGBTQ Community

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 GLBTQ Legal Advocates & Defenders (GLAD) in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26. GLAD is a New England-based public interest legal organization dedicated to ending discrimination based on gender identity and expression, HIV status, and sexual orientation. Every year, thousands of people reach out to GLAD through our free and confidential legal information line, GLAD Answers, to obtain information about their legal rights or to seek assistance on legal matters. GLAD regularly hears from people who are denied critical medical services or receive substandard medical care because of their gender identity and expression, HIV status, and/or sexual orientation. Everyone has the fundamental right to receive the highest attainable health care, but the proposed regulation puts that fundamental right in jeopardy, especially for lesbian, gay, bisexual, transgender, and queer (LGBTQ) people.

The proposed regulation is overly broad and will only exacerbate the discriminatory barriers LGBTQ people face when trying to access health care services. Freedom of religion is a deeply held value in the United States of America, but sweeping exemptions that obstruct access to care are a fundamental distortion of that principle.

1. **Expanding religious refusals will exacerbate the barriers to care that LGBTQ individuals already face.**

A recent study from the Center for American Progress showed that "LGBTQ people experience discrimination in health care settings; that discrimination discourages them from seeking care; and that LGBTQ people may have trouble finding alternative services if they are turned away."[1]

[1] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2016),

LGBTQ survey respondents reported, among other things, that health care providers refused to see them because of their actual or perceived sexual orientation or gender identity; refused to recognize their family, including a child or a same-sex spouse or partner; and subjected them to harsh or abusive language, including intentional misgendering and use of wrong names of transgender patients.[2]

A recent intake GLAD received from a same-sex married couple in New Hampshire mirrors the reported experiences of survey respondents. The couple, who contacted GLAD in February of this year, reported that a religiously affiliated hospital in New Hampshire refused them joint entry into the emergency room despite being made aware that they were a married couple. Although opposite-sex spouses were seen accompanying their spouses into the emergency room for treatment, the husband of the same-sex couple was eventually ejected from the premises because of his insistence on accompanying his sick spouse into the emergency room. In addition to ejecting the husband from the hospital premises, the sick spouse seeking treatment for kidney failure was also denied treatment and was forced to seek life-saving care at a different hospital that was further away.

For transgender people, exclusion from health care settings is even more prevalent. In the Fall of 2017, GLAD was contacted by a transgender activist who battled severe depression and anxiety. When the activist sought inpatient care for mental health services at a hospital in Massachusetts, the activist was denied sleeping accommodations in a double room because of her transgender status. Instead, the activist was segregated and isolated in a single room in the psychosis ward even though the activist did not display any psychosis symptoms. While housed in the single room in the psychosis ward, the activist was threatened with physical harm by another patient. This threat of harm prevented the activist from venturing out of her room to attain appropriate and medically necessary treatment for her severe depression and anxiety. In January 2018, the activist died in her home at the age of 26, but is remembered as an activist for trans rights and mental health care reform.

These instances of discrimination, exclusion, and substandard care deter LGBTQ people from seeking basic medical services. As illustrated by the late transgender activist, avoiding or postponing health care services due to discrimination, including past experiences of discrimination or fear of future discrimination, can have deadly consequences. This is especially true for LGBTQ people of color who, according to a Lambda Legal study, are "more likely than their white counterparts to experience discrimination and substandard care" due to the combined impact of racism and anti-LGBTQ sentiments.[3] Thus, LGBTQ people of color are more likely than their white counterparts "to have concerns about their ability to obtain needed health care because of their sexual orientation, gender identity, or HIV status."[4]

The proposed regulation provides greater opportunity for LGBTQ people to be denied necessary access to health care, which not only imposes immediate life-threatening consequences, but future deadly consequences for those who fear being denied the care they need.

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

[2] *Id.*

[3] Lambda Legal Defense and Education Fund, Inc., *When Health Care Isn't Caring: LGBT People of Color and People of Color Living with HIV Results from Lambda Legal's Health Care Fairness Survey* (2009), https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-insert_lgbt-people-of-color.pdf.

[4] *Id.*

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.[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

[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/

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.

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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,

Allison Wright, Esq.
GLBTQ Legal Advocates & Defenders
617-426-1350 x. 6961
awright@glad.org

Exhibit 78

GLMA
Health Professionals
Advancing LGBT Equality

March 27, 2018

US 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:

On behalf of GLMA: Health Professionals Advancing LGBT Equality, we write you in response to the request for public comment to strongly oppose the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26.

GLMA—previously known as the Gay & Lesbian Medical Association—is a national membership association of lesbian, gay, bisexual, and transgender healthcare professionals and their allies whose mission is to ensure equality in healthcare for LGBT individuals and for LGBT healthcare professionals. Since its founding in 1981, GLMA has employed the expertise of our medical and health professionals in education, policy and advocacy, patient education and referrals, and the promotion of research to improve the health and well-being of LGBT people and their families.

GLMA believes in the critical importance of eliminating health disparities and ensuring that all people, including lesbian, gay, bisexual, and transgender (LGBT) individuals and their families, do not face discriminatory barriers when seeking quality, affordable healthcare and coverage. Numerous surveys, studies, and reports have documented the widespread extent of the discrimination experienced by LGBT individuals and their families in the health system. *When Health Care Isn't Caring*, a nationwide survey assessing the healthcare experiences of LGBT people and people living with HIV, found that the majority of the almost 5,000 respondents reported experiencing at least one of the following types of discrimination when accessing healthcare:[1]

- Health care providers refusing to touch them or using excessive precautions

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

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- Health care providers using harsh or abusive language
- Health care providers being physically rough or abusive
- Health care providers blaming them for their health status

The US Transgender Survey, the largest survey detailing the experiences of transgender people in the United States, further documents the pervasive discrimination faced by transgender and gender nonconforming individuals in healthcare settings. According to the study, "[o]ne-third (33%) of those who saw a health care provider had at least one negative experience related to being transgender, such as being verbally harassed or refused treatment because of their gender identity." [2]

These encounters with discrimination have serious negative consequences for the health and wellbeing of LGBT individuals. They also exacerbate the significant health disparities that affect the LGBT population at large. Sources such as the National Academy of Medicine[3] (formerly the Institute of Medicine), the Centers for Disease Control and Prevention, and Healthy People 2020 report that discrimination threatens the health of the LGBT population in ways that include:[4]

- Increasing risk factors for poor physical and mental health such as smoking and other substance use;[5]
- Driving high rates of HIV among transgender women and gay and bisexual men;[6]
- Barring access to appropriate health insurance coverage, especially for transgender people;[7]
- Obstructing access to preventive screenings;[8] and
- Putting LGBT people at risk of poor treatment from health care providers who are unprepared to meet the needs of LGBT patients.[9]

As an organization of health professionals who often serve and care for patients from the LGBT community, we know that discrimination against LGBT individuals in healthcare access and coverage remains a pervasive problem and that too often this discrimination is based in religious

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[2] Sandy E. James et al., *The Report of the 2015 US Transgender Survey* (2016), *available at* http://www.transequality.org/sites/default/files/docs/usts/USTS%20Full%20Report%20-%20FINAL%201.6.17.pdf.

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

[4] U.S. Department of Health and Human Services, *Healthy People 2020: LGBT Health Topic Area* (2015), *available at* http://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health.

[5] Center for Disease Control and Prevention, *Lesbian, Gay, Bisexual, and Transgender Health* (2014), *available at* http://www.cdc.gov/lgbthealth/about.htm.

[6] Office of National AIDS Policy, *National HIV/AIDS Strategy* (2015).

[7] Laura E. Durso, Kellan E. Baker, and Andrew Cray, *LGBT Communities and the Affordable Care Act: Findings from a National Survey* (2013), *available at* http://www.americanprogress.org/wp-content/uploads/2013/10/LGBT-ACAsurvey-brief1.pdf.

[8] Fenway Institute, *Promoting Cervical Cancer Screening Among Lesbians and Bisexual Women* (2013), *available at* http://www.lgbthealtheducation.org/wp-content/uploads/Cahill_PolicyFocus_cervicalcancer_web.pdf.

[9] Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV.*

objections. GLMA members have reported numerous instances of discrimination in care based on religious grounds. Since the Department issued the proposed regulation, GLMA members have shared with us the ways they have seen religious objections used to the detriment of the healthcare of LGBT patients, including members who have said:

- "I see patients nearly every day who have been treated poorly by providers with moral and religious objections… Patients with HIV who have been told they somehow deserved this for not adhering to God's law. Patients who are transgender who have been told that 'we don't treat your kind here'. The psychological and physical damage is pervasive."
- "[Some providers in my clinic] do not wish to have contact with transgender patients, mumbling religious incompatibilities when asked why. These people have made our transgender patients feel very uncomfortable and unwelcome at times, making them more potentially more hesitant to use the health services they may need."
- "The impact on my patients who were directly denied care was both psychological and physical. With regard to their mental wellbeing they clearly felt marginalized and disrespected. With regard to their physical wellbeing, they experienced delay in care, and in some cases disruption of their routine medication dosing or diagnostic assessment."

The proposed regulation ignores the prevalence of discrimination and damage it causes and will undoubtedly lead to increased discrimination and flat-out denials of care for some of the most vulnerable members of our community. We all deeply value freedom of religion, but sweeping exemptions that obstruct access to care are a fundamental distortion of that principle. Americans deserve better.

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

LGBT people, women, and other vulnerable groups around the country already face enormous barriers to getting the care they need.[10] 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

[10] Institute of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding*; Sandy E. James et al., *The Report of the 2015 US Transgender Survey* 93–126; Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV*; 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.

rural women live more than 30 minutes away from a hospital that provides basic obstetric care.[11] 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.[12]

This means if these patients are turned away or refused treatment, it is much harder—and sometimes not possible—for them to find a viable alternative. In a recent study, nearly one in five LGBT people, including 31% of transgender people, said that it would be very difficult or impossible to get the healthcare they need at another hospital if they were turned away. That rate was substantially higher for LGBT people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider.[13] For these patients, being turned away by a medical provider is not just an inconvenience: it often means being denied care entirely with nowhere else to go.

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

The regulation purports, among other things, to clarify current "religious refusal clauses" related to abortion and sterilization in three federal statutes. Each of these statutes refers to specific, limited circumstances in which healthcare providers or healthcare 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* healthcare service or information for a religious or moral reason—potentially including not just sterilization and abortion procedures, but also infertility care, treatments related to gender dysphoria, even HIV prevention or 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.[14]

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[11] 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.

[12] Sandy E. James et al.,*The Report of the 2015 US Transgender Survey* 99.

[13] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care.*

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

Healthcare providers may be misled into believing they may refuse on religious grounds to administer an HIV test or an HIV prevention regimen to a gay or bisexual man, or refuse screening for a urinary tract infection for a transgender man.[15] 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 healthcare workers to obstruct or delay access to a healthcare service even when they have only a tangential connection to delivering that service, such as scheduling a procedure or running lab tests to monitor side-effects of a medication. The extension and broadening of this clause will impair LGBT 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 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.

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 healthcare. 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 healthcare. 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.

[15] Sharita Gruberg & Frank J. Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial.*

4. The proposed rule stands in direct contradiction to the ethical and professional standards that exist across health professions to ensure nondiscrimination for LGBT patients.

The proposed rule also presents a direct conflict with nondiscrimination standards adopted by the Joint Commission and all the major health professional associations who have already recognized the need to ensure LGBT patients are treated with respect and without bias or discrimination in hospitals, clinics and other healthcare settings. Many of these efforts were prompted at least in part by GLMA's efforts through the years. For example, GLMA representatives, in coordination with other LGBT health experts, participated in the development and implementation of hospital accreditation nondiscrimination standards and guidelines developed by the Joint Commission designed to protect and ensure quality care for LGBT patients.

Similarly, GLMA has worked with the American Medical Association, among other health professional associations, over the last 15 years to ensure AMA policies prevent discrimination against LGBT patients and recognize the specific health needs of the LGBT community. All the leading health professional associations—including the AMA, American Osteopathic Association, American Academy of Physician Assistants, American Nurses Association, American Academy of Nursing, American College of Physicians, American College of Obstetricians and Gynecologists, American Psychiatric Association, American Academy of Pediatricians, American Academy of Family Physicians, American Public Health Association, American Psychological Association, National Association of Social Workers, and many more—have adopted policies that state healthcare providers should not discriminate in providing care for patients and clients because of their sexual orientation or gender identity. By allowing discrimination against patients on the grounds of moral and religious freedom, the proposed rule obviates the ethical standards that healthcare professionals are charged to uphold.

5. 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 ensure 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 standards 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.

We are particularly concerned about the Department's attempt to radically redefine what it means to provide a referral for a patient. There is no legal basis to support the proposed transformation of the term from its plain meaning as it is used in healthcare—that is, transferring the care of a patient to a particular healthcare provider[16]—to "the provision of *any* information…pertaining to a health care service" so long as the healthcare entity believes that the healthcare service is a "possible outcome" of providing that information.[17]

This breathtakingly broad definition can exempt providers not only from refusing to transfer care to another healthcare provider, but from providing information that has an exceedingly remote connection to a procedure if the provider simply believes that it is not impossible that doing so may lead the patient to receive the treatment—even if they do not believe that it is likely or plausible. For example, it may permit a healthcare provider to refuse to inform a woman about a pregnancy complication she is experiencing, even if it can be treated, based on their belief that it is *possible* though unlikely she will opt to terminate the pregnancy. While the Department claims that statutory language—such as references to "referring for" an abortion or "making arrangements to provide referrals"—suggests that Congress intended for this term to be interpreted broadly,[18] the definition that it proposes extends so far beyond the plain meaning of the term that it amounts to a radical revision of the statutory language that undermines rather than effectuates Congress' intent for its scope.

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

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

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

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[16] American Academy of Family Physicians, *Consultations, Referrals, and Transfers of Care* (2017), https://www.aafp.org/about/policies/all/consultations-transfers.html ("A referral is a request from one physician to another to assume responsibility for the management of one or more of a patient's specific problems.... This represents a temporary or partial transfer of care to another physician for a particular condition.")

