Exhibit 72

STATE OF WASHINGTON
DEPARTMENT OF HEALTH

March 26, 2018

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

The Washington State Department of Health (DOH) appreciates the opportunity to comment on the proposed rule, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," printed in the Federal Register on January 26, 2018 (83 FR 3880). We are specifically responding to the request for feedback on the rule's potential to improve or worsen health outcomes.

The proposed rule significantly broadens the criteria by which people or entities can claim conscience objections to deny patients care, the types of entities that must accommodate their employees' or volunteers' objections, and the types of activities to which an entity can object. This threatens to directly reduce access to essential health care services, especially for vulnerable populations—including those living in rural areas—and thereby worsen health outcomes. In addition, the proposed rule conflicts with program requirements in existing successful HHS programs (e.g., immunizations and family planning) that have been shown to improve outcomes. This change will jeopardize the integrity of and funding for these programs. This would further reduce access to care and lead to poorer health outcomes and wider inequities.

The proposed rule does not appropriately balance the conscience rights of providers with health outcomes of their patients or the public health system's role to ensure access to health care services for *all* people.

For these reasons, we recommend HHS withdraw the proposed rule.

If not withdrawn, we strongly urge HHS to revise the language to:

- Allow entities, including states, health systems, clinics, providers, and insurers, to consider significant public health concerns, such as patient access to care, when managing conscience objections.
- Remove requirements for accommodations when they directly conflict with the statutory requirements of HHS programs as determined by the U.S. Congress.

The rule proposes definitions that broaden the type of entity who can claim a conscience objection and the types of activities for which a moral or religious objection could be made, including referrals. The proposed definitions for "assist in the performance," "health care entity,"

and "referral/refer for," taken in conjunction with one another, significantly broaden the number of entities or persons who have a basis to file a complaint and will lead to significant unintended consequences.

First, the broadening of these definitions will make it difficult for some organizations to manage conscience objections without harming their business operations. Small clinics cannot afford multiple schedulers, billers, or assistants who may raise moral or religious objections, which previously were accommodated only for healthcare providers.

It is also our expectation these expanded definitions would create substantial gaps in access to preventive services and limit referrals to services that are provided elsewhere. These gaps could be especially harmful for vulnerable populations such as women and families with low incomes; people who are lesbian, gay, bisexual, or transgender (LGBT); people of color; and people living in rural or otherwise underserved areas. While 20 percent of the population lives in rural areas, less than 10 percent of physicians practice in rural areas. As a result, many individuals across the U.S. already have limited options to receive medical care, including preventive services such as family planning or vaccinations. If the only provider in an area does not administer vaccines because it is against his or her personal religious beliefs, for example, entire communities could be left vulnerable to devastating infectious diseases. Similarly, all women in a given community could find themselves without access to contraception or other reproductive health care if the only provider in the area asserts moral or religious objections.

Finally, the broadening of these definitions may create confusion or be interpreted in a way that facilitates discrimination against women, low-income individuals, LGBT people, or people of color, under the guise of a conscience objection. These groups already face barriers to care and experience health inequities. The proposed rule could further decrease their access to necessary health care and worsen health outcomes and disparities. This clearly runs counter to the mission of HHS "to enhance and protect the health and well-being of all Americans," and it neglects the responsibility of our public health system to ensure access to quality health services.

The proposed rule conflicts with existing requirements in HHS programs.

Definitions in the proposed rule allow for refusals that conflict with the requirements of some existing HHS programs. These programs have a documented history of providing quality preventive health care services, improving health outcomes, and saving costs. This proposed rule will jeopardize the integrity and continued success of these programs, funding for them, and the delivery of the quality services they provide.

- The Vaccines for Children program requires participating healthcare providers to offer all routinely recommended vaccines to eligible at-risk children (42 USC 1396s(c)(2)(B)(i)). Under this proposed rule change, a person or entity may object to administering a vaccine. States and health care providers may struggle to comply with federal requirements for at-risk children to access and receive the recommended standard-of-care vaccines, because of an expanded number and basis for conscience objections.

- The Title X family planning projects are designed to "consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children" (42 CFR 59.1). The Title X statute specifically requires that "all pregnancy counseling shall be nondirective" (Public Law 112-74, p. 1066-1067), and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination (42 CFR 59.5(a)(5)).

The proposed rule protects individuals and entities who refuse to provide some essential services or provide complete information about all of a woman's pregnancy options. The proposed rule could force the Washington State Department of Health and Title X sub-recipients to choose between violating the Title X requirements or violating the proposed rule.

The Emergency Medical Treatment and Active Labor Act (EMTALA) requires emergency department to provide emergency treatment to *anyone* seeking treatment. The proposed rule could potentially conflict with EMTALA statutory requirements. For example, a hospital or provider could decline service to a woman with possible complications following an abortion. These proposed rules could jeopardize patient lives.

Preserving religious freedom in the U.S. is important, and so is our responsibility as government leaders to ensure access to health care services for all people. Existing laws have sought to preserve balance between conscience objections based on sincerely held religious beliefs and moral convictions, and the needs of patients and the public health. It is imperative to the nation's health and well-being that this rule does the same. Unfortunately, the rule as written fails to strike an appropriate balance, clearly placing the health of patients and the public at risk. I urge you to withdraw it.

Sincerely,

John Wiesman, DrPH, MPH
Secretary of Health

Exhibit 73

American Hospital Association

800 10th Street, NW
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100 Phone
www.aha.org

March 26, 2018

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

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

Dear Mr. Severino:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinical partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Department of Health and Human Services (HHS) Office for Civil Rights' (OCR) proposed rule regarding certain statutory conscience protections.

Hospitals and health systems are committed to respecting the conscience objections of hospital employees and medical staff. Conscience protections for health care professionals are long-standing and deeply rooted in our health care delivery system. For decades, the AHA and its members have supported policies to accommodate the differing convictions of our employees and medical staff by making provisions for them to decline to participate in delivering services they say they cannot perform in good conscience. Existing federal and state laws protect health care workers who express religious objections related to performing certain procedures.

At the same time, hospitals and health systems have obligations to their patients and are committed to providing the care they need. Existing laws create protections for patients and impose certain obligations on providers to ensure that patients have access to necessary care. Hospitals and health systems value every individual they have the opportunity to serve, and oppose discrimination against patients based on characteristics such as race, religion, national origin, sexual orientation or gender identity.

The intersection of these equally important obligations can present unique challenges. Neither obligation can or should be addressed in a vacuum. OCR's framework for enforcing the conscience protections at issue should account for this intersection of hospitals' obligation to ensure needed care for patients and the obligation to honor conscience objections of employees.

With this as a backdrop, we make the following recommendations.

THE POLICIES, PRACTICES, AND COURT PRECEDENT GOVERNING ENFORCEMENT OF OTHER CIVIL RIGHTS PROTECTIONS SHOULD BE THE MODEL FOR ENFORCEMENT OF THE CONSCIENCE PROTECTIONS AT ISSUE.

OCR observes that the conscience protections at issue are civil rights to be enforced no less than other civil rights protections. The AHA agrees that the conscience protections are among the civil rights of hospital employees and medical staff. They should, therefore, be duly protected.

In keeping with the principle that the conscience protections should be treated akin to other civil rights, the AHA urges OCR to ensure that the enforcement policies and practices applicable to the conscience protections are comparable to the long-standing policies and practices applicable when guaranteeing other civil rights protections for employees and staff. OCR should not invent new, distinct, or additional policies and practices that add unnecessary complexity and burden or prefer conscience protections over other civil rights. Rather, OCR should use existing civil rights frameworks as the model for the conscience protections at issue. This not only would place the conscience protections on a level playing field with other civil rights, but would ensure that the conscience protections are guaranteed through an enforcement framework that already has proven effective in analogous civil rights contexts.

To this end, **OCR should explicitly adopt a reasonable accommodation framework that provides the flexibility for HHS to take into account particular facts and circumstances to determine that a hospital has done all it reasonably could under the circumstances to accommodate conscience objections of employees or medical staff** (*Bruff v. North Miss. Health Servs.*, 244 F.3d 495 (5th Cir. 2001)).

Employment discrimination on the basis of religion is prohibited and employers are required to reasonably accommodate the sincerely held religious beliefs of employees, absent a showing of undue hardship on the employer (*See* 29 C.F.R. § 1605.2). This has been true for over a half century, and this framework has successfully protected employees, including those of hospitals and health systems, from religious discrimination. Analogous reasonable accommodation frameworks also have been successfully employed in other civil rights contexts, such as the Rehabilitation Act of 1973.

This framework has proven successful in the hospital context, in part, because it allows for an assessment of the reasonableness of a requested accommodation in context. The requirement of reasonably accommodating the sincerely held religious beliefs of employees and medical staff, absent a showing of undue hardship, guarantees robust protections for the religious beliefs of hospital employees and medical staff.

