EXHIBIT 35

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 36

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

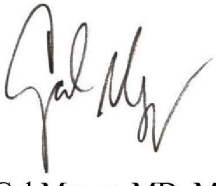
[16] American Academy of Family Physicians, *Consultations, Referrals, and Transfers of Care* (2017), https://www.aafp.org/about/policies/all/consultations-transfers.html ("A referral is a request from one physician to another to assume responsibility for the management of one or more of a patient's 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 37

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

VIA ELECTRONIC SUBMISSION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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[13] American College of Obstetricians and Gynecologists, *Committee Opinion No. 516: Health Care Systems for Underserved Women* (Jan. 2012), http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-Systems-for-Underserved-Women.

[14] *See, e.g.*, Kaiser Family Foundation, *Women and Health Care: A National Profile* 24 (July 2005), *available at* https://kaiserfamilyfoundation.files.wordpress.com/2013/01/women-and-health-care-a-national-profile-key-findings-from-the-kaiser-women-s-health-survey.pdf.

[15] Gretchen Borchelt, *Pharmacists Can't Be Allowed to Deny Women Emergency Contraception*, U.S. NEWS & WORLD REPORT, Oct. 15, 2012, http://www.usnews.com/opinion/articles/2012/10/15/pharmacists-cant-be-allowed-to-deny-women-emergency-contraception.

[16] Id.

[17] *See* National Women's Law Center, *Fact Sheet: If You Care about Religious Freedom You Should Care about Reproductive Justice!* (2014), https://nwlc.org/resources/if-you-care-about-religious-freedom-you-should-care-about-reproductive-justice/, (citing U.S. Department of Health & Human Services, *Facts about . . . Rural Physicians*, http://www.shepscenter.unc.edu/rural/pubs/finding_brief/phy.html).

[18] Id.

[19] *See* Jaime M. Grant et al., *Injustice at Every Turn: a Report of the National Transgender Discrimination Survey*, NATIONAL GAY AND LESBIAN TASK FORCE & NATIONAL CTR. FOR TRANSGENDER EQUALITY (2011), http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf.

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

[21] Id.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

II. The Proposed Rule Violates the Administrative Procedure Act

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

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

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

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

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

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

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

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

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

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

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

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

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

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[43] 5 U.S.C.A. § 706(2)(A).
[44] Encino Motorcars, LLC v. Navarro, 136 S. Ct. 2117, 2125 (June 20, 2016) (citing Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co., 463 U.S. 29, 103 (1983)). Typically, a court will find an agency action to be arbitrary and capricious if the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (internal citations omitted); Envtl. Def. Fund, Inc. v. Costle, 657 F.2d 275, 283 (D.C. Cir. 1981) ("While we are admonished from rubber stamping agency decisions as correct, our task is complete when we find that the agency has engaged in reasoned decisionmaking within the scope of its Congressional mandate.") (internal citations and quotations omitted).
[45] U.S. Department of Health and Human Services FY19 Budget in Brief 124, https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf.
[46] Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 76 Fed. Reg. 9968, 9972 (2011).
[47] Exec. Order No. 13563, 76 FR 3821 at Sec. 1(b) (Jan. 18, 2011).
[48] Id. at Sec. 1(c).

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

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

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

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

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

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[49] National Women's Law Center, *When health care providers refuse: The impact on patients of providers' religious and moral objections to give medical care, information or referrals*, Apr. 2009, https://www.nwlc.org/wp-content/uploads/2015/08/April2009RefusalFactsheet.pdf.
[50] Rachel K. Jones et al., *Differences in Abortion Service Delivery in Hostile, Middle-Ground and Supportive States in 2014,* WOMEN'S HEALTH ISSUES (2018), http://www.whijournal.com/article/S1049-3867(17)30536-4/abstract.
[51] Rachel K. Jones & Jenna Jerman, *How Far Did US Women Travel for Abortion Services in 2008*, 22 J. WOMEN'S HEALTH 706 (2013).
[52] Diana Greene Foster et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 108 AM. J. PUB. H. 407 (2018), http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2017.304247.

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

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

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

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

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

[54] National Research Service Award Act of 1974, Pub. L. No. 93-348, 353-54 (1974).

[55] 120 Cong. Rec. 16, 21540 (June 27, 1974) (Statement of Sen. Biden).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[74] Id. at 3892.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

By allowing providers, including hospital and healthcare institutions, to refuse to provide patients with information, the proposed rule seeks to deprive patients of full information regarding their treatment options. While HHS claims the rule will improve communication between patients and providers, in truth it will deter open, honest conversations that are vital to ensuring that a patient can control their medical circumstances.

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

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

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

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

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

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

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

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

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[102] Lois Uttley & Christine Khaikin, *Growth Of Catholic Hospitals And Health Systems: 2016 Update Of The Miscarriage Of Medicine Report,* MergerWatch (2016), http://static1.1.sqspcdn.com/static/f/816571/27061007/1465224862580/MW_Update-2016-MiscarrOfMedicine-report.pdf?token=sNLtMbWH41ZXGppQwJUb6n2ztV8%3D.

[103] Id.

[104] Id.

[105] National Women's Law Center, *When health care providers refuse: The impact on patients of providers' religious and moral objections to give medical care, information or referrals* (Apr. 2009), https://www.nwlc.org/wp-content/uploads/2015/08/April2009RefusalFactsheet.pdf. *See also*, Debra B. Stulberg et al., *Tubal Ligation in Catholic Hospitals: A Qualitative Study of Ob-Gyns' Experiences*, 90 CONTRACEPTION 422 (2014) ("Cesarean delivery in Catholic hospitals raised frustration for obstetrician-gynecologists when the hospital prohibited a simultaneous tubal ligation and, thus, sent the patient for an unnecessary subsequent surgery. [. . .] Some obstetrician-gynecologists reported that Catholic policy posed greater barriers for low-income patients and those with insurance restrictions.").

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

V. The Proposed Rule Is Unconstitutional

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

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

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

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

VI. Conclusion

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

The Center for Reproductive Rights

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