[17] Proposed Rule, 83 Fed. Reg. at 3924.

[18] *Id.* at 3895.

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 healthcare 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,

Gal Mayer, MD, MS
GLMA President

Hector Vargas, JD
GLMA Executive Director

Exhibit 79

GREATER NEW YORK HOSPITAL ASSOCIATION
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March 27, 2018

Via Electronic Mail
http://www.regulations.gov

Roger Severino
Director, Office for Civil Rights
US Department of
Health and Human Services
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, SW
Washington, D.C. 20201

Re: HHS—OCR—2018—0002, Protecting Statutory Conscience Rights in Health Care, Delegations of Authority; Proposed Rule (Vol. 83, No. 18) Jan. 26, 2018, RIN 0945-ZA03

Dear Mr. Severino:

On behalf of the 160 members of Greater New York Hospital Association (GNYHA), I am writing to comment on the Department of Health and Human Services' (the Department) proposed rule, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority.

Our membership includes not-for-profit community hospitals and large academic medical centers, providing a wide range of health care services to millions of patients across New York, New Jersey, Connecticut, and Rhode Island. In many cases, our members are among the largest employers in their communities. As such, they have decades of experience protecting the conscience rights of their employees and prohibiting unlawful discrimination in all its forms. And they have done this while also upholding their primary reason for being—to provide the very best patient care to all those in need.

Health care workers' conscience rights must be balanced with patients' rights and providers' ethical duties. The detailed comments below reflect our view that the proposed rule does not give enough credence to this principle and focuses too heavily on only one side of the equation.

GNYHA

Any Regulations on Conscience Rights Must Reflect Hospitals' Obligation to Balance Health Care Workers' Rights with the Ethical Duty of Care

The Department gives as one of the reasons for the proposed rule an American Congress of Obstetricians and Gynecologists (ACOG) ethics opinion that noted,

> In an emergency in which referral is not possible or might negatively affect a patient's physical or mental health, providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections.[1]

This statement goes to the heart of the interests that must be balanced when protecting conscience rights in health care.

As set forth in the 2013 edition of *The Hastings Center Guidelines for Decisions on Life-Sustaining Treatment and Care Near the End of Life* (*The Hastings Center Guidelines*), a widely used and cited source of guidance in health care settings, health care providers have a fundamental "duty of care" to patients. This duty prohibits them from "abandoning patients and requires them to meet standards of care and honor patients' rights."[2] Policies in hospitals and other health care institutions support ethical practice by reflecting the duty of care, which is also reflected in a range of legal and regulatory obligations, e.g., the Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S.C. § 1395dd, and New York State Education Law § 6530 (30) (defining patient abandonment as a form of professional misconduct for physicians and other licensed professionals).

Laws and regulations protecting conscience rights have been enacted since the 1970s. Institutional policies have long reflected these rights, including the conscience rights of individual workers and of institutions themselves. Because of this long American tradition of explicitly articulating conscience rights through institutional policy and processes, and explaining these rights in the context of the fundamental duty of care, hospitals are familiar with how to balance workers' conscience rights with patients' rights.

The *Hastings Center Guidelines* recommend that health care institutions "should aim to accommodate [providers'] requests to withdraw from a case on religious or other moral grounds without compromising standards of professional care and the rights of patients." The accommodation process should also hold the provider responsible "for maintaining his or her duty of care by assisting in the orderly transfer of the patient to another professional."[3] This appropriately balances the rights of patients and the rights of providers.

These recommendations, which reflect broad consensus in health care professions and health care ethics, are consistent with actual hospital policies and procedures. These policies generally

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[1] "The Limits of Conscientious Refusal in Reproductive Medicine," *ACOG Committee Opinion*, no. 385 (November 2007; *reaffirmed 2016*)
[2] N. Berlinger, B. Jennings, S. Wolf, *The Hastings Center Guidelines for Decisions on Life Sustaining Treatment and Care Near the End of Life* (Oxford University Press, 2013), 17.
[3] Ibid.

include the worker's duty to notify[4] the hospital on hire, or at another appropriate time, of his or her request not to participate in a particular aspect of patient care or treatment, and the basis of that request. The duty to notify is an important feature of ethical practice to ensure minimal disruption to hospital operations in evaluating and accommodating individual conscience rights. Personal convictions must be communicated and managed in a professional setting, and only the holder of those convictions can start that process. Once notified, the hospital then evaluates and makes efforts to reasonably accommodate the request, taking into account the facts and circumstances of the situation.

In rare cases where the employee notification occurs during the course of providing care to a patient, hospital policies generally require the worker to maintain appropriate standards of care until patient care responsibilities can be transferred. Patient care is the heart of hospital operations, and the duty of care applies throughout the process of finding a reasonable accommodation of the individual's conscience rights.

The Department Should Incorporate a "Reasonable Accommodation" Framework, as It Supports a Balanced Approach to Protecting Conscience Rights

Hospital conscience policies generally mirror the framework for other legally mandated requests for reasonable accommodations. Thus, as the Department revisits its enforcement model for conscience rights, it should take note of the standards developed through the body of law concerning reasonable accommodations under Title VII of the Civil Rights Act and similar models.

Title VII requires employers to grant employees' requests for reasonable accommodation based on religion, unless doing so would cause an undue hardship.[4] Employers are not required to adopt the precise accommodation requested.[5] Further, the employer is entitled to inquire into whether the employee's professed beliefs are in fact sincerely held and religious in nature.[6] Indeed, "[s]ocial, political, or economic philosophies, as well as mere personal preferences, are not 'religious' beliefs protected by Title VII."[7] This framework, shaped over years of enforcement and litigation, provides useful standards to apply in the context of the Office for Civil Rights' (OCR) evaluation and enforcement on the Federal conscience laws, and as such, the Department should explicitly adopt it.

Comments on Specific Regulatory Proposals

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[4] New York State Civil Rights Law, Sec. 79-i, prohibits discrimination against individuals who refuse to perform abortions due to conscience or religious beliefs and provides a mechanism for notifying hospitals and other entities of such refusal in writing.

[4] Reasonable accommodation without undue hardship as required by section 701(j) of Title VII of the Civil Rights Act of 1964, 29 CFR §1605.2(b)(1).

[5] Reasonable accommodation without undue hardship as required by section 701(j) of Title VII of the Civil Rights Act of 1964, 29 CFR §1605.2(c)(2).

[6] "Religious" nature of a practice or belief, 29 CFR §1605.1; see also, *United States v. Seeger*, 380 U.S. 163 (1969).

[7] "EEOC Compliance Manual, Religious Discrimination, Section 12-I(A)(1)–Definition of Religion," (July 22, 2008). https://www.eeoc.gov/policy/docs/religion.html, (accessed March 26, 2018).

"Assist in the Performance"

The Department proposes defining the term "Assist in the Performance" to mean "participate *in any activity with an articulable connection* to a procedure, health service or health service program, or research activity … [emphasis added]." Included would be "counseling, referral, training, and other arrangements for the procedure, health service, or research activity" (FR 3892).

The Department's intent appears to be to broaden the field of individuals covered by the Federal conscience laws. Putting aside whether this would be consistent with each of the underlying statutes, such a broad definition runs the risk of creating unintended consequences for patient care.

By expanding the field of individuals who may refuse to perform their duties, based solely on their ability to articulate a "connection" to the subject procedure or service, the Department runs the risk of turning what is currently a rare occurrence—direct conflicts between conscience rights and the duty of care—into a more common event. It would also make more difficult the process of predicting and planning for scenarios in which conscience rights might need to be exercised. Finally, including referral in the definition could undermine one of the core ethical principles outlined above—the requirement that providers make an appropriate referral when their values conflict with a patient's treatment choices.

"Discriminate" or "Discrimination"

The Department seeks to apply the general principles of nondiscrimination from Title VI of the Civil Rights Act and notes that being free from discrimination also includes "being free not to act contrary to one's beliefs" (FR 3892). But such freedom is not absolute in the health care context; certain rules and precepts, such as the duty of care, should not be viewed as targeting religious or conscience-motivated conduct merely because they reflect workers' and institutions' patient care obligations. And given the complexity of interests at issue, they should not be viewed through a "disparate impact" lens. It is vitally important that health care institutions have the discretion and tools to balance patient rights, including their own right not to be discriminated against, with individuals' conscience rights without fear of unreasonable enforcement action. Conscience rights should not stand above all other civil rights protected by Federal, State, and local laws.

Compliance Requirements

The Department proposes certain new compliance requirements, including that Recipients inform their Departmental funding component of any compliance review, investigation, or complaint and report any such matters brought within the prior five years in any application for new or renewed Federal Financial Assistance or Departmental funding. In addition to being extremely burdensome, these requirements are unfair in that they do not distinguish among the varieties of inquiries that a Recipient may be facing and whether they were substantiated or not. These requirements are also unnecessary because OCR will have custody of all of the relevant information, which it can make available to the Departmental funding components.

Enforcement Authority

The Department proposes for OCR to "[i]n coordination with the relevant component or components of the Department, take other appropriate remedial action as the Director of OCR deems necessary and as allowed by law …" (FR 3898). OCR should defer to the conscience laws, and any existing administrative regimes, on sanctioning and due process. The Departmental funding components already have such procedures in place. The Department should delineate the grounds for various types of sanctions with respect to the conscience laws.

Conclusion: The Proposed Rule is Arguably Unnecessary, and At Minimum, Should be Reframed and Streamlined

The Department cites many reasons for issuing the proposed rule, but one of its primary goals is to enhance awareness of the Federal conscience protections among the public and the health care community. This awareness-raising began when OCR recently announced the establishment of its new "Conscience and Religious Freedom Division," and certainly new regulations are not necessary for OCR to undertake additional public education efforts.

This type of rulemaking seems to be exactly what President Trump intended to thwart with the issuance of his executive order, Reducing Regulation and Controlling Regulatory Costs.[8] The proposed rule stands in contrast with the Administration's regulatory streamlining goals and should be reframed and significantly scaled back, in accordance with the foregoing comments.

Thank you for taking our comments into consideration.

Very Truly Yours,

Kenneth E. Raske
President

[8] "Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs," (January 30, 2107). https://www.whitehouse.gov/presidential-actions/presidential-executive-order-reducing-regulation-controlling-regulatory-costs/ (accessed March 26, 2018).

Exhibit 80

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: RIN 0945–ZA03, Protecting Statutory Conscience Rights in Health Care

The Guttmacher Institute is writing in opposition to the above-referenced rule proposed by the Department of Health and Human Services (HHS) on January 26, 2018, to interpret and enforce more than 20 federal statutory provisions related to "conscience and religious freedom."

Collectively, as interpreted by this proposed rule, these statutes would grant broad powers to individuals and organizations in the health care field and beyond to refuse to provide or be involved with services, information and referrals to which they have religious or moral objections. That includes services related to abortion, contraception, end-of-life care, global health care assistance, vaccination, and much more. The proposed regulations and steps to enforce them have real potential to undermine existing legal and ethical protections for patients' access to sexual and reproductive health information and services, and other critical care. For these reasons, as detailed further below, we urge that the rule be withdrawn.

Redefining Statutory Terms to Expand Their Reach

In proposing the new rule, HHS insists that it is seeking to clarify key terms in statutes that have been on the books for years—in one case (the Church Amendment), since the early 1970s. In truth, HHS is attempting to redefine many of those terms in order to expand the laws' reach.

For example, the regulations broadly define "assist in the performance" as participating "in any program or activity with an articulable connection" to a given procedure or service. The definition goes on to include several specific examples, including "counseling, referral, training, and other arrangements," and it is so broad as to include the provision of even basic factual information. Similarly, the definition for "referral" encompasses "any information...by any method...that could provide any assistance" to someone seeking care or financing for that care.

The regulations define the actors as broadly as it does the actions. Notably, "workforce" would include not just employees, but also "volunteers, trainees, contractors...and providers holding admitting

privileges." The term "health care entity" would include a wide array of individuals (not just health care professionals, but any personnel) and institutions (not just health care facilities and insurance plans, but also plan sponsors and state and local governments). A "recipient" or "sub-recipient" of federal funds may include not only U.S.-based entities but also "foreign or international organizations (such as agencies of the United Nations)."

All of these definitions get tied together in the rule's expansive definition of "discriminate." Under that definition, in responding to religious or moral objections, government agencies and private institutions would be barred from denying or restricting: grants and contracts; certifications and accreditations; jobs, positions and titles; or any benefits or privileges. The definition of discrimination also includes enacting and enforcing "laws, regulations, policies, or procedures…that tends to subject individuals or entities…to any adverse effect." This definition of discrimination seems to elevate religious and moral objections above all laws and rules.

In all of these cases, HHS is going beyond common understanding of what these terms mean and how they have been interpreted by prior administrations, state officials and the courts over years and, in some cases, decades.

Undermining Patient Protections

The clear intent of HHS's proposed regulations and its attempts to expansively redefine key terms is to allow individuals and institutions claiming religious and moral objections to undermine a wide range of existing patient protections. The examples described below are by no means all-inclusive, and it is impossible to predict all of the potential consequences of the proposed regulations. However, by attacking existing patient protections, HHS is undermining individuals' access to health care information and services, and threatening their health, rights and dignity. With these proposed regulations, HHS is making its priorities clear: If there is ever a conflict between religious and moral objections and patients' health and rights, HHS will always side with religious and moral objections.

Insurance Coverage Requirements

The HHS regulations explicitly target laws in several states (currently, California, New York and Oregon) that require many health insurance plans to cover abortion care. HHS argues that the Obama administration misinterpreted federal law (the Weldon Amendment) by ruling that employers sponsoring health insurance plans for their employees and dependents did not count as health care entities with conscience rights. The proposed regulations overturn that earlier guidance and add plan sponsors to the definition of "health care entities," laying the groundwork for HHS to issue a different ruling and undermine these state laws.