Consistent with this framework, a hospital should be responsible for providing *reasonable* conscience-based accommodations and an employee is responsible for providing fair notice of a specific and sincerely held religious or moral objection. A hospital should not be sanctioned for failing to accommodate the moral or religious beliefs of an employee or medical staff where, despite being on notice of his or her right to do so, the individual did not give the hospital advance notice of his or her objection (*Wessling v. Kroger Co.*, 554 F. Supp. 548 (E.D. Mich. 1982) (no Title VII violation when the employee did not give the employer notice of a desire for a religious accommodation)).

Adoption of this framework in the conscience rule would assure hospitals that they may continue with a time-tested way of honoring their responsibilities to ensure access to necessary care for all patients, while effectively protecting the religious and other conscience rights of employees and medical staff. It also would avoid the unnecessary and duplicative administrative burdens for hospitals that imposing an additional and different framework would create.

Hospitals have existing policies, procedures, and best practices. They also have decades of experience with how to meet their responsibility to provide reasonable accommodations. Adopting a parallel framework for the conscience protections would enable hospitals to seamlessly incorporate the conscience rights of employees and medical staff into the existing compliance frameworks. The religious and moral beliefs of hospital employees and medical staff would be protected, while reducing the complexity and burden for hospitals. **OCR should expressly affirm these guiding principles.**

DUE PROCESS PROTECTIONS SHOULD BE EXPLICITLY INCLUDED IN THE REGULATIONS.

The proposed regulations are silent on procedural protections for a recipient of funding before the Department may take an adverse action. OCR should affirmatively recognize the due process rights of recipients of federal funds. The regulations should reinforce those rights with a clear acknowledgement of the procedural protections applicable to any action by the Department that would adversely affect a recipient's continued receipt of, or future eligibility for, federal funding. For example, the Social Security Act controls whether participation in, or receipt of funding from, the Medicare program may be limited or terminated; the Medicare law and regulations control the procedural protections for providers.

As discussed above, there are existing and proven civil rights policies and practices that should apply equally here. In particular, the conscience regulations should expressly adopt the longstanding due process protections for Title VI enforcement. The same protections should apply for challenges to any finding of noncompliance with the conscience protections that OCR may make or any penalty or other adverse action for noncompliance with the conscience protections that OCR may seek to impose.

Additionally, the regulations should be explicit about the grounds for imposing any contemplated sanction and the procedural protections. The proposed regulation lists numerous potential adverse actions available to OCR or the Department without delineating the specific circumstances that must occur before taking any such action. The implication is that they are

available at OCR's or the Department's discretion, without reference to any reasonable standards. The regulation should expressly identify which sanction is applicable under which circumstances. It also should identify the related procedural protections, including notice and hearing rights. This would further the government's interests in not only ensuring fundamental fairness but also avoiding inappropriate disruption of health services that are federally funded.

REGULATORY BURDEN SHOULD BE EASED WHEREVER POSSIBLE.

The proposed requirement that a recipient report reviews, investigations, and complaints to any component of the Department from which it receives funding is burdensome and unnecessary. So, too, is the proposed requirement that a recipient seeking new or renewed funding report reviews, investigations, and complaints from the prior five years. No such requirements apply in other civil rights contexts. Because OCR will know of all such reviews, investigations, and complaints, OCR should instead be the source of this information within the Department. OCR will be the central repository of all such data and can make it readily available to other Departmental components, greatly reducing unnecessary burden on regulated parties.

Additionally, the sweep of these proposed disclosures is problematic. There is no distinction in the proposed treatment of, for example, general compliance reviews (unprompted by any particular concern), rejections of frivolous complaints, findings of compliance, or cases where a sanction is ultimately overturned. With new, renewed, or continuing funding at stake, the proposed reporting requirement risks inappropriately suggesting to the decision-maker that there is a cause for concern when there is in fact none, improperly biasing the decision-making against the recipient. The regulation should not effectively create a presumption of noncompliance. **The proposed reporting requirement should not be finalized.**

We appreciate your consideration of these issues. Please contact me if you have questions or feel free to have a member of your team contact Maureen Mudron, AHA deputy general counsel, at (202) 626-2301 or mmudron@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President

Exhibit 74

IN OUR OWN voice
National Black Women's Reproductive Justice Agenda

March 26, 2018

Submitted via www.regulations.gov
Docket ID # HHS-OCR-2018-002

Roger Severino
Director
Office of Civil Rights, Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW., Room 509F
Washington, DC 20201

Attention: Conscience NPRM, RIN 0945-ZA03

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

Dear Director Severino:

On behalf of *In Our Own Voice: National Black Women's Reproductive Justice Agenda*, we welcome the opportunity to comment on the Department of Health and Human Services' (the "Department") proposed rule ("Proposed Rule") which seeks to permit discrimination in all aspects of health care.[1] *In Our Own Voice: National Black Women's Reproductive Justice Agenda* believes a health care provider's personal beliefs should never determine the care a patient receives, which leads us to strongly oppose the Department's Proposed Rule.

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

By issuing the Proposed Rule and creating a new division within the Office of Civil Rights ("OCR") – the new "Conscience and Religious Freedom Division" – the Department seeks to inappropriately use OCR's limited resources in order to affirmatively allow institutions,

[1] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (proposed

1300 I Street, NW, Suite 400E, Washington DC 20005
202-749-8365
www.blackrj.org

insurance companies, and almost anyone involved in patient care to use their personal beliefs to deny people the care they need. For these reasons, *In Our Own Voice: National Black Women's Reproductive Justice Agenda* calls on the Department and OCR to withdraw the Proposed Rule in its entirety.

In Our Own Voice: National Black Women's Reproductive Justice Agenda

In Our Own Voice: National Black Women's Reproductive Justice Agenda is a national Reproductive Justice organization focused on increasing the visibility of Black women at the national and regional levels in our ongoing policy fight to secure Reproductive Justice for all women and girls. *In Our Own Voice* is a national-state partnership with eight Black women's reproductive justice organizations: the Afiya Center in Texas, Black Women for Wellness in California, Black Women's Health Imperative, a national organization, New Voices for Reproductive Justice in Pennsylvania and Ohio, SisterLove, Inc., in Georgia, Sister Reach in Tennessee, SPARK Reproductive Justice NOW in Georgia and Women with a Vision in Louisiana.

In Our Own Voice provides an opportunity to have Black women and girls speak for ourselves and present a proactive strategy to advance reproductive health, rights and justice, including the right to safe and legal abortions, contraceptive equity and comprehensive sex education. Reproductive Justice will be attained when all people have the economic, social, and political power and means to make decisions about their bodies, sexuality, health, and family, with dignity and self-determination. Our health, safety and wellbeing are intrinsically linked. The Proposed Rule seeks to strip black women of the power to access quality health services and programs by allowing individuals or institutions to deny someone contraceptive access by stating that those services violate their religious beliefs.

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

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

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

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

[2] *See id.* at 12.

schedules procedures—to use their personal beliefs to determine a patient's access to care. What we at *In Our Own Voice* know to be tried and true is that only women should be making decisions about their health care. Reproductive justice will be attained when all people have the economic, social and political power and means to make fully informed decisions about their bodies, sexuality, health and families.

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

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

Similarly, the Proposed Rule defines common phrases and words used throughout existing refusals of care laws and civil rights laws in ways that stretch their intended meaning beyond recognition. For example, the definition of "assist in the performance" greatly expands the types of services that can be refused to include merely "making arrangements for the procedure" no matter how tangential.[6] This means individuals not "assisting in the performance" of a procedure within the ordinary meaning of the term, such as the hospital room scheduler, the technician charged with cleaning surgical instruments, and other hospital employees, can now assert a new right to refuse. The Proposed Rule's definition of "referral" similarly goes beyond any

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[3] *See, e.g.*, *Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/; Catherine Weiss, et al., *Religious Refusals and Reproductive* Rights, AM. CIVIL LIBERTIES UNION (2002), https://www.aclu.org/report/religious-refusals-and-reproductive-rights-report; Julia Kaye, et al., *Health Care Denied*, AM. CIVIL LIBERTIES UNION 1 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf; Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

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

[5] *See* Rule *supra* note 1, at 185.

[6] *Id.* at 180.

understanding of the term, allowing refusals to provide any information, including location or funding, that could help an individual to get the care they need.[7]

Furthermore, the Proposed Rule's new and unwarranted expanded definitions often exceed, or are not in accordance with, existing definitions contained within the statutes the Proposed Rule seeks to enforce. Specifically, under the Coats and Weldon Amendments "health care entity" is defined to encompass a limited and specific range of individuals and entities involved in the delivery of health care.[8] The Proposed Rule attempts to combine separate definitions of "health care entity" found in different statutes and applicable in different circumstances into one broad term.[9] Such an attempt to expand the meaning of a statutory term Congress already took the time to define not only fosters confusion, but goes directly against congressional intent. By expressly defining the term "health care entity" Congress implicitly rejected the inclusion of the other terms the Department now attempts to insert.[10]

When these impermissibly broad definitions are combined with the expansive interpretations of the underlying statutes, they work together to further expand refusals of care to allow more individuals and entities to refuse to provide access to health care. For example, one way the Weldon Amendment is expanded under the Proposed Rule is through the definition of "discrimination."[11] In particular, the Proposed Rule defines "discrimination" against a health care entity broadly to include a number of activities, including denying a grant or employment as well as an unspecified catch-all phrase "any activity reasonably regarded as discrimination."[12] In a Proposed Rule that seeks to protect those who want to discriminate, this broad definition is nonsensical and inappropriate. Further such a vague and inappropriate definition provides no functional guidance to entities on how to comply with the applicable requirements, thereby fostering confusion.