Along the same lines, the new refusal rule could be used to target state-level contraceptive coverage requirements. The Affordable Care Act's contraceptive coverage guarantee has famously generated dozens of lawsuits—several of which reached the U.S. Supreme Court—from employers and schools with religious objections to some or all contraceptive methods. The Trump administration (wrongly, in our view, as expressed in earlier comments to HHS) expanded religious and moral exemptions to this requirement in separate rules last year (currently enjoined), but those rules did not affect state-level requirements. The proposed refusal rule could be used to undermine those state-level requirements, particularly in cases where the plan sponsor wrongly asserts that methods of contraception are actually methods of abortion.

Antiabortion Counseling Centers

As another example of state law purportedly violating federal conscience rights, HHS points to laws requiring antiabortion counseling centers to post factual public notices. For example, California's Reproductive FACT Act requires facilities specializing in pregnancy-related care to post notices about the availability of public programs that provide free or subsidized family planning services, prenatal care and abortion, and for unlicensed facilities to disclose that that they do not provide medical services. By including public notices in the definition of "referral," HHS aims to prevent enforcement of these requirements and to influence ongoing court cases, including one at the U.S. Supreme Court.

Emergency Abortion Care

The HHS regulations also take issue with the idea that health care providers have obligations to patients in emergency circumstances. HHS criticizes an ethics opinion by the American College of Obstetricians and Gynecologists that providers have obligations to provide emergency care, as well as lawsuits brought against hospitals that refused to provide abortion-related information and care in emergency circumstances. HHS's apparent position is that federal refusal laws are not limited by legal or ethical obligations around emergency care.

On a related note, although federal law bars federal dollars from paying for abortions under Medicaid in most circumstances, state Medicaid programs are obligated to cover abortion when a women's life is endangered or in cases of rape or incest. States objecting to that requirement could cite the proposed refusal regulations in refusing to comply.

Counseling and Informed Consent

The HHS regulations are also an attack on patients' right to have the information they need to provide informed consent to care. Health care professionals have ethical and legal responsibilities to provide that information, but the proposed refusal regulations would allow them to deny information and counseling on topics and services they find objectionable—not just on abortion and contraception, but on any topic, such as STI testing and treatment, vaccination, blood transfusion, and end-of-life pain management.

As one specific example, the Title X national family planning program requires that Title X–supported providers must offer factual information and nondirective counseling on any of the full scope of legal pregnancy options, including abortion, as well as referral for any related services upon request. In 2008, when the George W. Bush administration promulgated similar refusal regulations (which were later rescinded), HHS argued explicitly that this Title X requirement would not be enforced for organizations objecting to it, without providing any indication of how patients' right to counseling and referral would be upheld.

The new proposed rules may also apply in the context of HHS-supported adolescent sexual health promotion programs, support services for new parents and other social services programs that provide health-related information or referral. That could allow entities or individual instructors to withhold factual information on contraception, prevention of HIV and other STIs, or other topics, regardless of a given federal grant program's requirements.

Protections Against Discrimination

The proposed regulations have the potential to pit "conscience" rights against anti-discrimination policies set by federal, state and local governments, and individual employers and schools. These laws

and policies vary widely, but are intended to protect patients, students and others against discrimination on the basis of a variety of characteristics, such as race, gender, sexual orientation, immigration status, disability and HIV status. Under the proposed regulations, it is unclear whether and in what circumstances an individual or institution would be allowed to ignore those protective policies and refuse to provide information or services in a discriminatory way. Further, health care entities could be hindered in their efforts to ensure that patients are treated appropriately under federal and state antidiscrimination laws and employers' own antidiscrimination policies.

Groups representing LGBTQ individuals are particularly concerned, because of numerous complaints and lawsuits asserting that protections against discrimination on the basis of sexual orientation or gender identity are in fact violations of religious freedom. For example, HHS specifically criticizes a lawsuit brought against a health care system that denied a hysterectomy to a transgender man, despite regularly performing hysterectomies for other patients. Separately, HHS has also signaled that it will back off from protecting LGBTQ rights under the Affordable Care Act's Section 1557 anti-discrimination provision. LGBTQ individuals, immigrants, people of color, and other groups subject to frequent discrimination, have good reason to view this refusal rule as yet another signal that HHS and the Trump administration more broadly will support and protect those who discriminate under the guise of religious liberty.

Impact on Employers and Public Programs

Currently, Title VII of the Civil Rights Act and related state laws govern religious discrimination in the workplace. Specifically, Title VII requires employers to accommodate an employee's religious practices (such as religious refusals), unless doing so would impose an undue hardship on the employer—something that, in the health care field, would include practices that undermine patient care. This legal standard and examples of how it applies in the health care field have been described in considerable detail by the Equal Employment Opportunity Commission (EEOC), which oversees implementation of Title VII, in the section of its compliance manual related to religious discrimination.

The proposed refusal regulations ignore this legal standard and the balance that it attempts to strike. Without that balance, health care institutions and public programs could be forced accommodate employees who refuse to perform central functions of their job or seek to discriminate against patients. For example, family planning clinics might be forced to employ individuals unwilling to provide, discuss or even schedule appointments for contraception. Hospitals could be forced to hire personnel refusing to honor their patients' end-of-life directives. Pharmacies could be forced to hire clerks refusing to ring up purchases for medications to fight HIV and AIDS. Notably, the Bush administration's similarly expansive refusal rule was opposed by that administration's own EEOC.

For government officials responsible for enacting new laws, promulgating new regulations and administering public programs, the potential consequences of the proposed regulations are severe in additional ways. With its expansive definition of "discrimination," HHS appears to be warning state governments against enacting and enforcing any law that social conservatives might argue is an infringement on their religious liberty. Similarly, HHS is signaling that religious and moral objections can function as a backdoor way to rewrite the rules governing federal and state programs; if a potential grantee objects to a program's requirement, that requirement is essentially null and void.

Impact Beyond the United States

The proposed regulations may pose particular problems for international, foreign and multilateral organizations. The regulations apply long-standing U.S. conscience laws (most notably, part of the

Church Amendment) to organizations outside of the United States in cases where U.S. funding is administered by HHS. In doing so, HHS does not appear to be giving any deference to existing federal law governing U.S. foreign policy, nor to the agencies entrusted to set this policy. This might create confusion among federal agencies about which laws to follow, generate conflict with policies promulgated by the Departments of State and Defense and the U.S. Agency for International Development, and lead to unforeseen foreign policy complications.

Moreover, it is unclear how large international agencies, such as the World Health Organization or the Global Fund to Fight AIDS, Tuberculosis and Malaria, could require, monitor and certify compliance by their numerous local sub-grantees, particularly in cases where U.S. "conscience" laws conflict with the laws of other countries. For example, such other countries' policies may require health care providers to offer referrals in cases of conscientious objection, a requirement that would be unenforceable under these regulations. This has the potential to force such international agencies out of HHS-administered programs altogether.

Potential Impact on Individuals

As described above, the proposed regulations cast doubt on the ability of the federal and state governments to enforce a wide variety of laws that guarantee access to reproductive health services and emergency care, that guide employers on how to address religious discrimination in the workplace, that govern international assistance, and that broadly protect individuals from discrimination. All of this is problematic from the standpoint of individuals who rely on these services and protections.

For example, undermining federal requirements for abortion-related counseling and referral under Title X, and for the limited coverage of abortion under Medicaid, could make it even more difficult for already-marginalized, low-income individuals to obtain needed services. This would further complicate situations that may already be difficult for individuals on a personal level and dangerous to their physical or emotional health. Allowing providers and institutions to ignore ethical and legal requirements to provide abortion-related emergency care can imperil individuals' fertility, long-term health and even their lives.

Similarly, undermining state and federal policies promoting access to contraceptive care could interfere with individuals' ability to use contraceptives consistently and effectively, and thereby increase their risk of unintended pregnancy. This would be particularly likely among low-income individuals who rely on public programs for their coverage and care, and who could struggle to find the resources to pay for contraceptives out-of-pocket, or to shop around for a health plan, hospital or pharmacy willing and able to serve them.

To the extent that the regulations could undermine U.S. international assistance programs, it would be low-income women overseas harmed the most, as they are the primary beneficiaries of a wide variety of the threatened public health programs. If states find themselves uncertain about enforcing their own anti-discrimination laws, LGBTQ individuals, immigrants, people of color and many others could face discrimination from health care providers and institutions.

HHS asserts that the regulations will foster "open and honest communication" between health care providers and patients, yet the regulations in truth undermine that communication. Providers are not

required to even notify patients and employers when they refuse to provide information or services, nor are institutions required to have safeguards in place to protect patients.

Moreover, the proposed regulations harm the provider-patient relationship by undermining informed consent protections, with far-reaching implications for patients. For example, individuals might rely on these regulations to justify their refusal to provide information or counseling about, for example, Pap tests or STI tests—or cervical cancer or STIs themselves—for adolescents or unmarried individuals they believe should be sexually abstinent. The regulations could also be used to justify denying patients information or referral for assisted reproductive technologies to individuals or couples they believe should not be parents because of their marital status, sexual orientation or other characteristics.

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To reiterate, for the reasons detailed above, we urge that this rule be withdrawn. If you need additional information about the issues raised in this letter, please contact Adam Sonfield in the Institute's Washington office. He may be reached by phone at 202-296-4012, or by email at asonfield@guttmacher.org.

Thank you for your consideration.

Sincerely,

Rachel Benson Gold
Vice President for Public Policy

Exhibit 81

HEALTH CARE FOR ALL

www.hcfama.org

One Federal Street
Boston, MA 02110
617.350.7279 **Office**
800.272.4232 **HelpLine**

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, 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:

Health Care For All respectfully submits these comments regarding the proposed rule entitled Protecting Statutory Conscience Rights in Health Care, published January 26.[1] Health Care For All is a non-profit consumer health advocacy organization that promotes health justice by working to reduce disparities and ensure coverage and access for everyone in Massachusetts. We are deeply concerned that the proposed rule will create unnecessary barriers to care for consumers in Massachusetts and across the nation.

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.

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

1. The rule improperly seeks to expand on existing religious refusal exemptions to potentially allow denial of any health care service based on a provider's personal beliefs or religious doctrine.
Existing refusal of care laws (such as for abortion and sterilization services) are already being used across

[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 country to deny patients the care they need.[2] The proposed rule attempts to expand on these laws in numerous ways that are directly contrary to the stated purpose of the existing laws. Specifically, the Department and its Office for Civil Rights (OCR) are attempting to require a broad swath of entities to allow individuals to refuse "*any* lawful health service or activity based on religious beliefs or moral convictions (emphasis added)."[3]

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

We are also concerned about potential enabling of care denials by providers based on their non-scientific personal beliefs about other types of health services. For example, certain religiously-affiliated hospitals and individual clinicians have refused to provide rape victims with emergency contraception to prevent pregnancy[5] based on the belief that it can cause an abortion, even though there is no scientific evidence that this is the case.

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 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.

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

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[2] *See, e.g., Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/; Uttley, L., et al, *Miscarriage of Medicine*, MergerWatch and the ACLU (2013), https://www.aclu.org/report/miscarriage-medicine.
[3] *See* Rule *supra* note 1, at 12.
[4] Hardaway, Lisa, *Settlement Reached in Case of Lambda Legal Lesbian Client Denied Infertility Treatment by Christian Fundamentalist Doctors*, Lambda Legal, September 29, 2009, accessed at https://www.lambdalegal.org/news/ca_20090929_settlement-reached.
[5] Erdely, Sabrina, *Doctors' beliefs can hinder patient care*, SELF magazine, June 22, 2007, accessed at http://www.nbcnews.com/id/19190916/print/1/displaymode/1098/

restrictions can operate to deprive patients of the complete and accurate information necessary to give informed consent."[6]

3. The rule does not address how a patient's needs would be met in an emergency situation.
There have been reported instances in which pregnant women suffering medical emergencies – including premature rupture of membranes (PPROM) and ectopic pregnancies[7] -- 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.

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.[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]

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[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

[8] 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).

[10] 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).

[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*

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

The Proposed Rule generates chaos through its failure to account for existing laws that conflict with the refusals of care it would create. For example, the proposed rule makes no mention of Title VII,[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.

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.[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]

7. 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.[18] One woman experiencing pregnancy complications rushed to the only hospital in her community, a religiously affiliated facility, where she was denied the miscarriage management she needed because the hospital objected to this care.[19] Another woman experiencing pregnancy loss was denied care for 10 days at a religiously affiliated hospital outside Chicago, Illinois.[20] In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital

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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

[13] 42 U.S.C. § 2000e-2 (1964).

[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.*

[16] *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 Catholic Health Care for Women of Color*, Pub. Rights Private Conscience Project 1, 6 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[20] *See* Julia Kaye, et al., *Health Care* Denied, Am. Civil Liberties Union 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

which refused to provide him a hysterectomy.[21] Another patient in Arkansas endured a number of dangerous pregnancy complications and could not risk becoming pregnant again. She requested a sterilization procedure at the time of her Cesarean delivery, but her Catholic hospital provider refused to give her the procedure.[22] Another woman was sent home by a religiously affiliated hospital with two Tylenol after her water broke at 18 weeks of pregnancy. Although she returned to the hospital twice in the following days, the hospital did not give her full information about her condition and treatment options.[23]

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

Refusals of care based on personal beliefs 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.[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]

8. 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

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[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-FS.pdf; Sandhya Somashekhar, *A Pregnant Woman Wanted her Tubes Tied. Her Catholic Hospital Said No.*, WASH. POST (Sept. 13, 2015), https://www.washingtonpost.com/national/a-pregnant-woman-wanted-her-tubes-tied-her-catholic-hospital-said-no/2015/09/13/bd2038ca-57ef-11e5-8bb1-b488d231bba2_story.html?utm_term=.8c022b364b75.

[23] *See* Kira Shepherd, et al., *supra* note 19, at 27.

[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/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.

[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.

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.[30] Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.[31] 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.[32] OCR must work to address these disparities, yet the proposed rule is antithetical to OCR's mission.