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

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

Across the country refusals of care based on personal beliefs have been invoked in countless ways to deny patients the care they need.[13] Fundamental human rights are violated when patients must endure preventable suffering, including death, health complications, mistreatment, discrimination, and denials of information and bodily autonomy. Religiously affiliated hospitals

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[7] *Id.* at 183.
[8] The Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009); Public Health Service Act, 42 U.S.C. § 238n (2018).
[9] *See* Rule *supra* note 1, at 182.
[10] The doctrine of expression unius est exclusion alterius (the expression of one thing implies the exclusion of others) as applied to statutory interpretation creates a presumption that when a statute designates certain persons, things, or manners of operation, all omissions should be understood as exclusions.
[11] *See* Rule *supra* note 1, at 180.
[12] *Id.*
[13] *See, e.g.*, *supra* note 3.

are often the only local health care provider, particularly in rural states, and are likely to be the provider of last resort for uninsured women. This is particularly important for Black women, who are more likely not to have health insurance. One woman experiencing pregnancy complications rushed to the only hospital in her community, a religiously affiliated facility, where she was denied the miscarriage management she needed because the hospital objected to this care.[14] Another woman experiencing pregnancy loss was denied care for ten days at a religiously affiliated hospital outside Chicago, Illinois.[15] In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy.[16] Another patient in Arkansas endured a number of dangerous pregnancy complications and could not risk becoming pregnant again. She requested a sterilization procedure at the time of her Cesarean delivery, but her Catholic hospital provider refused to give her the procedure.[17] Another woman was sent home by a religiously affiliated hospital with two Tylenol after her water broke at 18 weeks of pregnancy. Although she returned to the hospital twice in the following days, the hospital did not give her full information about her condition and treatment options.[18]

All patients should be fully informed and understand their health care options, regardless of the religious beliefs of providers. HHS must work to ensure that policies reflect the health needs and decisions of the patient.

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

Black women already receive disparate care and face increased barriers when accessing care compared to white women, often due to systemic racism and sexism. Historically, Black women and other women of color have been the targets of coercive health practices and policies, unethical testing, and misinformation.[19] Refusals of care based on personal beliefs are an added burden for many individuals to access health care and have real consequences for those denied the care they need because of a provider or hospital's religious beliefs. When women and

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

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

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

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

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

[19] Dorethy Roberts, *Killing the Black Body: Race, Reproduction, and the Mean of Liberty*, NEW YORK: VINTAGE PRESS (2017).

families are uninsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services or travel to another location, refusals bar access to necessary care.[20] This is especially true for immigrant patients who often lack access to transportation and may have to travel great distances to get the care they need.[21] In rural areas there may be no other sources of health and life preserving medical care.[22] In developing countries where many health systems are weak, health care options and supplies are often unavailable.[23] When these individuals encounter refusals of care, they may have nowhere else to go.

This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals. For example, new research shows that women of color in many states disproportionately receive their care at Catholic hospitals. In nineteen states, women of color are more likely than white women to give birth in Catholic hospitals.[24] These hospitals as well as many Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provides guidance on a wide range of hospital matters, including reproductive health care and can keep providers from offering the standard of care.[25] Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals, and as a result, women were delayed care or transferred to other facilities at great risk to their health.[26] The reach of this type of religious refusal of care is growing with the proliferation of both the types of entities using religious beliefs to discriminate and the number of religiously affiliated entities that provide health care and related services.[27]

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[20] In 2016, an estimated 11 percent of women between the ages of 19 to 64 were uninsured. Single mothers, women of color, and low-income women are more likely to be uninsured. *Women's Health Insurance* Coverage, KAISER FAMILY FOUND. 1, 3 (Oct. 31, 2017), http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage.

[21] Athena Tapales et al., *The Sexual and Reproductive Health of Foreign-Born Women in the United States*, CONTRACEPTION 8, 16 (2018), http://www.contraceptionjournal.org/article/S0010-7824(18)30065-9/pdf; Nat'l Latina Inst. For Reproductive Health & Ctr. For Reproductive Rights, *Nuestra Voz, Nuestra Salud, Nuestro Texas: the Fight for Women's Reproductive Health in the Rio Grande Valley* 1, 7 (2013), http://www.nuestrotexas.org/pdf/NT-spread.pdf.

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

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

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

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

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

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

In addition, in many of the countries where the Department implements global AIDS programs, many of the patients served already face numerous barriers to care, including a broad and harmful refusal provision contained within the statute governing such programs.[28]

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

By expanding refusals of care the Proposed Rule will exacerbate the barriers to health care services patients need. It is evident that the harm caused by this Proposed Rule will fall hardest on those most in need of care by allowing individuals and health care entities to use their personal beliefs to dictate patient care. The Department should remember, under Executive Order 13563, an agency may only propose regulations where it has made a reasoned determination that the benefits justify the costs and where the regulations are tailored "to impose the least burden on society."[29] The Proposed Rule plainly fails on both counts. Although the Proposed Rule attempts to quantify the costs of compliance, it completely fails to address the costs and burdens to patients who may be denied care and who then may incur and experience even greater social and medical costs.[30]

Moreover, the Establishment Clause of the First Amendment requires the government to adequately account for just these sorts of consequences when considering whether to grant religious exemptions and, in fact, bars granting an exemption when it would detrimentally affect any third party.[31] Because the Proposed Rule would cause substantial harm, including to patients, it would violate the Establishment Clause.[32]

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

The Proposed Rule would seemingly allow health care entities to receive grants and contracts under HHS-funded programs or other federal health programs, such as Title X, the only domestic

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

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

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

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

[32] Respecting religious exercise may not "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling." *See Burwell v. Hobby Lobby*, 134 S. Ct. at 2787. When considering whether the birth control coverage requirement was the least restrictive means in Hobby Lobby, the Court considered that the accommodation offered by the government ensured that affected employees "have precisely the same access to all FDA-approved contraceptives as employees of companies whose owners have no religious objections to providing coverage." *See id.* at 2759. In other words, the effect of the accommodation on women would be "precisely zero." *Id.* at 2760.

family planning program, while refusing to provide key services required by those programs.[33] For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling[34] and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.[35] Under the Proposed Rule, the Department would seemingly allow entities to apply for and receive federal funds while exempting them from the core legal and programmatic duties upon which such funds are generally conditioned.[36] The Proposed Rule creates uncertainty about whether Title X grantees may ensure that the sub-recipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. Such actions are particularly concerning in the context of federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for low-income populations.[37] When it comes to Title X, the Proposed Rule would not only sanction conduct at odds with pre-existing legal requirements, but could also undermine the program's fundamental objectives. Every year millions of low-income, including under-insured, and uninsured individuals, 21% of whom are black women,[38] rely on Title X clinics to access services they otherwise might not be able to afford.[39]

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

Existing refusals of care based on personal beliefs already undermine open communication between providers and patients, interfere with providers' ability to provide care according to medical standards, and ignore the reality that many providers want to provide comprehensive care. Hospital systems across the country use religious beliefs to prevent their employees from treating patients regardless of the professional, ethical, or moral convictions of these providers.[40] The Proposed Rule would exacerbate these problems by emboldening health care entities and institutions, including foreign and international organizations, to bind the hands of providers and attempt to limit the types of care they can provide.

The Proposed Rule threatens informed consent, a necessary principle of patient-centered decision-making intended to help balance the power dynamics between health providers and

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[33] *See* Rule *supra* note 1, at 180-181, 183. *See also Title X Family Planning*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (2018), https://www.hhs.gov/opa/title-x-family-planning/index.html; *Title X an Introduction to the Nation's Family Planning Program*, NAT'L FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOC. (2017) (*hereinafter* NFPRHA), https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf.
[34] *See, e.g.*, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).
[35] *See* What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).
[36] *See, e.g.*, Rule *supra* note 1, at 180-185.
[37] *See* NFPRHA *supra* note 34.
[38] *See* Title X: America's Family Planning Program, https://www.plannedparenthoodaction.org/issues/health-care-equity/title-x.
[39] *See id.*
[40] *See* Julia Kaye, et al., *Health Care Denied*, AM. CIVIL LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

patients and ensure patient-centered decision-making.[41] Informed consent requires providers disclose relevant and medically accurate information about treatment choices and alternatives so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.[42] By allowing providers, including hospital and health care institutions, to refuse to provide patients with information, the Proposed Rule makes it impossible for patients to have full information regarding treatment options. While the Department claims the Proposed Rule improves communication between patients and providers, in truth it will deter open, honest conversations that are vital to ensuring that a patient can control their medical circumstances.[43]

The Proposed Rule also disregards standards of care established by the medical community by allowing providers to opt out of providing medical care. Medical practice guidelines and standards of care establish the boundaries of medical services that patients can expect to receive and that providers should be expected to deliver. Yet, the Proposed Rule seeks to allow providers and institutions to ignore the standards of care, particularly surrounding reproductive and sexual health. Information, counseling, referral and provision of contraceptive and abortion services are part of the standard of care for a range of common medical conditions including heart disease, diabetes, epilepsy, lupus, obesity, and cancer.[44] Individuals seeking reproductive health care, regardless of their reasons for needing these services, should be treated with dignity and respect. Allowing providers to flout established medical guidelines and deny medically accurate, evidence-based care to patients harms them and impairs their ability to make the health care decision that is right for them.

In addition, the Proposed Rule ignores the many providers with deeply held moral convictions that affirmatively motivate them to provide patients with health care, including abortion, transition-related care, and end-of-life care. Moreover, the Proposed Rule fails to acknowledge the Church Amendments' protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce.[45] No health care professional should face discrimination from their employer because they treated or provided information to a patient seeking an abortion.

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[41] *See* TOM BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (4th ed. 1994); CHARLES LIDZ ET AL., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY (1984).

[42] *See id.*

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

[44] For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care. Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant. AM. DIABETES ASS'N, STANDARDS OF MEDICAL CARE IN DIABETES-2017, 40 DIABETES CARE § 114-15, S117 (2017), available at http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf. The American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics guidelines state that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually suggested regardless of fetal age or potential for survival. AM. ACAD. OF PEDIATRICS & AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES FOR PERINATAL CARE 232 (7th ed. 2012).

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

The Department is Abdicating its Responsibility to Patients

The Proposed Rule exceeds OCR's authority by abandoning OCR's mission to address health disparities and discrimination that harms patients.[46] Instead, the Proposed Rule appropriates language from civil rights statutes and regulations that were intended to improve access to health care and applies that language to situations for which it was not intended. By taking the language of civil rights laws and regulations out of context, the Proposed Rule creates a regulatory scheme that is not only nonsensical but is affirmatively harmful. For example, the notice and certification of compliance and assurance requirements simply do not make sense when applied to the laws the Proposed Rule seeks to enforce.[47] They will place a significant and burdensome requirement on health care providers and impose unique challenges for those working in other countries by taking resources away from patient care without adding any benefit.

The Department, including OCR, has an important role to play in ensuring equal opportunity to access health care and ending discriminatory practices that contribute to poor health outcomes and health disparities.[48] If finalized, however, the Proposed Rule will represent a radical departure from the Department's mission to combat discrimination, protect patient access to care, and eliminate health disparities. Through robust enforcement of civil rights laws, OCR has worked to reduce discrimination in health care by ending overtly discriminatory practices such as race segregation in health care facilities, segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.[49] These were immense steps in ensure equitable access to health care, particularly for black women.

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

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

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

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

Black women already face significant barriers to accessing reproductive health care. Black women have been systematically denied resources, services and information needed to make important personal decisions about their health. Black women are more likely to lack access to comprehensive sex education and contraception. And as a consequence, they experience higher rates of unintended pregnancy than women of any other ethnic or racial group. Black women are also more likely to experience pregnancy-related complications, or become gravely ill or die in childbirth. The Proposed Rule will exacerbate disparities as medical providers are allowed to withhold important information and health services from patients.

In addition to medical and public health practitioner bias, politics and bias continue to infringe upon the reproductive health rights of women, with constant and persistent threats to defund or limit federal allocations for family planning services, including contraceptives. The Proposed Rule would further divert limited resources away from ending discrimination. De facto segregation, for example, continues to contribute to poorer health outcomes for Black people. According to one study, over half of the racial disparity in survival for heart attack patients can be attributed to the lower performance of hospitals that serve predominantly people of color.[50] And these disparities do not occur in isolation. Black women, for example, are three to four times more likely than white women to die during or after childbirth.[51] Further, the disparity in maternal mortality is growing rather than decreasing,[52] which in part may be due to the reality that women have long been the subject of discrimination in health care and the resulting health disparities. For example, women's pain is routinely undertreated and often dismissed.[53] And due to gender biases and disparities in research, doctors often offer women less aggressive treatment, or even no treatment, for conditions such as heart disease.[54]

Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.[55] Barriers from homophobia and transphobia impede access to care, particularly in

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

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

[52] *See id.*

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

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

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

rural communities with shortages of health care providers and facilities.[56] Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a doctor or other health care provider had refused to see them because of their actual or perceived sexual orientation or gender identity in the year before the survey.[57]

OCR must work to address these disparities, yet the Proposed Rule seeks to prioritize the expansion of existing religious refusal laws beyond their statutory requirements and create new religious exemptions where none had previously existed rather than using already limited resources to protect patient access to health care. The Proposed Rule will harm patient care and is antithetical to OCR's mission—to eliminate discriminatory practices that contribute to persistent health inequality.[58]

The Proposed Rule Conflicts with Other Existing Federal Law

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

For example, the Proposed Rule makes no mention of Title VII,[59] the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[60] With respect to religion, Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer.[61] For decades, Title VII has established the legal framework for religious accommodations in the workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on patients, coworkers, public safety, and other legal obligations. The Proposed Rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both. Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.[62]

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[56] Barry D, Esenstad A, Ensuring Access to Family Planning for All, Washington, DC: Center for American Progress, 2014. Online: https://www.americanprogress.org/ issues/women/reports/2014/10/23/99612/ ensuring-access-to-family-planning-services-for-all/

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

[58] *See supra* note 46.

[59] 42 U.S.C. § 2000e-2 (1964).

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

[61] *See id.*

[62] Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), *available at* https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html.

Furthermore, the language in the Proposed Rule would seem to put health care entities in the position of being forced to hire people who intend to refuse to perform essential elements of a position even though Title VII would not require such an "accommodation." For example, there is no guidance about whether it is impermissible "discrimination" for a Title X-funded health center not to hire a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests because the applicant refuses to provide non-directive options counseling even though the employer would not be required to do so under Title VII.[63] It is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

In addition, the Proposed Rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. For example, in 2016, a 31-year-old woman was sent home from the emergency room although she was experiencing an ectopic pregnancy that would later burst and she was pressured into having a cesarean section. She was denied access to life-saving information about all available health options.[64] The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person to another facility.[65] Under EMTALA every hospital is required to comply – even those that are religiously affiliated.[66] Because the Proposed Rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

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

The Proposed Rule will have a chilling effect on the enforcement of and passage of state laws that protect access to health care and prevent discrimination against individuals seeking medical care. The HHS regulations explicitly target laws in specific states that require many health insurance plants to cover abortion care. The preamble of the Proposed Rule discusses at length state laws that the Department finds objectionable, such as state laws that require anti-abortion counseling centers to provide information about where reproductive health care services can be

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[63] *See* Rule *supra* note 1, at 180-181.

[64] *See* In Our Own Voice: National Black Women's Reproductive Justice Agenda, *Our Bodies, Our Lives, Our Voices: The State of Black Women & Reproductive Justice* (pp. 32-33, Rep.).

[65] 42 U.S.C. § 1295dd(a)-(c) (2003).

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

obtained or whether facilities have licensed medical staff, as well as state laws that require health insurance plans to cover abortion.[67] Moreover, the Proposed Rule invites states to further expand refusals of care by making clear that this expansive rule is a floor, and not a ceiling, for religious exemption laws.[68]

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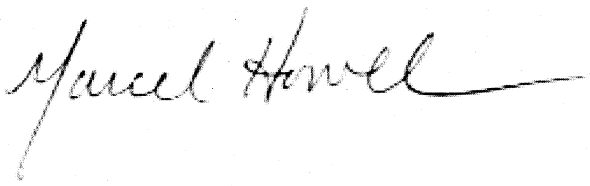
The Proposed Rule will allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care. The Proposed Rule is discriminatory, violates multiple federal statutes and the Constitution, ignores congressional intent, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons *In Our Own Voice: National Black Women's Reproductive Justice Agenda* calls on the Department to withdraw the Proposed Rule in its entirety.

If you require additional information about the issues raised in this letter, please contact Jessica Pinckney, Deputy Director of Government Affairs at jessica@blackrj.org.

Sincerely,



Marcela Howell
Founder and Executive Director
1012 14th Street, NW
Suite 450
Washington, DC 20005

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

Exhibit 75

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

Introduction

On behalf of National Association of Councils on Developmental Disabilities, we submit these comments to the federal Department of Health and Human Services ("Department") and its Office for Civil Rights ("OCR") in opposition to the proposed regulation entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority."[1]

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

Most important, the regulations fail to account for the significant burden that will be imposed on patients, a burden that will fall disproportionately and most harshly on women, people of color, people living with disabilities, and Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ) individuals. These communities already experience severe health disparities and discrimination, conditions that will be exacerbated by the proposed rule, possibly ending in in poorer health outcomes. By issuing the proposed rule along with the newly created "Conscience and Religious Freedom Division," the Department seeks to use OCR's limited resources in order to affirmatively allow institutions, insurance companies, and almost anyone involved in patient care to use their personal beliefs to deny people the care they need. For these reasons, the National Health Law Program calls on the Department and OCR to withdraw the proposed rule in its entirety.