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

The proposed rule will have a chilling effect on the enforcement 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 Health Care For All calls on the Department to withdraw the proposed rule in its entirety.

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[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.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.

[32] *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.

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

Exhibit 82

FEDERAL AIDS POLICY PARTNERSHIP
HIV HEALTH CARE ACCESS WORK GROUP

March 26, 2018

Submitted via the Federal e-Rulemaking Portal

Roger Severino
Director, Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: HHS-OCR-2018-0002-0001 proposed rule

Dear Mr. Severino:

We are writing on behalf of the HIV Health Care Access Working Group to urge HHS to uphold its duty to "enhance the health and well-being of all Americans" by withdrawing the proposed rule on "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority. " HHCAWG is a coalition of over 100 national and community-based HIV service organizations representing HIV medical providers, public health professionals, advocates, and people living with HIV who are all committed to ensuring access to critical HIV- and hepatitis C-related health care and support services.

We are deeply concerned that this rule would open the door wider to discrimination by physicians, nurses, and other professionals against people with HIV, people at risk for HIV and LGTBQ individuals. Federal resources must not be used to empower people to deny medical care, especially to those who have few options to obtain it. As HHS acknowledges, current law sufficiently protects the religious rights of providers.

While the stated intent of the proposed rule is to protect health care providers, we are concerned that the ultimate impact of the rule will be to compromise the health of individuals most in need of care, including people at risk for HIV and people living with HIV. Under the guise of civil rights protections, the rule will allow providers to disregard clinical standards of care when it comes to HIV prevention and treatment, putting patient safety and access at risk. Implementing this rule and actively sheltering discriminatory health providers will be a significant setback to progress made in responding to the HIV epidemic.

The stigma and discrimination experienced by people with HIV persists in many facets of their lives including in accessing health care services.[i] Despite the availability of highly effective prevention and treatment tools – 15 percent of people in the U.S. who are living with HIV are undiagnosed and just 50 percent of diagnosed individuals are fully benefiting from treatment (or virally suppressed).[ii] Improving access to effective treatment and increasing the number fully benefiting from treatment is important to

the health of people living with HIV and to reduce the spread of HIV. The risk of transmitting HIV is virtually zero when virally suppressed.

We highlight key areas of concern regarding the potential implications of the proposed rule below.

- **HIV Prevention:** Despite the availability of highly effective prevention tools including pre-exposure prophylaxis or (PrEP) -- a once-a-day pill recommended for individuals at higher risk for HIV – the number of new HIV infections is around 40,000 annually. Allowing providers to ignore CDC clinical guidelines[iii] for use of PrEP and other HIV prevention interventions will hinder our efforts to reduce new HIV infections, particularly for populations most at risk for HIV including gay men and transgender individuals. Individuals who turn to health care providers for HIV and STD testing, PrEP, HIV treatment, or prevention and treatment for any communicable disease, should never be denied access to these services because of a provider's religious beliefs. This is particularly important in underserved areas where health care provider access can be severely limited and travel to other providers can be prohibitive due lack of transportation and/or distance.

- **LGBTQ Care, Particularly Transgender Care**: LGBTQ individuals continue to face significant discrimination and stigma. Ensuring that this population has access to culturally competent and sensitive providers is critical to our efforts to address the HIV-related disparities faced by gay men and transgender individuals.[iv] [v] Transgender individuals in particular are at high risk for HIV and have low rates of health coverage in the U.S.[vi] In many jurisdictions, transgender patients are already denied gender-affirming and medically necessary care. Denying transgender individuals the gender-related medical care they need will lead to fear and distrust of health care providers and of the health care system leaving them even more vulnerable to HIV and less likely to learn they are HIV-positive, to access care, and to effectively manage their HIV. Provider shortages in many areas will leave transgender individuals without viable alternatives for preventive and health care services if their local provider denies care.

- **Women's Health Care**: Women with HIV and all women have a right to reproductive health services including contraception and abortion. Granting health care providers and institutions the right to withhold medical information regarding prevention or treatment options or to deny women these services based on personal religious beliefs puts their health at risk.

For nearly two decades, HHCAWG has been advocating for expanding access to health coverage and health care services for people at risk for HIV and living with HIV to improve their health outcomes and to improve public health. Until recently, many people with HIV and the populations at higher risk for HIV, including gay men and transgender individuals, were denied health care coverage or the coverage available to them was priced out of reach. The Patient Protection and Affordable Care Act's non-discrimination protections (Section 1557) have been critical to improving access to health care coverage and services for people with HIV. However, even with these protections, we continue to see health plans discourage enrollment of people with HIV through discriminatory benefit and formulary designs. These practices have been reported to the HHS Office of Civil Rights (OCR), which is charged with investigating complaints related to these practices. To date, there's little evidence that enforcement of these protections is taking place. We urge OCR to focus its attention on challenging discriminatory practices that are impeding access to health care for people with HIV and others rather than defending health care providers who counter to their pledge to "do no harm" are denying individuals medically appropriate health care services.

We strongly urge HHS not to undermine the current non-discrimination protections that are making a difference in the lives of people at risk for HIV and living with HIV by providing health care providers the license to discriminate against patients based on their religious beliefs. Please withdrawal the proposed rule (HHS-OCR-2018-0002-0001 proposed rule) and commit to monitoring and enforcing existing non-discrimination protections to uphold HHS' mission of improving the health for all Americans, including people living with HIV, LGBT individuals and women.

Should you have any questions or need additional information, please contact HHCAWG co-chairs Robert Greenwald with the Treatment Access Expansion Project at rgreenwa@law.harvard.edu, Amy Killelea with the National Alliance of State and Territorial AIDS Directors at akillelea@NASTAD.org, or Andrea Weddle with the HIV Medicine Association at aweddle@hivma.org.

Respectfully submitted by:

ADAP Educational Initiative |AIDS Alabama | AIDS Action Baltimore | AIDS Alliance for Women, Infants, Children, Youth & Families | AIDS Foundation of Chicago | AIDS Research Consortium of Atlanta | AIDS United | American Academy of HIV Medicine | APLA Health | AIDS Resource Center of Wisconsin | Bailey House, Inc. | Communities Advocating Emergency AIDS Relief (CAEAR) | Community Access National Network (CANN) | Equality California | Equality Federation |Georgia AIDS Coalition | Harm Reduction Coalition | HealthHIV | HIV Medicine Association| Housing Works | Legal Council for Health Justice | Los Angeles LGBT Center |Michigan Positive Action Coalition | Minnesota AIDS Project | National Alliance of State and Territorial AIDS Directors | National Latino AIDS Action Network | NMAC | Out2Enroll | Positive Women's Network - USA| Project Inform | Rocky Mountain CARES | San Francisco AIDS Foundation | SisterLove | Southern AIDS Coalition | Southern HIV/AIDS Strategy Initiative | The AIDS Institute | Treatment Access Expansion Project | Treatment Action Group |

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[i] HIV.gov.Activities Combating HIV Stigma and Discrimination. https://www.hiv.gov/federal-response/federal-activities-agencies/activities-combating-hiv-stigma-and-discrimination. Accessed 3/22/18.

[ii] Centers for Disease Control and Prevention. HIV Continuum of Care, U.S.,2014, Overall and by Age, Race/Ethnicity, Transmission Route and Sex. July 2017.

[iii] CDC.Pre-Exposure Prophylaxis For The Prevention of HIV Infection In The United States - 2014 A Clinical Practice Guideline. https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf.

[iv] CDC. HIV Among Gay and Bisexual Men. https://www.cdc.gov/hiv/group/msm/index.html. Accessed 3/22/18.

[v] Trinh, MH, et al. .Health and healthcare disparities among U.S. women and men at the intersection of sexual orientation and race/ethnicity: a nationally representative cross-sectional study. BMC Public Health. 2017 Dec 19;17(1):964.

[vi] CDC.HIV Among Transgender People. https://www.cdc.gov/hiv/group/gender/transgender/index.html. Accessed 3/22/18.

Exhibit 83

hivma
hiv medicine association

1300 Wilson Boulevard Suite 300 / Arlington, VA 22209
703-299-1215 / f 703-299-8766 / info@hivma.org / www.hivma.org

March 27, 2018

Submitted via the Federal e-Rulemaking Portal

Roger Severino
Director, Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: Proposed Rule Docket ID HHS-OCR-2018-0002-0001

Dear Mr. Severino:

I am writing on behalf of the HIV Medicine Association (HIVMA) regarding the proposed rule on "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority." HIVMA represents more than 6,000 physicians and other health care professionals who provide HIV prevention and care services and conduct research in communities across the United States.

We strongly urge HHS to uphold its mission to "*enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services*" by reconsidering this proposed rule that would allow health care providers and institutions that received federal funding to discriminate against people at risk for HIV, LGBTQ populations, women and countless other Americans.

While we firmly uphold the importance of religious freedom, these rights are clearly enshrined in the Constitution and existing federal law, and the creation of this rule adds nothing to these basic protections. Instead, the rule you propose protects discrimination in the delivery of health care services. Medical providers have a solemn obligation to first do no harm. By allowing the exercise of prejudice, and shielding providers who act on their prejudices, your office is authorizing physicians, nurses, and other professionals to break their oaths to patients. Federal resources should not be used to deny medical care, especially to those who have few options to obtain it. The text of this proposed rule fails to consider the well-documented discrimination and care denial that many have experienced,[1,2] and by the Department's own admission, in cases where a provider has been unnecessarily mistreated due to their religious beliefs, current federal law is sufficient.

While the proposed rule professes to protect health care providers, we are deeply concerned that this rule will jeopardize access to life-saving services for people at risk for HIV and living with HIV. Since HIV was first diagnosed more than three decades ago, the stigma and discrimination experienced by people

with HIV within the health care setting and in communities has prevented them from seeking care and contributed to the challenge we continue to have managing the epidemic despite the availability of highly effective treatment and prevention tools. The Ryan White HIV/AIDS Program was created in 1990 because of the challenges that people with HIV faced accessing care, including stigma and discrimination, and was named in memory of Ryan White for his courage in overcoming the discrimination that he experienced as a 13-year old living with HIV. Decades later, stigma and discrimination against people with HIV and the populations disproportionately affected by HIV including men who have sex with men, people of color and transgender individuals both persist and remain acute especially in certain regions of the country.

People with stigmatized conditions like HIV/AIDS, mental health issues, and substance use disorders face undue burden accessing and paying for health care because of their condition and the health care services they need, as do women and people who are LGBTQ.[3,4,5,6,7] These populations experience greater challenges finding quality and culturally competent health providers in many regions of the country. Implementing this rule and actively sheltering discriminatory health providers will further threaten access to life-saving health services.

For patients accessing therapeutic or preventive HIV care, or patients with HIV who require other life-saving medical procedures, consider the following scenarios in which evidence-based services may be are denied:

- **HIV Prevention:** Among medical providers nationwide, lack of education on scientifically accurate and modern HIV prevention tools such as pre-exposure prophylaxis (PrEP) is already a barrier to accessing them for many people at risk of HIV infection. Health care providers should be required to follow widely accepted care standards including the CDC's clinical guidelines[8] for use of PrEP. The proposed rule may mislead providers into believing that refusal to administer an HIV or STD test, offer sexual risk reduction counseling including recommending condom use, or prescribing PrEP to a gay or bisexual patient is allowable on religious grounds. No individual who seeks prevention or treatment services for any communicable disease should ever be refused treatment by a health care provider based on the provider's religious views.

- **LGBTQ Transgender Care**: LGBTQ individuals continue to face significant discrimination and stigma. Ensuring that this population has access to culturally competent and quality health care services is an essential part of addressing the HIV-related disparities faced by gay men and transgender individuals.[9] [10] Transgender women face the highest rates of HIV and low rates of health coverage in the U.S.[11] In most jurisdictions, transgender patients are already denied gender-affirming and medically necessary care. Denying transgender people the gender-related medical care they need will lead to fear and distrust of health care providers and the health care system, leaving them even more vulnerable to HIV infection and less likely to be diagnosed and effectively managed with HIV treatment. Provider shortages in many areas will leave transgender individuals without viable alternatives for preventive and health care services.

- **Women's Health Care**: All women, including women living with HIV, have a right to reproductive health services including contraception and abortion. Granting health care providers and institutions the right to withhold medical information regarding prevention or treatment options or to deny women these services based on personal religious beliefs puts their health at risk. In addition, denial of contraceptive services to women with HIV could lead to an increase in the rate of perinatal HIV infection, which we seek to eliminate in the U.S.

- **Refusal to Treat**: While there have been improvements in some parts of the country, for decades people with HIV have been refused medical treatment by specialists. While this behavior is illegal under the Americans with Disabilities Act, the Department of Justice and HHS Office for Civil Rights continue to prosecute cases of medical discrimination against people with HIV today.[12,13] The proposed rule's reinterpretation and broadening of the longstanding legal interpretation of section (d) of the Church Amendment opens the door to justify discrimination by health care providers. While discriminating against patients with HIV is wholly unlawful, any delay or outright denial of care to people with HIV is detrimental to the health of individuals and their communities.

Even if these scenarios are unintended by the proposed rule, the language will be interpreted by some medical providers as granting them protection if they elect to deny patients these services, and patients will have little recourse to challenge these actions. The patient's health, trust in the healthcare system, and relationship with medical providers are could be irrevocably damaged. The aggregate cost of these damages over time will be detrimental to our nation's public health, and will actively obstruct our efforts to end the domestic HIV epidemic.

The foundation for medical decisions—no matter who you are or where you live—must continue to be based on sound, scientific practice and not health care providers' personal beliefs. HIVMA strongly urges withdrawal of the proposed rule. Its adoption will be a major setback for the progress made in addressing HIV and other public health crises. We would be happy to discuss this issue further with you. Please contact HIVMA's Senior Policy and Advocacy Manager, George Fistonich, at gfistonich@hivma.org with questions regarding our comments.