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

Civil rights laws and Constitutional guarantees, such as due process and equal protection, are designed to ensure full participation in civil society. The proposed rule,

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

while cloaked in the language of non-discrimination, is designed to deny care and exclude disadvantaged and vulnerable populations. The adverse consequences of health care refusals and other forms of discrimination are well documented. As the Department stated in its proposed rulemaking for § 1557,

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

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

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

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

Women, individuals living with disabilities, LGBTQ persons, people living in rural communities, and people of color face severe health and health care disparities, and these disparities are compounded for individuals who hold these multiple identities. For example, among adult women, 15.2 percent of those who identified as lesbian or gay reported being unable to obtain medical care in the last year due to cost, as compared to 9.6 percent of straight individuals.[5] Women of color experience health care disparities such as high rates of cervical cancer and are disproportionately impacted by HIV.[6]

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[2] Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172, 54,194 (Sept. 8, 2015) (codified at 45 C.F.R. pt. 2).
[3] 83 Fed. Reg. 3917.
[4] *Id.*
[5] Brian P. Ward et al., *Sexual Orientation and Health Among U.S. Adults: National Health Interview Survey*, NAT'L CTR. FOR HEALTH STATISTICS, 2013 9 (2014), https://www.cdc.gov/nchs/data/nhsr/nhsr077.pdf.
[6] In 2014, Latinas had the highest rates of contracting cervical cancer and Black women had the highest death rates. *Cervical Cancer Rates By Rates and Ethnicity*, CTRS. FOR DISEASE CONTROL & PREVENTION, (Jun. 19, 2017), https://www.cdc.gov/cancer/cervical/statistics/race.htm.;At the end of 2014, of the total

Meanwhile, people of color in rural America are more likely to live in an area with a shortage of health professionals, with 83% of majority-Black counties and 81% of majority-Latino/a counties designated by the federal Health Resources and Services Administration (HRSA) as Health Professional Shortage Areas (HPSAs).

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

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

Broadly-defined and widely-implemented refusal clauses undermine access to basic health services for all, but can particularly harm low-income women. The burdens on low-income women can be insurmountable when women and families are uninsured,[7] underinsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services nor travel to another location. This is especially true for immigrant women. In comparison to their U.S. born peers, immigrant women are more likely to be uninsured.[8] Notably, immigrant, Latina women have far higher rates of uninsurance than Latina women born in the United States (48 percent versus 21 percent, respectively).[9]

According to a recent report, doctors often fail to inform Black women of the full range of reproductive health options regarding labor or delivery possibly due to stereotypes about Black women's sexuality and reproduction.[10] Young Black women noted that they were shamed by providers when seeking sexual health information and contraceptive care in part, due to their age, and in some instances, sexual orientation.[11]

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number of women diagnosed with HIV, 60 percent were Black. *HIV Among Women,* CTRS. FOR DISEASE CONTROL & PREVENTION, Nov. 17, 2017, https://www.cdc.gov/hiv/group/gender/women/index.html.

[7] In 2016, an estimated 11 percent of women between the ages of 19 to 64 were uninsured. Single mothers, women of color, and low-income women are more likely to be uninsured. KAISER FAMILY FOUND., *Women's Health Insurance Coverage* 3 (Oct. 31, 2017), http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage.

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

[9] *Id.* at 8, 16.

[10] CTR. FOR REPROD. RIGHTS, NAT'L LATINA INST. FOR REPROD. HEALTH & SISTERSONG WOMEN OF COLOR REPROD. JUSTICE COLLECTIVE, *Reproductive Injustice: Racial and Gender Discrimination in U.S. Health Care* 20-22 (2014), *available at* https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/CERD_Shadow_US_6.30.14_Web.pdf [hereinafter *Reproductive Injustice*]; IN OUR OWN VOICE: NAT'L BLACK WOMEN'S REPROD. JUSTICE AGENDA, *The State of Black Women & Reproductive Justice* 32-33 (2017), *available at* http://blackrj.org/wp-content/uploads/2017/06/FINAL-InOurVoices_Report_final.pdf.

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

New research also shows that women of color in many states disproportionately receive their care at Catholic hospitals, subjecting them to treatment that does not comply with the standards of care.[12] In nineteen states, women of color are more likely than white women to give birth in Catholic hospitals.[13] In New Jersey, for example, women of color make up 50 percent of women of reproductive age in the state, yet have twice the number of births at Catholic hospitals compared to their white counterparts.[14] These hospitals as well as many Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provides guidance on wide range of hospital matters, including reproductive health care. In practice, the ERDs prohibit the provision of emergency contraception, sterilization, abortion, fertility services, and some treatments for ectopic pregnancies. Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals and as a result, women were delayed care or transferred to other facilities, risking their health.[15] The proposed rule will give health care providers a license, such as Catholic hospitals, to opt out of evidence-based care that the medical community endorses. If this rule were to be implemented, more women, particularly women of color, will be put in situations where they will have to decide between receiving compromised care or seeking another provider to receive quality, comprehensive reproductive health services. For many, this choice does not exist.

b. The proposed rule will negatively impact rural communities

The ability to refuse care to patients will leave many individuals in rural communities with no health care options. Medically underserved areas already exist in every state,[16] with over 75 percent of chief executive officers of rural hospitals reporting physician shortages.[17] Many rural communities experience a wide array of mental health, dental health, and primary care health professional shortages, leaving individuals in rural communities with less access to care that is close, affordable, and high quality, than their urban counterparts.[18] Among the many geographic and spatial barriers that exist, individuals in rural areas often must have a driver's license and own a private car to access care, as they must travel further distances for regular checkups, often on poorer

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[12] Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT (2018), *available at* https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
[13] *Id* at 12.
[14] *Id* at 9.
[15] Lori R. Freedman et al., *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.
[16] Health Res. & Serv. Admin, *Quick Maps – Medically Underserved Areas/Populations*, U.S. DEP'T OF HEALTH & HUM. SERV., https://datawarehouse.hrsa.gov/Tools/MapToolQuick.aspx?mapName=MUA, (last visited Mar. 21, 2018).
[17] M. MacDowell et al., *A National View of Rural Health Workforce Issues in the USA,* 10 RURAL REMOTE HEALTH (2010), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3760483/.
[18] Carol Jones et al., *Health Status and Health Care Access of Farm and Rural Populations,* ECON. RESEARCH SERV. (2009), *available at* https://www.ers.usda.gov/publications/pub-details/?pubid=44427.

quality roads, and have less access to reliable public transportation.[19] This scarcity of accessible services leaves survivors of intimate partner violence (IPV) in rural areas with fewer shelter beds close to their homes, with an average of just 3.3 IPV shelter beds per rural county as compared to 13.8 in urban counties.[20] Among respondents of one survey, more than 25 percent of survivors of IPV in rural areas have to travel over 40 miles to the nearest support service, compared to less than one percent of women in urban areas.[21]

Other individuals in rural areas, such as people with disabilities, people with Hepatitis C, and people of color, have intersecting identities that further exacerbate existing barriers to care in rural areas. Racial and ethnic minority communities often live in concentrated parts of rural America, in communities experiencing rural poverty, lack of insurance, and health professional shortage areas.[22] People with disabilities experience difficulties finding competent physicians in rural areas who can provide experienced and specialized care for their specific needs, in buildings that are barrier free.[23] Individuals with Hepatitis C infection find few providers in rural areas with the specialized knowledge to manage the emerging treatment options, drug toxicities and side effects.[24] All of these barriers will worsen if providers are allowed to refuse care to particular patients.

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

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[19] Thomas A. Arcury et al., *The Effects of Geography and Spatial Behavior on Health Care Utilization among the Residents of a Rural Region*, 40 HEALTH SERV. RESEARCH (2005) *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1361130/.

[20] Corinne Peek-Asa et al., *Rural Disparity in Domestic Violence Prevalence and Access to Resources,* 20 J. OF WOMEN'S HEALTH (Nov. 2011) *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3216064/.

[21] *Id.*

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

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

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

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

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

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

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

LGBTQ people continue to face discrimination in many areas of their lives, including health care, on the basis of their sexual orientation and gender identity. The Department's Healthy People 2020 initiative recognizes, "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights."[27] LGBTQ people still face discrimination in a wide variety of services affecting access to health care, including reproductive services, adoption and foster care services, child care, homeless shelters, and transportation services – as well as physical and mental health care services.[28] In a recent study published in *Health Affairs*, researchers examined the intersection of gender identity, sexual orientation, race, and economic factors in health care access.[29] They concluded that discrimination as well as insensitivity or disrespect on the part of health care providers were key barriers to health care access and that increasing efforts to provide culturally sensitive services would help close the gaps in health care access.[30]

i. Discrimination against the transgender community

Discrimination based on gender identity, gender expression, gender transition, transgender status, or sex-based stereotypes is necessarily a form of sex discrimination.[31] Numerous federal courts have found that federal sex discrimination

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[27] *Healthy People 2020, Lesbian, Gay, Bisexual, and Transgender Health*, U.S. DEPT. HEALTH & HUMAN SERV., https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health, (last accessed on Mar. 8, 2018).