Sincerely,

Melanie Thompson

Melanie Thompson, MD
Chair, Board of Directors

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

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[3] National Women's Law Center. 2014. Health Care Refusals Harm Patients: The Threat to LGBT People and Individuals Living with HIV/AIDS. https://nwlc.org/wp-content/uploads/2015/08/lgbt_refusals_factsheet_05-09-14.pdf.

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[6] Lopez K, Reid D. Discrimination Against Patients With Substance Use Disorders Remains Prevalent And Harmful: The Case For 42 CFR Part 2. Health Affairs Blog, April 13, 2017. DOI: 10.1377/hblog20170413.059618.

[7] Knaak S, Mantler E, Szeto A. 2017. Mental illness-related stigma in healthcare: Barriers to access and care and evidence-based solutions. Healthcare Management Forum, 30(2), 111–116. http://doi.org/10.1177/0840470416679413.

[8] CDC. Pre-Exposure Prophylaxis For The Prevention of HIV Infection In The United States - 2014 A Clinical Practice Guideline. https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf.

[9] CDC. HIV Among Gay and Bisexual Men. https://www.cdc.gov/hiv/group/msm/index.html. Accessed 3/22/18.

[10] Trinh, MH, et al. .Health and healthcare disparities among U.S. women and men at the intersection of sexual orientation and race/ethnicity: a nationally representative cross-sectional study. BMC Public Health. 2017 Dec 19;17(1):964.

[11] CDC.HIV Among Transgender People. https://www.cdc.gov/hiv/group/gender/transgender/index.html. Accessed 3/22/18.

[12] United States Department of Justice, Civil Rights Division. DOJ HIV/AIDS Enforcement: Settlement Agreements, Consent Decrees and Letters of Finding. https://www.ada.gov/hiv/ada_aids_enforcement.htm

[13] United States Department of Health and Human Services, Office for Civil Rights. Case Examples: Civil Rights Enforcement Examples Involving HIV/AIDS. https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/examples/aids/index.html.

Exhibit 84

RE: Proposed Regulation, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03

Dear HHS Office of Civil Rights,

As a healthcare provider, I am in full agreement with our professional standards that put the care of patients first, ensuring equal and quality care for all. But the proposed HHS rule, titled "Protecting Statutory Conscience Rights in Health Care," would allow healthcare providers and institutions to discriminate on the basis of moral and religious objections, placing vulnerable populations such as LGBTQ individuals and people living with HIV at risk of being denied necessary and even life-saving care. By allowing discrimination against patients on the grounds of moral and religious objections, the proposed rule obviates the ethical standards that healthcare professionals are charged to uphold.

Research shows that LGBTQ people, especially transgender individuals and people of color, people with disabilities, and lower income populations face significant discrimination and barriers to quality care. The proposed regulation will lead to increased discrimination and flat-out denials of care for some of the most vulnerable members of our community by expanding religious exemptions in a way that could result in dangerous denials of medically necessary and life-saving care. Additionally, the proposed regulation lacks safeguards to protect patients should they be denied care on the basis of religious beliefs. In extending religious accommodations, there should be an equal extension of protections to ensure all patients receive clinically and culturally competent care. LGBTQ and all Americans deserve better.

Many of our patients at Howard Brown Health—who identify as LGBTQ, are living with HIV, women, street based youth, people with low-income, to name a few—often come to our clinics as a result of having experienced care elsewhere that is not affirming of their identities or responsive to their needs. Howard Brown serves nearly 30,000 patients in the Chicago area annually; these patients seek care that will not only be tolerant but affirming. This proposed rule wills only exacerbate the stigma already faced by our patients and community, moving us backward from establishing systems of care that are affirming to systems that are intolerant and fuel stigma. This rule could effectively make it even harder for our patients to access their (often lifesaving) healthcare, healthcare that we consider a human right.

The proposed rule presents a direct conflict with nondiscrimination standards adopted by the Joint Commission and all the major health professional associations who have recognized the need to ensure LGBTQ patients are treated with respect and without bias or discrimination in hospitals, clinics and other healthcare settings. Along with many other healthcare providers and professionals, I oppose this proposed regulation. Promoting discrimination on the basis of moral and religious beliefs is wrong, and will harm millions of Americans in accessing medically necessary and life-saving healthcare.

Sincerely,

David E. Munar, CEO
Howard Brown Health
4025 N Sheridan Rd
Chicago, IL 60613

Exhibit 85

HUMAN
RIGHTS
CAMPAIGN

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

To Whom It May Concern:

On behalf of the Human Rights Campaign's more than three million members and supporters nationwide, I write in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26. As the nation's largest organization working on behalf of lesbian, gay, bisexual, transgender, and queer (LGBTQ) people, we are deeply troubled by the likely impact of the proposed regulation on LGBTQ people—who already face significant barriers to accessing quality healthcare. The proposed regulation sets forth a problematic standard that prioritizes individual providers' beliefs ahead of patient health and well-being. As proposed, this regulation adopts an overly expansive interpretation of existing conscience protections that will undoubtedly empower healthcare providers to deny life-saving care to some of the most vulnerable patients.

The Proposed Regulation is Overly Broad and Fails to Address the Impact on Vulnerable Health Minorities, Including LGBTQ People.

Discrimination against LGBTQ People is Real and Causes Irreparable Harm.

LGBTQ patients face an increased risk of discrimination at the hands of healthcare providers. Numerous surveys, studies, and reports have documented the widespread extent of the discrimination faced by LGBT individuals and their families in the health care system. One

nationwide study found that 56 percent of lesbian, gay, and bisexual (LGB) respondents and 70 percent of transgender respondents reported experiencing discrimination by health care providers, including providers being physically rough or abusive, using harsh or abusive language, or refusing to touch them.[1] In the same study, 8 percent of LGB respondents and 27 percent of transgender respondents reported being refused necessary medical care outright.[2] Similarly, the 2015 National Transgender Discrimination Survey found that 33 percent of respondents had negative experiences when seeing a health care provider in the past year.[3] The survey also found that respondents were three times more likely to have to travel more than 50 miles for transgender-related care than for routine care.[4]

Beyond each of these numbers is an individual story – and too often a nightmare. The Human Rights Campaign gathered over 13,000 individual comments and stories in response to the Department's request for public comment regarding the proposed regulation implementing Section 1557 of the Affordable Care Act. Thousands of our members shared personal, heartbreaking stories of discrimination and denial when seeking healthcare. Our members recounted incidents of hostility including homophobic statements, intrusive and unnecessary questioning, and unwarranted physical removal of a same-sex partner from a doctor's visit. One of the most common stories of hostility and harassment reported by our members in their public comments included unwanted proselytizing by hospital or clinic staff. Unwanted proselytizing is a distinct form of bullying. It undermines patient care and can prevent individuals from seeking much needed care in the future.

Amongst the thousands of stories we received, many members shared stories of outright denial of care. For example, a nurse assigned to care for an elderly gay man in an assisted living facility refused to bath him or provide the necessary day-to-day care that he needed and deserved simply because he was gay. We have also received calls from individuals who have been denied access to treatment because they are in a same-sex couple. In one particular instance two nurses serving in the military and stationed in Missouri had been denied fertility treatment by every local clinic and by the military hospital because of their sexual orientation. The couple was forced to drive five hours round trip to a clinic in another city to receive treatment. This denial of care was not only a threat to their dignity, but required a costly and time-consuming alternative.

HHS has Consistently Found LGBTQ People to be Vulnerable to Discrimination

For almost a decade HHS has consistently considered LGBTQ people to be a health disparity population for purposes of HHS-funded programs and services. Healthy People 2020 provides

[1] Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People*
[2] *Id.*
[3] S.E. James, C. Brown, & I. Wilson, *2015 U.S. Transgender Survey*, 97 (National Center for Transgender Equality 2017).
[4] *Id.* at 98.

that, "Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion."[5] The Healthy People report provides science-based national objectives designed to improve the health of every American.[6] One of the five core missions detailed by the initiative is to identify critical research areas and data collection needs and opportunities.[7] Healthy People 2020 specifically provides that recognizing the impact of social determinants on health – which include factors like sexual orientation and gender identity – is essential to improving the health and well-being of the nation.[8]

The National Institutes of Health has also formally designated sexual and gender minorities as a health disparity population for purposes of NIH research.[9] The term "sexual and gender minorities" includes lesbian, gay, bisexual, transgender, and queer people.[10] This designation recognizes the devastating health disparities facing LGBTQ people across the nation and the need for a concerted federal research response. In announcing this designation NIH provided that, "mounting evidence indicates that SGM populations have less access to health care and higher burdens of certain diseases, such as depression, cancer, and HIV/AIDS."[11]

The proposed rule is silent as to how hospitals should navigate the impact of the proposed "protections" on patient care, including the anticipated increase in discriminatory denials. The absence of any protections for vulnerable populations, including those who are LGBTQ, is a marked departure from longstanding HHS policies regarding patient care and access.

LGBTQ People will be Disparately Impacted by the Proposed Regulation's Expansive Interpretation of Conscience Laws

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 interpretation that

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[5] Healthy People 2020, *Disparities*, https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities (last visited Mar. 26, 2017).
[6] Healthy People 2020, *About Healthy People*, https://www.healthypeople.gov/2020/About-Healthy-People (last visited Mar. 26, 2017).
[7] *Id.*
[8] *Disparities*, https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities (last visited Mar. 26, 2017).
[9] Eliseo J. Pérez-Stable, M.D., *Director's Message: Sexual and Gender Minorities Formally Designated as a Health Disparity Population for Research Purposes*, National Institute on Minority Health and Health Disparities (Oct. 6, 2016) https://www.nimhd.nih.gov/about/directors-corner/message.html.
[10] *Id.*
[11] *Id.*

goes far beyond what longstanding legal tradition and public policy understanding have understood 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."[12] Even though longstanding legal interpretation has applied 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.[13]

Doctors may be misled into believing they may refuse 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.[14] 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

[12] 42 U.S. Code § 300a–7(d).
[13] Sharita Gruberg and Frank J. Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial*, Center for American Progress (Mar. 7, 2018) https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/.
[14] *Id.*

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 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 ensure 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.

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.

The Proposed Regulation Will Undermine Hospital and Provider Autonomy as Centers of Care and as Private Employers.

Over the past decade, many hospitals and health systems have followed the recommendations of major accrediting bodies including the Joint Commission and have taken significant steps to ensure that LGBTQ patients receive consistent, quality, culturally competent care. Hospitals and health systems have trained staff, developed nondiscrimination patient and personnel policies, and have made other structural changes to ensure that facilities are welcoming. However, the proposed regulation could cause these hospitals and organizations to feel restricted in their ability to create inclusive and welcoming environments for both their staff, as well as their patients. The proposed regulation may empower staff to deny to provide services beyond the scope of existing law. Many hospitals facing the threat of a costly federal complaint and

investigation process may acquiesce to even unnecessary denials in order to avoid an investigation regardless of the merit of the complaint.

The proposed regulation also interferes with hospital and health systems' personnel decisions. Title VII requires employers to reasonably accommodate the sincerely-held religious beliefs, observances, and practices of its applicants and employees, when requested, unless the accommodation would impose an undue hardship on business operations.[15] This is defined as more than a de minimis cost. The proposed regulation fails to mention Title VII and the balancing of employee rights and provider hardships. The Equal Employment Opportunity Commission (EEOC) addressed this problematic intersection in its public comment in response to the 2008 regulation that had the substantively identical legal problem, noting that "Introducing another standard under the Provider Conscience Regulation for some workplace discrimination and accommodation complaints would disrupt this judicially-approved balance and raise challenging questions about the proper scope of workplace accommodation for religious, moral or ethical beliefs."[16] In this public comment the EEOC concluded that, "Title VII should continue to provide the legal standards for deciding all workplace religious accommodation complaints. HHS's mandate to protect the conscience rights of health care professionals could be met through coordination between EEOC and HHS's Office for Civil Rights, which have had a process for coordinating religious discrimination complaints under Title VII for over 25 years."[17]

Conditions for Federal Healthcare Funding Must be Grounded in Promoting Health Outcomes

"Enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services."[18] This is the mission statement that HHS asserts drives its programs, policies, and in turn this regulation. Conditions of receipt of funding for participation in HHS programs are routinely patient centered. The Conditions of Participation (CoPs) that guide the Medicare and Medicaid programs directly address patient care including infection control, nurse-bed ratios, and staffing requirements. Grant programs operated through HHS condition funding on beneficiary well-being and service delivery. For example, organizations receiving funding to serve runaway and homeless youth must certify that they are appropriately training staff to best meet the needs of youth. Domestic violence shelters receiving HHS grants must take steps to keep their delivery of services confidential to protect survivors. Patients and

[15] Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e.
[16] Letter in response to request for public comment from Reed L. Russell, Legal Counsel, EEOC, to Brenda Destro, Department of Health and Human Services (Sept. 24, 2008) https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html.
[17] *Id.*
[18] Department of Health and Human Services, *Mission Statement*, https://www.hhs.gov/about/strategic-plan/introduction/index.html (last visited Mar. 26, 2017).

beneficiaries are at the center of these conditions. Holding organizations and hospitals accountable for delivering quality, accessible services and care is essential.

The proposed regulation offers no quantifiable description of a direct patient benefit. In fact, of the 216 page proposed rule, HHS dedicates a mere three paragraphs to what it describes as "ancillary" benefits to patients.[19] Webster's Dictionary defines "ancillary" as "subordinate," or "placed in or occupying a lower class, rank, or position: inferior."[20] We believe this description to be troublingly accurate. One of these inferior patient benefits includes the ability to seek health care providers who share a patient's deepest held beliefs—asserting that this will strengthen the doctor-patient relationship. The proposed regulation provides that "open communication in the doctor-patient relationship will foster better over-all care for patients. . . Facilitating open communication between providers and their patients also helps to eliminate barriers to care, particularly for minorities."[21] We could not agree more. However, as proposed the regulation does nothing to improve communication between patients and doctors, and will in fact dramatically undermine the relationship for any patient wary of discrimination. While the insertion of a physician's personal religious belief within the healthcare relationship might be welcome by some, it will come at a devastating cost to a myriad of vulnerable and traditionally underserved communities.

Studies already show that fear of discrimination causes LGBTQ people to delay or wholly avoid necessary care – even in an emergency. The proposed regulation requires that entire facilities be put on notice that a range of health care workers can deny care based on their own moral or religious beliefs. As a result, the proposed regulation also puts many patients on notice that if they are honest and open about critical clinical factors including their medical history, behavior, and even marital status and family structure that they can be turned away from care. For communities with long histories of discrimination, like the LGBTQ community, the proposed regulation's so-called "protections" will do nothing to promote open doctor-patient relationships. Instead, they provide a concrete, federally sanctioned requirement that may necessitate that they hide their own identities to get critical care.

The proposed regulation boldly asserts that it will "generate benefits by securing a public good—a society free from discrimination, which permits more personal freedom and removes unfairness."[22] The Human Rights Campaign and our members work every day to create such a society. This is why we must oppose this regulation in its entirety.

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[19] Protecting Statutory Conscience Rights in Health Care, 83 Fed. Reg. 18, 3916 (proposed Jan. 26, 2018).
[20] *Ancillary*, Merriam-Webster.com. Accessed March 26, 2018. https://www.merriam-webster.com/dictionary/ancillary.
[21] Protecting Statutory Conscience Rights in Health Care, 83 Fed. Reg. at 3917.
[22] *Id.* at 3916.

Exhibit 86

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HUMAN RIGHTS WATCH

HRW.org

March 27, 2018

Secretary Alex Azar
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW., Room 445-G
Washington, DC 20201

RE: Proposed Rule on Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Secretary Azar,

Human Rights Watch opposes the Proposed Rule on Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (83 Fed. Reg. 3880). The proposed rule would dramatically expand the discretion that religious or moral objectors have to refuse care in healthcare settings without any meaningful safeguards to ensure that the rights and health of others are protected. The rule would function not only as a shield for people asserting objections on religious or moral grounds but also as a sword that permits them to withhold care from women; lesbian, gay, bisexual, and transgender (LGBT) people; and others.

The proposed rule fails to appreciate the significant barriers that women, LGBT people, and others already face when attempting to access health care that meets their needs, and the likelihood that the rule would exacerbate those barriers and prevent people from accessing care. The rule codifies vague, open-ended definitions that would permit unfettered discrimination in healthcare settings. And it breaks from a long tradition of religious or moral exemptions under domestic and international law by providing blanket protection for religious exercise without any mechanism to ensure that the rights and health of others are not jeopardized as a result.

I. Women and LGBT People Already Face Barriers to Care

Under Executive Order 13563, the Department of Health and Human Services may only propose a rule where it has made a reasoned determination that the rule's benefits outweigh its costs and it is

tailored to impose "the least burden on society."[1] However, the proposed rule fails to incorporate an understanding of the barriers that women and LGBT people already face in accessing care and the ways in which the proposed rule could exacerbate health disparities.

Women face significant barriers in access to health care, particularly reproductive health services. Despite significant increases in the number of women with health insurance as a result of the Affordable Care Act, women are less likely than men to be insured through an employer and more likely to be insured as a dependent of another family member.[2] This leaves women more vulnerable to a loss of insurance if they become widowed or divorced, or if their spouses lose insurance. One in ten women have no health insurance, and uninsured women have poorer access to care and lower rates of use of important preventative services, such as mammograms, pap smears, and contraceptive services.[3] Low-income women, women of color, and immigrant women are at greatest risk of being uninsured.[4] An estimated 1.1 million women in states that have not expanded Medicaid under the Affordable Care Act fall into the "coverage gap" between being eligible for Medicaid and qualifying for subsidies for private insurance. Another 1.5 million undocumented women are uninsured and ineligible for either Medicaid or private insurance coverage.[5]

For women who do have health insurance, the Affordable Care Act prohibits discrimination by healthcare and insurance providers on the basis of sex, and requires coverage for key women's health services, such as preventative screenings for breast and cervical cancer, contraception, maternity care, and breastfeeding support services.[6] The proposed rule fails to indicate how the anti-discrimination and substantive coverage provisions of the ACA would be balanced against claims for religious or moral exemptions. This creates a dangerous ambiguity that could undermine the ACA's anti-discrimination provisions.

There are also significant challenges in access to constitutionally-protected abortion services, particularly for low-income women and women of color. Poor women are five times more likely than higher income women to have an unintended pregnancy, and rates of unintended pregnancy among women of color are more than twice the

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[1] 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 (accessed March 26, 2018).

[2] Henry J. Kaiser Family Foundation, "Women's Health Insurance Coverage," https://www.kff.org/womens-health-policy/fact-sheet/womens-health-insurance-coverage-fact-sheet/ (accessed March 26, 2018).

[3] Ibid.

[4] Ibid.

[5] Ibid.

[6] Usha Ranji, Alina Salganicoff, Laurie Sobel & Caroline Rosenzweig, "Ten Ways That the House American Health Care Act Could Affect Women," Henry J. Kaiser Family Foundation, May 8, 2017, https://www.kff.org/womens-health-policy/issue-brief/ten-ways-that-the-house-american-health-care-act-could-affect-women/#Essential (accessed March 26, 2018).

rates for white women; the federal ban on funding for Medicaid coverage for abortions contributes significantly to these disparities.[7] Current US law provides extensive grounds for religious and conscience-based objection to abortion and abortion related services, including the Church Amendment, the Coats-Snowe Amendment, the Weldon Amendment, the Medicaid or Medicare Conscience Protections, and the Affordable Care Act Conscience and Religious Exemption Laws.[8] Rule proponents have produced no compelling evidence of the necessity of supplementing these provisions. Furthermore, the proposed rule may risk further limiting access to abortion services and exacerbate existing racial and socio-economic health disparities. It does not appear that these possible harms have been seriously considered in formulating the rule.

LGBT people also face significant disparities in access to health care, with LGBT individuals twice as likely to be uninsured than their non-LGBT counterparts.[9] Moreover, discrimination in healthcare settings is problematic; in 2010, more than half of LGBT people surveyed by Lambda Legal reported a discriminatory experience while seeking healthcare services.[10] Transgender individuals in particular experience high levels of discrimination. In a 2017 survey, nearly 1 in 3 reported denial of health care on the basis of their gender identity.[11]

Congress has not enacted explicit federal non-discrimination protections for LGBT people, and fewer than half of the states offer such protection. In this environment, broad and vaguely worded religious exemption laws threaten to increase discrimination on the basis of sexual orientation and gender identity. In numerous states that have recently passed religious exemption laws without adequate protection against discrimination, Human Rights Watch has documented discriminatory denials of health care and services to LGBT people.[12] According to

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[7] American Public Health Association, "Restricted Access to Abortion Violates Human Rights, Precludes Reproductive Justice, and Demands Public Health Intervention," November 3, 2015, https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2016/01/04/11/24/restricted-access-to-abortion-violates-human-rights (accessed March 26, 2018).

[8] 42 USC 300-a(7); 42 USC 238(n); Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, Tit. V, sec. 507(d); 42 U.S.C. 18023(c)(2)(A)(i)-(iii), (b)(1)(A) and (b)(4); 42 U.S.C. 1395w-22(j)(3)(B) and 1396u-2(b)(3)(B).

[9] Kellan Baker and Laura E. Durso, "Why Repealing the Affordable Care Act is Bad Medicine for LGBT Communities," Center for American Progress, March 22, 2017, https://www.americanprogress.org/issues/lgbt/news/2017/03/22/428970/repealing-affordable-care-act-bad-medicine-lgbt-communities/ (accessed March 26, 2017).

[10] Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination Against LGBT People and People with HIV*, 2010, https://www.lambdalegal.org/publications/when-health-care-isnt-caring (accessed March 26, 2018).

[11] Shabab Ahmed Mirza & Caitlin Rooney, "Discrimination Prevents LGBTQ People from Accessing Health Care," Center for American Progress, January 18, 2018, https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/ (accessed March 26, 2018).

[12] Human Rights Watch, "*All We Want is Equality": Religious Exemptions and Discrimination against LGBT People in the United States*, February 19, 2018, https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people.

Lambda Legal: "In the health care field, where patients are especially vulnerable, religion-based harassment and refusals of medically necessary care have been a persistent, profoundly harmful problem."[13] People living with HIV also continue to face discrimination in healthcare settings; as recently as December 2017 the Department of Justice reached a settlement under the Americans with Disabilities Act against a surgeon in Ohio who refused care on the basis of the claimant's HIV status.[14] In many of the countries where HHS implements global HIV/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.[15] The proposed rule lacks consideration of existing anti-LGBT and HIV-related discrimination in health care and contains no mechanism for avoiding or reducing potential harm.

The complaints received by the Office of Civil Rights (OCR) suggest that civil rights violations in health care are far more common than religious liberty violations. Between November 2016 and January 2018, OCR received 34 complaints alleging violations of federal laws permitting religious refusals; from the fall of 2016 to the fall of 2017, OCR received more than 30,000 complaints alleging HIPAA or civil rights violations.[16] While Human Rights Watch recognizes that violations of religious freedom are a significant and valid concern, HHS has not demonstrated that existing safeguards are insufficient to protect religious objectors; that the benefits of broader exemptions outweigh the costs they will impose; or that the proposed rule is tailored to impose the least burden on society.

As detailed below, Human Rights Watch believes the proposed rule would embolden providers to discriminate against women, LGBT people, and others based on their religious beliefs. Worse, it would do so at a time when HHS has weakened access to contraceptive services under the Affordable Care Act (ACA);[17] removed online

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[13] Lambda Legal, "Trump Administration Plan to Expand Religious Refusal Rights of Health Professionals: Legal Issues and Concerns," https://www.lambdalegal.org/health-care-analysis (accessed March 26, 2018).

[14] Settlement Agreement between the United States of America and Advanced Plastic Surgery Solutions under the Americans with Disabilities Act, December 6, 2017, https://www.ada.gov/adv_plastic_surgery_sa.html (accessed March 26, 2018).

[15] See Henry J. Kaiser Family Foundation, "The Mexico City Policy: An Explainer," June 1, 2017, https://www.kff.org/global-health-policy/fact-sheet/mexico-city-policy-explainer/ (accessed March 26, 2018).

[16] US Department of Health and Human Services, "FY 2019 Budget in Brief," February 19, 2018, https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf (accessed March 26, 2018) p. 124.

[17] Human Rights Watch, "Human Rights Watch Comment on Interim Final Rule on Moral Exemptions and Accommodations Under the ACA," December 5, 2017, https://www.hrw.org/news/2017/12/05/human-rights-watch-comment-interim-final-rule-moral-exemptions-and-accommodations-0.

resources for lesbian and bisexual women;[18] and intends to roll back protections for transgender people under Section 1557 of the ACA.[19]

II. The Proposed Rule Represents a Troubling Expansion of the Scope of Religious and Moral Exemptions

While the proposed rule purports to clarify federal law, it redefines key terms in ways that would significantly broaden the scope of religious and moral exemptions. In the absence of any protections that might mitigate harm, these redefinitions risk greatly exacerbating the discrimination and barriers to access women and LGBT people already experience. Among the definitions that give cause for concern are the following:

- The proposed rule broadens the definition of the term "entity" to encompass the definition of "person" in 1 U.S.C. 1, which includes "corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals."[20]
- The proposed rule broadens the definition of the term "health care entity" with an illustrative, non-exhaustive list of providers, leaving little clarity about the scope of the exemptions that could be claimed under the proposed rule and providing little guidance for providers and patients alike.[21]
- The proposed rule broadens what it means to "assist in the performance of" a healthcare service, permitting anyone with an "articulable connection" to the healthcare service they consider objectionable – instead of a "direct connection" – to decline to participate. The expanded definition would allow objectors, including administrative or technical personnel, to refuse to perform a task because they can identify some connection, no matter how attenuated, to a service they consider objectionable.[22] For example, a hospital room scheduler could refuse to book a room or a technician could refuse to clean surgical instruments for procedures they consider objectionable.
- The proposed rule allows exemptions from a broad range of referral requirements, defining "referral" or "refer for" to include the provision of basic information about a healthcare service, activity, or procedure.[23]

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[18] Dan Diamond, "HHS Strips Lesbian, Bisexual Health Content from Women's Health Website," *Politico*, March 21, 2018, https://www.politico.com/story/2018/03/21/hhs-strips-lesbian-bisexual-health-content-from-womens-health-website-430123 (accessed March 26, 2018).

[19] National Center for Transgender Equality, "Trump Administration Says It Will Try to Legalize Anti-Transgender Discrimination in Health Care," May 2, 2017, https://transequality.org/press/releases/trump-administration-says-it-will-try-to-legalize-anti-transgender-discrimination-in (accessed March 26, 2018).

[20] Rule at 56. For the broader definition of "person," see 1 U.S.C. 1.

[21] Rule at 58-59.

[22] Rule at 52.

[23] Rule at 63-66.

At the same time, the proposed rule does not define key terms like "religious beliefs," "moral convictions," or "moral or religious grounds." This gives objectors virtually unfettered discretion to couch any refusal in moral or religious terms.

These drastic expansions of existing law could come at a cost to patients, and the rule fails to consider this. Human Rights Watch research has documented how recent religious exemptions jeopardize the health of women and LGBT people.[24] In some instances, these exemptions are invoked to justify discrimination and refuse service to individuals seeking care. Even before refusals occur, however, sweeping religious or moral exemptions put women and LGBT people on notice that they may be turned away or discriminated against, deterring them from seeking care at all.

III. The Proposed Rule Lacks Safeguards to Protect Patients

The prevalence of discrimination against women and LGBT people in health care and the sheer breadth of the proposed rule put the rights of patients at risk. These harms are exacerbated by the lack of safeguards in the proposed rule, which breaks from the US' traditional approach towards religious exemptions.

The proposed rule fails to account for the adverse impact that religious or moral refusals may have on the state's interests or the rights of others – something that has generally been a core element of religious and moral exemptions under US law.