[28] HUMAN RIGHTS WATCH, *All We want is Equality: Religious Exemptions and Discrimination against LGBT People in the United States*, (Feb. 2018), https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people.

[29] Ning Hsieh and Matt Ruther, HEALTH AFFAIRS, *Despite Increased Insurance Coverage, Nonwhite Sexual Minorities Still Experience Disparities In Access To Care* (Oct. 2017) 1786–1794.

[30] *Id.*

[31] *See, e.g.*, *EEOC v. R.G. & G.R. Harris Funeral Homes*, No. 16-2424 (6th Cir. Mar. 7, 2018); *Whitaker v. Kenosha Unified Sch. Dist.*, 858 F.3d 1034 (7th Cir. 2017) (Title IX and Equal Protection Clause); Doddsv. U.S. Dep't of Educ., 845 F.3d 217 (6th Cir. 2016) (Title IX and Equal Protection Clause); *Barnes v. City of Cincinnati*, 401 F.3d 729 (6th Cir. 2005) (Title VII of the 1964 Civil Rights Act); Smith v. City of Salem, 378 F.3d 566 (6th Cir. 2004) (Title VII); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213 (1st Cir. 2000) (Equal Credit Opportunity Act); *A.H. ex rel. Handling v. Minersville Area School District*, 3:17-CV-391, 2017 WL 5632662 (M.D. Pa. Nov. 22, 2017) (Title IX and Equal Protection Clause); *Stone v. Trump*, ---F.Supp.3d ---, No. 17–2459 (D. Md. Nov. 21, 2017) (Equal Protection Clause); Doe v. Trump, ---F.Supp.3d ---, 2017 WL 4873042 (D.D.C. Oct. 30, 2017) (Equal Protection Clause); *Prescott v. Rady Children's Hospital-San Diego*, ---F.Supp.3d ---, 2017 WL 4310756 (S.D. Cal. Sept. 27, 2017) (Section 1557); *E.E.O.C. v. Rent-a-Center East, Inc.*, ---F.Supp.3d ---, 2017 WL 4021130 (C.D. Ill. Sept. 8, 2017) (Title VII); *Brown v. Dept. of Health and Hum. Serv.*, No. 8:16DCV569, 2017 WL 2414567 (D. Neb. June 2, 2017) (Equal Protection Clause); *Smith v. Avanti*, 249 F.Supp.3d 1194 (D. Colo. 2017) (Fair Housing Act); *Students & Parents for Privacy v. U.S. Dep't of Educ.*, No. 16-cv-4945, 2016 WL 6134121 (N.D. Ill.

statutes reach these forms of gender-based discrimination.[32] In 2012, the Equal Employment Opportunity Commission (EEOC) likewise held that "intentional discrimination against a transgender individual because that person is transgender is, by definition, discrimination based on sex and such discrimination therefore violates Title VII."[33]

Twenty-nine percent of transgender individuals were refused to be seen by a health care provider on the basis of their perceived or actual gender identity and 29 percent experienced unwanted physical contact from a health care provider.[34] Additionally, the 2015 U.S. Transgender Survey found that 23 percent respondents did not see a provider for needed health care because of fears of mistreatment or discrimination.[35] Data obtained by Center for American Progress (CAP) under a FOIA request indicates the Department's enforcement was effective in resolving issues of anti-LGBTQ discrimination. CAP received information on closed complaints of discrimination based on sexual orientation, sexual orientation-related sex stereotyping, and gender identity that were filed with the Department under Section 1557 of the ACA from 2012 through 2016.

- "In approximately 30% of these claims, patients alleged denial of care or insurance coverage simply because of their gender identity – not related to gender transition."
- "Approximately 20% of the claims were for misgendering or other derogatory language."

Oct. 18, 2016) (Title IX); *Mickens v. Gen. Elec. Co.* No. 16-603, 2016 WL 7015665 (W.D. Ky. Nov. 29, 2016) (Title VII); *Fabian v. Hosp. of Cent. Conn.*, 172 F.Supp.3d 509 (D. Conn. 2016) (Title VII); *Cruz v. Zucker*, 195 F.Supp.3d 554 (S.D.N.Y. Jul. 5, 2016) (Section 1557); *Doe v. State of Ariz.*, No. CV-15-02399-PHX-DGC, 2016 WL 1089743 (D. Ariz. Mar. 21, 2016) (Title VII); *Dawson v. H&H Elec., Inc.*, No. 4:14CV00583 SWW, 2015 WL 5437101 (E.D. Ark. Sept. 15, 2015) (Title VII); *U.S. v. S.E. Okla. State Univ.*, No. CIV–15–324–C, 2015 WL 4606079 (W.D. Okla. 2015) (Title VII); *Rumble v. Fairview Health Serv.*, No. 14–cv–2037, 2015 WL 1197415 (D. Minn. Mar. 16, 2015) (Section 1557); *Finkle v. Howard Cty.*, 12 F.Supp.3d 780 (D. Md. 2014) (Title VII); *Schroer v. Billington*, 577 F. Supp. 2d 293 (D.D.C. 2008) (Title VII); *Lopez v. River Oaks Imaging & Diagnostic Grp.*, Inc., 542 F.Supp.2d 653 (S.D. Tex. 2008) (Title VII); *Mitchell v. Axcan Scandipharm,* Inc., No. Civ.A. 05-243, 2006 WL 456173 (W.D. Pa. 2006) (Title VII); *Tronettiv. Healthnet Lakeshore Hosp.*, No. 03–CV–0375E, 2003 WL 22757935 (W.D.N.Y. Sept. 26, 2003) (Title VII).

[32] *See, e.g.*, *Smith v. City of Salem*, 378 F.3d 566, 572-75 (6th Cir. 2004); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213, 215-16 (1st Cir. 2000) (Equal Credit Opportunity Act); *Schwenk v. Hartford*, 204 F.3d 1187 (9th Cir. 2000) (Gender Motivated Violence Act). *See also* Statement of Interest of the United States at 14, *Jamal v. Saks*, No. 4:14-cv-02782 (S.D. Tex. Jan. 26, 2015).

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

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

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

- "Patients denied care due to their gender identity or transgender status included a transgender woman denied a mammogram and a transgender man refused a screening for a urinary tract infection."[36]

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

ii. Discrimination Based Upon Sexual Orientation

Many LGBTQ people lack insurance and providers are not competent in health care issues and obstacles that the LGBTQ community experiences.[37] LGBTQ people still face discrimination. According to one survey, 8 percent of lesbian, gay, bisexual, and queer individuals had an experience within the year prior to the survey where a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation and 7 percent experienced unwanted physical contact and violence from a health care provider.[38]

Fear of discrimination causes many LGB people to avoid seeking health care, and, when they do seek care, LGB people are frequently not treated with the respect that all patients deserve. The study "When Health Care Isn't Caring" found that 56 percent of LGB people reported experiencing discrimination from health care providers – including refusals of care, harsh language, or even physical abuse – because of their sexual orientation.[39] Almost ten percent of LGB respondents reported that they had been denied necessary health care expressly because of their sexual orientation.[40] Delay and avoidance of care due to fear of discrimination compound the significant health disparities that affect the lesbian, gay, and bisexual population. These disparities include:

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

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

[38] Mirza, *supra* note 34.

[39] LAMBDA LEGAL, *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination Against LGBT People and People with HIV* 5 (2010), *available at* .http://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf.

[40] *Id.*

- LGB individuals are more likely than heterosexuals to rate their health as poor, have more chronic conditions, and have higher prevalence and earlier onset of disabilities.[41]
- Lesbian and bisexual women report poorer overall physical health than heterosexual women.[42]
- Gay and bisexual men report more cancer diagnoses and lower survival rates, higher rates of cardiovascular disease and risk factors, as well as higher total numbers of acute and chronic health conditions.[43]
- Gay and bisexual men and other men who have sex with men (MSM) accounted for more than half (56 percent) of all people living with HIV in the United States, and more than two-thirds (70 percent) of new HIV infections.[44]
- Bisexual people face significant health disparities, including increased risk of mental health issues and some types of cancer.[45]

This discrimination affects not only the mental health and physical health of LGBTQ people, but that of their families as well. One pediatrician in Alabama reported that "we often see kids who haven't seen a pediatrician in 5, 6, 7 years, because of fear of being judged, on the part of either their immediate family or them [identifying as LGBTQ]".[46] It is therefore crucial that LGBTQ individuals who have found unbiased and affirming providers, be allowed to remain with them. If turned away by a health care provider, 17 percent of all LGBTQ people, and 31 percent of LGBTQ people living outside of a metropolitan area, reported that it would be "very difficult" or "not possible" to find the same quality of service at a different community health center or clinic.[47]

The proposed rule allowing providers to deny needed care would reverse recent gains in combatting discrimination and health care disparities for LGBT persons. Refusals also implicate standards of care that are vital to LGBTQ health. Medical professionals are expected to provide LGBTQ individuals with the same quality of care as they would anyone else. The American Medical Association recommends that providers use culturally appropriate language and have basic familiarity and competency with LGBTQ issues as they pertain to any health services provided.[48] The World Professional

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[41] David J. Lick, Laura E. Durso & Kerri L. Johnson, *Minority Stress and Physical Health Among Sexual Minorities*, 8 PERS. ON PSYCHOL. SCI. 521 (2013), *available at* http://williamsinstitute.law.ucla.edu/research/health-and-hiv-aids/minority-stress-and-physical-health-among-sexual-minorities/.