Under international law, religious freedom protections have distinguished between the freedom of religious belief, which is inviolable, and the freedom of religious exercise, which may be limited when it infringes upon the rights of others or the state's interests. While federal law frequently collapses the distinction between religious belief and religious exercise, exemptions have typically contained some mechanism to balance protections for conscience with the state's interests, including its protection of the rights of other people.[25] The proposed rule not only fails to distinguish between belief and exercise, but does not give any explicit weight whatsoever to the rights of others or state interests.

In addition, the proposed rule does not include safeguards to minimize the harm inflicted on those who are denied service or turned away. It does not require healthcare facilities to ensure that, when a provider has an objection, a non-

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[24] Human Rights Watch, *"All We Want is Equality": Religious Exemptions and Discrimination against LGBT People in the United States*, February 19, 2018, https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people.

[25] See, for example, Title VII, which requires employers to reasonably accommodate employees' religious beliefs – including in healthcare settings – unless the accommodation would impose an 'undue hardship' on the employer. The Religious Freedom Restoration Act, which prohibits the government from substantially burdening religious exercise but allows such restrictions where the burden is the least restrictive means necessary to advance a compelling governmental interest. 42 U.S.C. 2000bb et seq.

objecting provider is available to offer the service in their stead. It does not require healthcare facilities to refer patients to another healthcare facility where they can obtain the treatment or services they seek or provide information about their options.

IV. Rights at Stake

a. Right to Health

Under international law, everyone has the right "to the enjoyment of the highest attainable standard of physical and mental health" without discrimination on the basis of sex, age, or other prohibited grounds.[26] The right to health is also inextricably linked to provisions on the right to life and the right to non-discrimination that are included in the International Covenant on Civil and Political Rights (ICCPR), which the US has ratified.[27]

The Committee on Economic, Social and Cultural Rights, the body charged with interpreting and monitoring the implementation of the ICESCR, has identified four essential components to the right to health: availability, accessibility, acceptability and quality.[28] Even though the US is not a party to the ICESCR, the Committee's interpretation represents a useful and authoritative guide to the steps governments should take to realize and protect the right to health and other human rights. The proposed rule will reduce the availability and accessibility of healthcare services, particularly sexual and reproductive healthcare services, in communities across the US.

Sexual and reproductive health and rights are addressed specifically in a number of international treaties and other authoritative sources.[29] Article 12 of the Convention

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[26] The US has signed, but not ratified, the ICESCR and as such is not legally bound by its provisions. It does, however, have an obligation not to take actions that would undermine the object and purpose of the treaty. International Covenant on Economic, Social and Cultural Rights (ICESCR), adopted December 16, 1966, G.A. Res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 49, U.N. Doc. A/6316 (1966), 993 U.N.T.S. 3, entered into force January 3, 1976, art. 12(1).

[27] International Covenant on Civil and Political Rights (ICCPR), adopted December 16, 1966, G.A. Res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 52, U.N. Doc. A/6316 (1966), 999 U.N.T.S. 171, entered into force March 23, 1976, ratified by the United States on June 8, 1992, art. 10.

[28] Committee on Economic, Social and Cultural Rights (CESCR), "Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights," General Comment No. 14, The Right to the Highest Attainable Standard of Health, E/C.12/2000/4 (2000), http://www.refworld.org/pdfid/4538838d0.pdf (accessed March 26, 2018), para. 12.

[29] In the 1994 Cairo Programme of Action on Population and Development, delegates from governments around the world pledged to eliminate all practices that discriminate against women and to assist women to "establish and realize their rights, including those that relate to reproductive and sexual health." In the 1995 Beijing Declaration and Platform for Action, delegates from governments around the world recognized that women's human rights include their right to have control over and decide freely and responsibly on matters related to their sexuality free of coercion, discrimination, and violence. See United Nations, *Programme of Action of the United Nations International Conference on Population and Development* (New York: United Nations Publications, 1994),

on the Elimination of Discrimination Against Women (CEDAW) provides that "[s]tates parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services [...]."[30] The US has signed, but not ratified, CEDAW. The CEDAW Committee in its General Recommendation 24 affirmed states parties' obligation to respect women's access to reproductive health services and to "refrain from obstructing action taken by women in pursuit of their health goals."[31] As with the ICESCR, even though the US is not a party to CEDAW, the Committee's interpretation represents a useful and authoritative guide to the steps governments should take to realize and protect the range of human rights addressed under the Convention.

b. Right to Information

The right to information is set forth in numerous human rights treaties.[32] CEDAW asserts that states should provide women "[t]he same rights to decide freely and responsibly on the number and spacing of their children and to have access to the information, education and means to enable them to exercise these rights."[33] The ICESCR obliges state parties to provide complete and accurate information necessary for the protection and promotion of rights, including the right to health.[34] Furthermore, the CESCR Committee in its General Comment 14 has stated that the right to health includes the right to health-related education and information, including on sexual and reproductive health.[35] The CEDAW Committee has also noted that, under article 10(h) of CEDAW, women must have access to information about contraceptive measures, sex education and family-planning services in order to make informed decisions.[36]

The proposed rule expands existing protections to allow providers to decline to provide information they deem morally or religiously objectionable to their patients, while doing nothing to ensure that those patients have reliable alternative routes to secure that information. Denying medically accurate information to patients leaves

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A/CONF.171/13, 18 October 1994, para. 4.4(c) and United Nations, *Beijing Declaration and Platform for Action* (New York: United Nations Publications, 1995), A/CONF.177/20, 17 October 1995, para. 223.

[30] Convention on the Elimination of All Forms of Discrimination against Women (CEDAW), adopted December 18, 1979, G.A. res. 34/180, 34 U.N. GAOR Supp. (No. 46) at 193, U.N. Doc. A/34/46, entered into force September 3, 1981, art. 12.

[31] CEDAW Committee, "General Recommendation 24, Women and Health (Article 12)," U.N. Doc. No. A/54/38/Rev.1 (1999), para. 14.

[32] ICCPR, art. 19(2); American Convention on Human Rights, art. 13(1). See also Inter-American Court, Claude-Reyes and others Case, Judgment of September 19, 2006 Inter-Am Ct.H.R., Series C. No. 151, para. 264.

[33] CEDAW, art. 16(e).

[34] See ICESCR, article 2(2). See also CESCR, "General Comment No. 14, The Right to the Highest Attainable Standard of Health," U.N. Doc. E/C.12/2000/4 (2000), paras. 12(b), 18, 19.

[35] Ibid., para. 11.

[36] CEDAW Committee, "General Recommendation no. 21, on equality in marriage and family relations," HRI/GEN/1/Rev.9 (Vol. II), para. 22.

them in the dark about their treatment options and prevents them from making an informed choice about which options to pursue.

c. The Right to Non-Discrimination

Non-discrimination is a central principle of international human rights law.[37] As a party to the ICCPR, the US is obligated to guarantee effective protection against discrimination, including discrimination based on sex, sexual orientation, and gender identity.[38] CEDAW mandates that state parties take action to "eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to healthcare services."[39]

The UN Human Rights Committee, which provides authoritative guidance on the ICCPR, has clarified that the freedom of thought, conscience, and religion does not protect religiously motivated discrimination against women, or racial and religious minorities.[40] It has urged states considering restrictions on the manifestation of religion or belief to "proceed from the need to protect all rights guaranteed under the Covenant, including the right to equality and non-discrimination."[41]

As Human Rights Watch has documented, recent religious exemptions at the state level have emboldened service providers to discriminate against women and LGBT people. Indeed, there is substantial evidence that permitting such discrimination is the primary motivation for some of these exemptions.[42] By granting virtually unfettered discretion to religious objectors who refuse to meet the healthcare needs

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[37] International protections for the right to non-discrimination include: ICCPR, arts. 2, 4, 26; ICESCR art.2(2); CEDAW, art. 2; International Convention on the Elimination of All Forms of Racial Discrimination (ICERD), adopted December 21, 1965, G.A. Res. 2106 (XX), annex, 20 U.N. GAOR Supp. (No. 14) at 47, U.N. Doc. A/6014 (1966), 660 U.N.T.S. 195, entered into force January 4, 1969, ratified by the United States on October 21, 1994, art. 5; International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families (Migrant Workers Convention), adopted December 18, 1990, G.A. Res. 45/158, annex, 45 U.N. GAOR Supp. (No. 49A) at 262, U.N. Doc. A/45/49 (1990), entered into force July 1, 2003., art. 1(1), art. 7.

[38] ICCPR, art. 26.

[39] CEDAW, art. 12.

[40] See Human Rights Committee, General Comment 28, "Article 3 (The Equality of Rights Between Men and Women)," March 29, 2000, UN Doc. CCPR/C/21/Rev.1/Add.10, para. 21 ("Article 18 may not be relied upon to justify discrimination against women by reference to freedom of thought, conscience, and religion."); Human Rights Committee, General Comment 22, "Article 18: Compilation of General Comments and General Recommendations Adopted by Human Rights Treaty Bodies," 1994, UN Doc. HRI/GEN/1/Rev.1, para. 2 ("The committee therefore views with concern any tendency to discriminate against any religion or belief for any reason, including the fact that they are newly established, or represent religious minorities that may be the subject of hostility on the part of a predominant religious community."); Ibid., at 7 (noting that "no manifestation of religion or belief may amount to … advocacy of national, racial, or religious hatred that constitutes incitement to discrimination" and that "States parties are under the obligation to enact laws to prohibit such acts.").

[41] Human Rights Committee, General Comment 22, "Article 18: Compilation of General Comments and General Recommendations Adopted by Human Rights Treaty Bodies," para. 8.

[42] Human Rights Watch, "*All We Want is Equality": Religious Exemptions and Discrimination against LGBT People in the United States*, February 19, 2018, https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people; Letter from Sen. Patty Murray to Secretary Alex Azar on March 23, 2018, https://twitter.com/dominicholden/status/977276347532890114.

of women and LGBT people – and declining to provide any safeguards to mitigate the harm that such refusals inflict – the proposed rule likely fails to satisfy the US's obligations under international law.

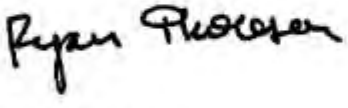
V. Conclusion

While religious freedom is an important human right, the proposed rule fails to advance that right in a responsible and rights-respecting manner. It fails to appreciate the effectiveness of existing protections for conscience and the worrying prevalence of discrimination against women and LGBT people in the United States. It broadens existing protections for conscience in ways that jeopardize access to healthcare and risk exacerbating discrimination and mistreatment against women and LGBT people. It gives little to no regard to those whose rights are jeopardized by blanket religious exemptions and breaks with a long tradition of religious exemptions that seek to ensure that the rights of all are respected. In these ways, it jeopardizes the right to health, the right to information, and the principle of non-discrimination under international law. For all of these reasons, Human Rights Watch calls on HHS to reject the proposed rule.

Sincerely,

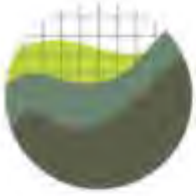
Amanda Klasing
Senior Researcher, Women's Rights Division
Human Rights Watch

Megan McLemore
Senior Researcher, Health and Human Rights Division
Human Rights Watch



Ryan Thoreson
Researcher, LGBT Rights Program
Human Rights Watch

Exhibit 87



Institute *for*
Policy Integrity
NEW YORK UNIVERSITY SCHOOL OF LAW

March 27, 2018

VIA ELECTRONIC SUBMISSION

U.S. Department of Health and Human Services

Attn: Office for Civil Rights

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

The Institute for Policy Integrity ("Policy Integrity") at New York University School of Law[1] respectfully submits the following comments to the Department of Health and Human Services ("HHS" or "the Department") regarding its proposed rule on statutory conscience protections in health care ("Proposed Rule").[2] Policy Integrity is a non-partisan think tank dedicated to improving the quality of government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy.

Our comments focus, first, on HHS's failure to provide a reasoned explanation for disregarding relevant prior findings and, second, on serious errors and oversights in the Department's Regulatory Impact Analysis for the Proposed Rule. Specifically, we note the following:

- HHS disregards, without explanation, concerns that it raised in its 2011 rulemaking on conscience protections ("2011 Rule"), such as the possibility that an overly broad conscience protections rule would interfere with patients' ability to offer informed consent and the possibility that an overly broad rule would lead providers to believe—mistakenly—that statutory conscience protections allow them to discriminate against certain types of patients.
- HHS's Regulatory Impact Analysis ignores the Proposed Rule's potentially substantial indirect costs, such as reduced access to health care for patients and increased personnel expenses for providers.
- The Regulatory Impact Analysis fails to assess the distributional impacts of the Proposed Rule.
- The Regulatory Impact Analysis underestimates the number of entities covered by the Proposed Rule's assurance and certification requirement and, as a result, understates the Proposed Rule's direct compliance costs.

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[1] This document does not purport to present New York University School of Law's views, if any.

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

I. HHS Fails to Provide a Reasoned Explanation for Disregarding Findings It Made in the 2011 Rule.

This is not HHS's first rulemaking on conscience protections. In 2008, the Department finalized a regulation ("2008 Rule") that, among other things, purported to clarify the scope of conscience protections under the Church Amendments, Section 245 of the Public Health Service Act, and the Weldon Amendment by expansively defining certain statutory terms.[3] HHS subsequently rescinded all of the 2008 Rule's definitions in the 2011 Rule, citing concerns about their potential to (1) compromise patients' ability to offer informed consent, (2) cause confusion about the scope of statutory protections, and (3) inadvertently encourage providers to discriminate against certain categories of patients.[4]

When an agency amends, suspends, or repeals a rule, the agency must provide "a reasoned explanation . . . for disregarding facts or circumstances that underlay or were engendered by the prior policy."[5] Underlying the 2011 Rule was a conclusion by HHS that expansive definitions of statutory terms would compromise patients' ability to offer informed consent and foster confusion and discrimination. Accordingly, before it can adopt the Proposed Rule, which defines statutory terms even more broadly than the 2008 Rule did, the Department must acknowledge its prior concerns about expansive definitions and explain either why those concerns are not implicated by the definitions proposed here or why the Proposed Rule is justified despite those concerns. In the absence of such an explanation, the Proposed Rule is arbitrary and capricious.