[42] *Id.*

[43] *Id.*

[44] CTRS FOR DISEASE CONTROL & PREVENTION, *CDC Fact Sheet: HIV Among Gay and Bisexual Men* 1(Feb. 2017), https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/cdc-msm-508.pdf.

[45] HUMAN RIGHTS CAMPAIGN ET AL., *Health Disparities Among Bisexual People* (2015) *available at* http://hrc-assets.s3-website-us-east-1.amazonaws.com//files/assets/resources/HRC-BiHealthBrief.pdf.

[46] HUMAN RIGHTS WATCH, *supra* note 28.

[47] Mirza, *supra* note 34.

[48] *Community Standards of Practice for the Provision of Quality Health Care Services to Lesbian, Gay, Bisexual, and Transgender Clients*, GAY LESBIAN BISEXUAL & TRANSGENDER HEALTH ACCESS PROJECT, http://www.glbthealth.org/CommunityStandardsofPractice.htm (last visited Jan. 26, 2018, 12:59 PM); *Creating an LGBTQ-friendly Practice*, A.M.A., https://www.ama-assn.org/delivering-care/creating-lgbtq-friendly-practice#Meet a Standard of Practice (last visited Jan. 26, 2018, 12:56 PM).

Association for Transgender Health guidelines provide that gender-affirming interventions, when sought by transgender individuals, are medically necessary and part of the standard of care.[49] The American College of Obstetricians and Gynecologists warns that failure to provide gender-affirming treatment can lead to serious health consequences for transgender individuals.[50] LGBTQ individuals already experience significant health disparities, and denying medically necessary care on the basis of sexual orientation or gender identity exacerbates these disparities.

In addition, LGBTQ individuals face disparities in medical conditions that may implicate the need for reproductive health services. For example, lesbian and bisexual women report heightened risk for and diagnosis of some cancers and higher rates of cardiovascular disease.[51] The LGBTQ community is significantly at risk for sexual violence.[52] Eighteen percent of lesbian, gay, bisexual students have reported being forced to have sex.[53] Transgender women, particularly women of color, face high rates of HIV.[54]

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

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

d. The proposed rule will hurt people living with disabilities

Many people with disabilities receive home and community-based services (HCBS), including residential and day services, from religiously-affiliated providers. Historically,

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[49] *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People*, WORLD PROF. ASS'N FOR TRANSGENDER HEALTH (2011), https://s3.amazonaws.com/amo_hub_content/Association140/files/Standards%20of%20Care%20V7%20-%202011%20WPATH%20(2)(1).pdf.

[50] *Committee Opinion 512: Health Care for Transgender Individuals*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (Dec. 2011), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-for-Transgender-Individuals.

[51] Kates, *supra* note 37, at 4.

[52] Forty-six percent of bisexual women have been raped and 47 percent of transgender people are sexually assaulted at some point in their lifetime. This rate is particularly higher for transgender people of color. Kates, *supra* note 37, at 8.; *2015 U.S. Transgender Survey*, *supra* note 35, at 5.

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

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

people with disabilities who rely on these services have sometimes faced discrimination, exclusion, and a loss of autonomy due to provider objections. Group homes have, for example, refused to allow residents with intellectual disabilities who were married to live together in the group home.[55] Individuals with HIV – a recognized disability under the ADA – have repeatedly encountered providers who deny services, necessary medications, and other treatments citing religious and moral objections. One man with HIV was refused care by six nursing homes before his family was finally forced to relocate him to a nursing home 80 miles away.[56] Given these and other experiences, the extremely broad proposed language at 45 C.F.R. § 88.3(a)(2)(vi) that would allow any individual or entity with an "articulable connection" to a service, referral, or counseling described in the relevant statutory language to deny assistance due to a moral or religious objection is extremely alarming and could seriously compromise the health, autonomy, and well-being of people with disabilities.

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

Finally, due to limited provider networks in some areas and to the important role that case managers and personal care attendants play in coordinating care, it may be more difficult for people with disabilities and older adults to find an alternate providers who can help them. For example, home care agencies and home-based hospice agencies in rural areas are facing significant financial difficulties staying open. Seven percent of all zip codes in the United States to not have any hospice services available to them.[57] Finding providers competent to treat people with certain disabilities can increase the challenge. Add in the possibility of a case manager or personal care attendant who

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

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

[57] Julie A. Nelson & Barbara Stover Gingerich, *Rural Health: Access to Care and Services*, 22 HOME HEALTH CARE MGMT. PRAC. (2010), *available at* http://globalag.igc.org/ruralaging/us/2010/access.pdf.

objects to helping and the barrier to accessing these services can be insurmountable. Moreover, people with disabilities who identify as LGBTQ or who belong to a historically disadvantaged racial or ethnic group may be both more likely to encounter service refusals and also face greater challenges to receive (or even know about) accommodations.

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

The proposed rule threatens informed consent, a necessary principle of patient-centered decision-making. Informed consent relies on disclosure of medically accurate information by providers so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.[58] This right relies on two factors: access to relevant and medically-accurate information about treatment choices and alternatives, and provider guidance based on generally accepted standards of practice. Both factors make trust between patients and health care professionals a critical component of quality of care.

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

In recent decades, the U.S. medical community has primarily looked to informed consent as key to assuring patient autonomy in making decisions.[59] Informed consent is intended to help balance the unequal balance of power between health providers and patients and ensure patient-centered decision-making. Moreover, consent is not a yes or no question but rather is dependent upon the patient's understanding of the procedure that is to be conducted and the full range of treatment options for a patient's medical condition. Without informed consent, patients will be unable to make medical decisions that are grounded in agency, their beliefs and preferences, and that meet their personal needs. This is particularly problematic as many communities, including women of color and women living with disabilities, have disproportionately experienced abuse and trauma at the hands of providers and institutions.[60] In order to ensure that patient

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[58] TOM BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (4th ed. 1994); CHARLES LIDZ ET AL., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY (1984).

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

[60] Gutierrez, E. R. *Fertile Matters: The Politics of Mexican Origin Women's* Reproduction, 35-54 (2008) (discussing coercive sterilization of Mexican-origin women in Los Angeles); Jane Lawrence, *The Indian Health Service and the Sterilization of Native American Women*, 24 AM. INDIAN Q. 400, 411-12 (2000) (referencing one 1974 study indicating that Indian Health Services would have coercively sterilized approximately 25,000 Native American Women by 1975); Alexandra Minna Stern, *Sterilized in the Name of Public Health*, 95 AM. J. PUB. H. 1128, 1134 (July 2005) (discussing African-American women forced

decisions are based on free will, informed consent must be upheld in the patient-provider relationship. The proposed rule threatens this principle and may very well force individuals into harmful medical circumstances.

According to the American Medical Association: "The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice."[61]The American Nursing Association similarly requires that patient autonomy and self-determination are core ethical tenets of nursing. "Patients have the moral and legal right to determine what will be done with their own persons; to be given accurate, complete and understandable information in a manner that facilitates an informed judgment; to be assisted with weighing the benefits, burdens and available options in their treatment."[62] Similarly, pharmacists are called to respect the autonomy and dignity of each patient.[63]

Various state and federal laws require that health care professionals inform and counsel patients on specific issues such as preventing the spread of HIV/AIDS, non-directional information on family planning and abortion options, and emergency contraception to prevent pregnancy from rape.[64] In *Brownfield v. Daniel Freeman Marina Hospital*, a California court addressed the importance of patients' access to information in regard to emergency contraception. The court found that:

> "The duty to disclose such information arises from the fact that an adult of sound mind has 'the right, in the exercise of control over [her] own body, to determine whether or not to submit to lawful medical treatment.' [citation omitted] Meaningful exercise of this right is possible only to the extent that patients are provided with adequate information upon which to base an intelligent decision with regard to the option available."[65]

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to choose between sterilization and medical care or welfare benefits and Mexican women forcibly sterilized). *See also Buck v. Bell*, 274 U.S. 200, 207 (1927) (upholding state statute permitting compulsory sterilization of "feeble-minded" persons); Vanessa Volz, *A Matter of Choice: Women With Disabilities, Sterilization, and Reproductive Autonomy in the Twenty-First Century*, 27 WOMEN RTS. L. REP. 203 (2006) (discussing sterilization reform statutes that permit sterilization with judicial authorization).