HHS Disregards Its Prior Findings on the Potential for Expansive Definitions to Compromise Patients' Ability to Provide Informed Consent

When it rescinded the majority of the 2008 Rule in 2011, HHS did so, in part, to "clarify any mistaken belief that [the 2008 Rule] altered the scope of information that must be provided to a patient by their provider in order to fulfill informed consent requirements."[6] The 2011

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[3] Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law, 73 Fed. Reg. 78,072, 78,073 (Dec. 19, 2008) (hereinafter "2008 Rule").

[4] Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 76 Fed. Reg. 9968, 9973-74 (Feb. 23, 2011) (hereinafter "2011 Rule").

[5] *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 516 (2009).

[6] 2011 Rule, 76 Fed. Reg. at 9973.

Rule emphasized that making a patient aware of all available health care options is "crucial to the provision of quality health care services."[7]

The Proposed Rule is likely to limit patients' awareness of their health care options to an even greater extent than the 2008 Rule would have.[8] For example, the Proposed Rule suggests that a provider has no obligation to offer patients a disclaimer regarding health care procedures to which the provider has a religious or moral objection.[9] In other words, providers need not warn patients that they are not being informed of all available treatment options. And yet HHS fails even to acknowledge its 2011 finding that a conscience protections rule could not properly "alter[ ] the scope of information that must be provided to a patient,"[10] much less explain why the Department no longer holds that view.

HHS Disregards Its Prior Findings on the Potential for Expansive Definitions to Cause Confusion About the Scope of Statutory Protections

The 2011 Rule highlighted commenters' concern that the definitions in the 2008 Rule "were far broader than scope of the federal provider conscience statutes."[11] In rescinding those definitions, the Department noted its agreement that the definitions "may have caused confusion regarding the scope" of statutory protections.[12]

Definitions included in the Proposed Rule are even broader than those adopted in 2008. For example, whereas the 2008 Rule interpreted statutory protections against "assist[ing] in in the performance" of an objectionable procedure to encompass any action with a "reasonable" connection to that procedure,[13] the Proposed Rule requires only an "articulable" connection to the procedure.[14] But the Proposed Rule nevertheless fails to acknowledge HHS's prior finding as to the potential for broad definitions to cause confusion. Nor does the Department explain why the Proposed Rule is justified in spite of this potential for confusion.

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[7] *Id.*

[8] Proposed Rule, 83 Fed. Reg. at 3924.

[9] *See id.* at 3894-95 (defining "referral or refer for" to include "disclaimers," and noting that referral was not defined in the 2008 Rule).

[10] 2011 Rule, 76 Fed. Reg. at 9973.

[11] *Id.*

[12] *Id.*

[13] 2008 Rule, 73 Fed. Reg. at 78,097.

[14] Proposed Rule, 83 Fed. Reg. at 78,090-91.

HHS Disregards Its Prior Findings on the Potential for Expansive Definitions to Encourage Discrimination Against Categories of Patients

HHS's 2011 decision to rescind the definitions in the 2008 Rule was also motivated by concern that the definitions would lead providers to believe, incorrectly, that statutory protections extended not just to refusals to perform particular procedures, but also to refusals to care for particular types of patients. As the Department explained in the 2011 Rule, statutory conscience protections "were never intended to allow providers to refuse to provide medical care to an individual because the individual engaged in behavior the health care provider found objectionable."[15] But the Department agreed with commenters that the 2008 Rule could nevertheless give the impression that "Federal statutory conscience protections allow providers to refuse to treat entire groups of people based on religious or moral beliefs."[16] As a result, HHS feared that the 2008 Rule could reduce access to "a wide range of medical services, including care for sexual assault victims, provision of HIV/AIDS treatment, and emergency services."[17]

Again, the definitions in the Proposed Rule are even broader than those that caused the Department concern in 2011 and are thus likely to give rise to the same harmful misimpressions about the scope of statutory conscience protections. But the Department neither acknowledges its prior concerns regarding the inadvertent encouragement of discrimination nor explains why proceeding with the Proposed Rule is reasonable despite those concerns.

II. HHS Fails to Consider the Proposed Rule's Indirect Costs

A rational cost-benefit analysis considers both the direct *and* indirect effects of a proposed rule. To that end, Executive Order 12,866 requires agencies to consider not just "direct cost . . . to businesses and others in complying with the regulation," but also "any adverse effects" the rule might have on "the efficient functioning of the economy, private markets . . . health, safety, and the natural environment."[18] Longstanding guidance on regulatory impact analysis from the White House Office of Management and Budget similarly instructs agencies to "look beyond the direct benefits and direct costs of [their] rulemaking and consider any important

[15] 2011 Rule, 76 Fed. Reg. at 9973-74.

[16] *Id.* at 9973.

[17] *Id.* at 9974.

[18] E.O. 12,866 § 6(a)(3)(C)(ii).

ancillary benefits and countervailing risks."[19] The Supreme Court, too, has made clear that "'cost' includes more than the expense of complying with regulations" and that "any disadvantage could be termed a cost."[20]

Despite HHS's clear obligation to consider indirect consequences, the Regulatory Impact Analysis for the Proposed Rule assesses only direct compliance costs and ignores the ways in which the Proposed Rule is likely to reduce patients' access to health care and increase providers' personnel expenses.

HHS Fails to Consider Costs to Patients from the Express Denial of Medical Services

For a variety of reasons, the Proposed Rule is likely to reduce the availability and consumption of medical services, negatively affecting patient health and wellbeing. As discussed in Section I of these comments, the Proposed Rule's expansive definitions of statutory terms are likely to lead some providers to adopt a much broader interpretation of statutory conscience protections than Congress intended. This, in turn, will increase the frequency with which patients are denied care due to a provider's religious or moral objections. Such denials can impose a variety of costs—financial, physical, and psychological—on patients.

At minimum, a patient denied care must incur the cost of seeking out an alternative provider. Assuming patients typically choose the most convenient healthcare provider available, a second-choice provider may be farther away than the first. Traveling farther away, the patient loses time and money spent on transportation, and may be required to request time off from work or pay for childcare services. For some patients, these costs may be insurmountable.

Furthermore, some patients who are denied care may be too discouraged to seek out alternative sources of healthcare services. These patients may eschew treatment altogether, leading to negative health consequences.

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[19] Office of Mgmt. & Budget, Circular A-4 (2003), https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/.

[20] *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015); *see also Competitive Enter. Inst. v. Nat'l Highway Traffic Safety Admin.*, 956 F.2d 321, 326-27 (D.C. Cir. 1992) (striking down fuel-efficiency rule for failure to consider indirect safety costs); *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1225 (5th Cir. 1991) (holding that EPA was required to consider the indirect safety effects of substitute options for car brakes when banning asbestos-based brakes under the Toxic Substances Control Act).

Finally, the Proposed Rule may discourage some patients from seeking medical services in the first place, simply because they *fear* being rejected by a provider. This assumption is reciprocal to the Department's assumption that some potential healthcare providers are currently (absent the Proposed Rule) discouraged from entering the profession because they fear they will be discriminated against for their religious and moral convictions.[21]

HHS Fails to Consider Costs to Patients from the Undisclosed Denial of Medical Services

The Proposed Rule's likely health costs extend beyond patients who are (or who fear that they will be) expressly denied care. As explained in Section I of these comments, the Proposed Rule encourages providers not merely to refuse to provide referrals for procedures or services to which they object, but also to refuse to warn patients that the provider is declining to recommend such treatments. A patient who does not realize she is being denied information about a particular health care option might choose an alternative that is less beneficial to her health or wellbeing.[22]

HHS Fails to Consider Indirect Personnel Costs for Providers

In addition to imposing health costs on patients, the Proposed Rule may indirectly increase personnel costs for some health care entities. For example, if the Proposed Rule causes support staff at a given health care facility to decline to perform services that they previously performed (or to decline to treat patients whom they previously treated), the facility will need to pay for additional labor to meet the same level of demand.

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[21] Proposed Rule, 83 Fed. Reg. at 3916.

[22] The Department solicits comment on methodologies that can be used to quantify ancillary health costs. There are a number of ways to assess such impacts, including: retrospective cohort studies (e.g., studying the conditions of women's health in the 1960's and 1970's when information on abortion was limited); cohort studies in other countries or states where abortion counseling and referral is restricted; prospective cohort studies (i.e., a pilot program testing the regulation on a subset of the population); self-report surveys administered to a sample population of women (assessing, for example, their awareness of the existence of and details of abortions procedures); estimations of the potential effects by using statistics in the current environment as indicators; or any other of a number of epidemiological and other studies that are routinely performed by public health professionals when evaluating policies that affect public health.

III. HHS Fails to Consider the Proposed Rule's Distributional Impacts

Executive Order 12,866 requires agencies to "consider . . . distributive impacts" that will result from a proposed regulatory action.[23] In addition to failing to take the aforementioned ancillary costs into consideration, the Department has failed to consider how these costs will burden certain groups disproportionately. The Department's failure to consider such distributional impacts is particularly egregious given that it lists the promotion of "a society free from discrimination" as one of the chief benefits of the Proposed Rule.[24] HHS cannot rationally tout the Proposed Rule's potential to reduce discrimination against religious health care providers while ignoring its potential to increase discrimination against other groups.[25]

Specifically, the Department should consider whether and to what extent the Proposed Rule will disproportionately burden the following subpopulations:

- Immigrant Women: Recent immigrants may be less well informed on the availability of reproductive health care in the U.S., and therefore in greater need of the counselling and referral services that the Proposed Rule covers.

- Rural Women: Increasing the incidence of health care providers refusing to provide counseling or referrals may create a greater problem for women who live in rural areas than for women at large, due to the increased search and travel costs associated with finding an alternative provider in rural areas.

- Low-Income Women: Women with lower incomes have fewer resources available to allocate to transportation and child care. If refused counseling or referral services, these women may suffer greater costs when seeking alternative health care providers. The refusal may even result in an insurmountable obstacle to obtaining the health service sought.

- Women of Color: Women of color disproportionately earn lower incomes and live in underserved areas. If refused counseling or referrals, these women may experience greater burdens to seek alternative health care providers.

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[23] E.O. 12,866 § 6(b)(5).

[24] Proposed Rule, 83 Fed. Reg. at 3903.

[25] *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (noting that "reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions"); *Sierra Club v. Sigler*, 695 F.2d 957, 979 (5th Cir. 1983) (an agency "cannot tip the scales . . . by promoting [an action's] possible benefits while ignoring [its] costs.").

- LGBTQ Individuals: As discussed in Section I, the Proposed Rule, like the 2008 Rule, may lead health care workers to believe they can permissibly refuse to provide any type of medical service to gay or transgender individuals (or their families) based on moral or religious objections. Such refusals would decrease the quantity and quality of health care available to that population.

- Individuals with HIV/AIDS: Similarly, the Proposed Rule may lead health care workers to believe that they can permissibly refuse to provide any type of medical service to individuals with HIV/AIDS. Again, such refusals would decrease the quantity and quality of health care available to that population.

- Interracial/Interfaith Families: Finally, the Proposed Rule may lead health care workers to believe that they can permissibly refuse to provide any type of medical services to interracial or interfaith families because they morally object to such relationships. As with LGBTQ patients and HIV-positive patients, this misimpression could result in reduced access to health care for interracial and interfaith families.

IV. HHS Underestimates the Number of Entities Affected by the Proposed Rule and, as a Result, Underestimates the Proposed Rule's Compliance Costs

In addition to overlooking the Proposed Rule's indirect costs, HHS also underestimates the Proposed Rule's *direct* costs. Section 88.4 of the Proposed Rule requires certain recipients of HHS funding "to submit written assurances and certifications of compliance" with statutory conscience protections.[26] In calculating compliance costs for this assurance and certification requirement, the Department estimates that the requirement would apply to between 94,279 and 152,519 individuals and entities.[27] But that estimate excludes a large number of individuals and entities that, under a plain reading of the Proposed Rule, would in fact be required to submit assurances and certifications.[28]

HHS assumes that "all physicians" will be exempt from complying with the assurance and certification requirement, either because they do not accept HHS funds or because they "meet the proposed criteria for exemption . . . in proposed § 88.4(c)(1)."[29] But § 88.4(c)(1) exempts physicians and physician offices only if they (1) participate in Medicare Part B and

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[26] Proposed Rule, 83 Fed. Reg. at 3896.

[27] *Id.* at 3910.

[28] *Id.* at 3910, 3915.

[29] *Id.* at 3909-10.

(2) "are not recipients of Federal financial assistance or other Federal funds from the Department through another instrument, program, or mechanism."[30] It is patently unreasonable for the Department to assume that this exemption encompasses every physician who receives HHS funds. Some physicians, for example, accept both Medicare *and* Medicaid funding.

HHS makes a similar error in estimating the number of individuals and entities that would be exempt from the assurance and certification requirement due to § 88.4(c)(2), which exempts recipients of funding under certain grant programs administered by the Administration for Children and Families that have a purpose unrelated to health care provision or medical research. The Department assumes that "all persons and entities that provide child and youth services . . . [and] all entities providing services for the elderly and persons with disabilities . . . would fall within this exemption."[31] As with the exemption for physicians, however, the § 88.4(c)(2) exemption is unavailable if HHS money is accepted from any other source. It seems unlikely that *no* entities that provide services for children, the elderly, or the disabled receive HHS funding from *any* source other than non-healthcare-related grant programs administered by the Administration for Children and Families.

Because it underestimates the number of entities that will be obligated to comply with the Proposed Rule's assurance and certification requirement, HHS also underestimates the Proposed Rule's total compliance costs.

Respectfully,

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[30] *Id.* at 3929.

[31] *Id.* at 3910.