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

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

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

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

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

In addition, the proposed rule does not provide any protections for health care professionals who want to provide, counsel, or refer for health care services that are implicated in this rule, for example, reproductive health or gender affirming care. Due to the rule's aggressive enforcement mechanisms and its vague and confusing language, providers may fear to give care or information. The inability of providers to give comprehensive, medically accurate information and options that will help patients make the best health decisions violates medical principles such as, beneficence, nonmaleficence, respect for autonomy, and justice. In particular, the principle of beneficence "requires that treatment and care do more good than harm; that the benefits outweigh the risks, and that the greater good for the patient is upheld."[66] In addition, the proposed rule undermines principles of quality care. Health care should be safe, effective, patient-centered, timely, efficient, and equitable.[67] Specifically, the provision of the care should not vary due to the personal characteristics of patients and should ensure that patient values guide all clinical decisions.[68] The expansion of religious refusals as envisioned in the proposed rule may compel providers to furnish care and information that harms the health, well-being, and goals of patients.

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

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

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

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[66] Amy G. Bryant & Jonas J. Schwartz, *Why Crisis Pregnancy Centers Are Legal but Unethical*, 20 AM. MED. ASS'N J. ETHICS 269, 272 (2018).
[67] INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 3 (Mar. 2001), *available at* http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf.
[68] *Id.*

The opioid epidemic continues to claim too many lives. According to the Centers for Disease Control and Prevention (CDC), over 63,000 people in the U.S. died from drug overdose in 2016.[69] The latest numbers show a 2017 increase in emergency department overdose admissions of 30% across the country, and up to 70% in some areas of the Midwest.[70]

The clear, evidence-based treatment standard for opioid use disorder (OUD) is medication-assisted treatment (MAT).[71] Buprenorphine, methadone, and naltrexone are the three FDA-approved drugs for treating patients with opioid use disorder. MAT is so valuable to treatment of addiction that the World Health Organization considers buprenorphine and methadone "Essential Medications."[72] Buprenorphine and methadone are, in fact, opioids. However, while they operate on the same receptors in the brain as other opioids, they do not produce the euphoric effect of other opioids but simply keep the user from experiencing withdrawal symptoms. They also keep patients from seeking opioids on the black market, where risk of death from accidental overdose increases. Patients on MAT are less likely to engage in dangerous or risky behaviors because their physical cravings are met by the medication, increasing their safety and the safety of their communities.[73] Naloxone is another medication key to saving the lives of people experiencing an opioid overdose. This medication reverses the effects of an opioid and can completely stop an overdose in its tracks.[74] Information about and access to these medications are crucial factors in keeping patients suffering from SUD from losing their jobs, losing their families, and losing their lives.

However, stigma associated with drug use stands in the way of saving lives.[75] America's prevailing cultural consciousness, after decades of treating the disease of addiction as largely a criminal justice and not a public health issue, generally perceives drug use as a moral failing and drug users as less deserving of care. For example, a needle exchange program designed to protect injection drug users from contracting blood

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[69] Holly Hedegaard M.D., et al. *Drug Overdose Deaths in the United States, 1999-2016*, NAT'L CTR. FOR HEALTH STATISTICS1-8 (2017).
[70] *Vital Signs*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vitalsigns/opioid-overdoses/.
[71] U.S. DEP'T HEALTH & HUM. SERV., PUB NO. (SMA)12-4214, MEDICATION-ASSISTED TREATMENT FOR OPIOID ADDICTION IN OPIOID TREATMENT PROGRAMS (2012), https://store.samhsa.gov/shin/content/SMA12-4214/SMA12-4214.pdf; National Institute on Drug Abuse, *Effective Treatments for Opioid Addiction*, https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction.
[72] World Health Organization, 19th WHO Model List of Essential Medicines (April 2015), http://www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf
[73] OPEN SOC'Y INST., BARRIERS TO ACCESS: MEDICATION-ASSISTED TREATMENT AND INJECTION-DRIVEN HIV EPIDEMICS 1 (2009), https://www.opensocietyfoundations.org [https://perma.cc/YF94-88AP].
[74] *See* James M. Chamberlain & Bruce L. Klein, *A Comprehensive Review of Naloxone for the Emergency Physician*, 12 AM. J. EMERGENCY MED. 650 (1994).
[75] Ellen M. Weber, *Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance*, 13 J. HEALTH CARE L. & POL'Y 49, 56 (2010); German Lopez, *There's a highly successful treatment for opioid addiction. But stigma is holding it back.*, VOX, Nov. 15, 2017, https://www.vox.com/science-and-health/2017/7/20/15937896/medication-assisted-treatment-methadone-buprenorphine-naltrexone.

borne illnesses such as HIV, Hepatitis C, and bacterial endocarditis was shut down in October 2017 by the Lawrence County, Indiana County Commission due to their moral objection to drug use, despite overwhelming evidence that these programs are effective at reducing harm and do not increase drug use.[76] One commissioner even quoted the Bible as he voted to shut it down. Use of naloxone to reverse overdose has been decried as "enabling these people" to go on to overdose again.[77]

In this frame of mind, only total abstinence is seen as successful treatment for SUD, usually as a result of a 12-step or faith-based program. MAT is considered by many to be simply "substituting one drug for another drug."[78] This belief is so common that even the former Secretary of the Department is on the record as opposing MAT because he didn't believe it would "move the dial," since people on medication would be not "completely cured."[79] The scientific consensus is that SUD is a chronic disease, and yet many recoil from the idea of treating SUD with medication like any other illness such as diabetes or heart disease.[80] The White House's own opioid commission found that "negative attitudes regarding MAT appeared to be related to negative judgments about drug users in general and heroin users in particular."[81]

People with SUD already suffer due to stigma and have a difficult time finding appropriate care. For example, it can be difficult to find access to local methadone clinics in rural areas.[82] Other roadblocks, such as artificial caps on the number of patients to whom doctors can prescribe buprenorphine, further prevent people with SUD from receiving appropriate care.[83] Only one-third of treatment programs across the country provide MAT, even though treatment with MAT can cut overdose mortality rates in half and is considered the gold standard of care. [84] The current Secretary of the

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

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

[78] Lopez, *supra* note 75.

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

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

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

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

[83] 42 C.F.R. §8.610.

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

Department has noted that expanding access to MAT is necessary to save lives and that it will be "impossible" to quell the opioid epidemic without increasing the number of providers offering the evidence-based standard of care.[85] This rule, which allows misinformation and personal feelings to get in the way of science and lifesaving treatment, will not help achieve the goals of the administration; it will instead trigger countless numbers of deaths.

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

Medical practice guidelines and standards of care establish the boundaries of medical care that patients can expect to receive and that providers should be expected to deliver. The health services impacted by refusals are often related to reproductive and sexual health, which are implicated in a wide range of common health treatment and prevention strategies. Information, counseling, referral and provisions of contraceptive and abortion services are part of the standard of care for a range of common medical conditions including heart disease, diabetes, epilepsy, lupus, obesity, and cancer. Many of these conditions disproportionately affect women of color.[86] The expansion of these refusals as outlined in the proposed rule will put women, particularly women of color, who experience these medical conditions at greater risk for harm.

Moreover, a 2007 survey of physicians working at religiously-affiliated hospitals found that nearly one in five (19 percent) experienced a clinical conflict with the religiously-based policies of the hospital.[87] While some of these physicians might refer their patients to another provider who could provide the necessary care, one 2007 survey found that as many as one-third of patients (nearly 100 million people) may be receiving

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https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/plenary-addres-to-national-governors-association.html.

[85] Azar, *supra* note 84.

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

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

care from physicians who do not believe they have any obligations to refer their patients to other providers.[88] Meanwhile, the number of Catholic hospitals in the United States has increased by 22 percent since 2001, and now own one in six hospital beds across the country.[89] The increase of Catholic hospitals poses a danger for women seeking reliable access to medical services, many of whom do not understand the full range of services that may be denied them. One public opinion survey found that, among the less than one-third of women who understood that a Catholic hospital might limit care, only 43 percent expected limited access to contraception, and a mere 6 percent expected limited access to the morning-after pill.[90]

a. Pregnancy prevention

The importance of the ability of women to make decisions for themselves to prevent or postpone pregnancy is well-established within the medical guidelines across a range of practice areas. Millions of women live with chronic conditions such as cardiovascular disease, diabetes, lupus, and epilepsy, which if not properly controlled, can lead to health risks to the pregnant woman or even death during pregnancy. Denying these women access to contraceptive information and services violates medical standards that recommend pregnancy prevention for these medical conditions. For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care.[91] Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant.[92]

Moreover, women who are struggling to make ends meet are disproportionately impacted by unintended pregnancy. In 2011, 45% of pregnancies in the U.S. were unintended – meaning that they were either unwanted or mistimed.[93] Low-income women have higher rates of unintended pregnancy as they are least likely to have the resources to obtain reliable methods of family planning, and yet, they are most likely to be impacted negatively by unintended pregnancy.[94] The Institute of Medicine has

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

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

[90] Nadia Sawicki, *Mandating Disclosure Of Conscience-Based Limitations On Medical Practice*, 42 AM. J. OF LAW & MED. 85-128 (2016) *available at* http://journals.sagepub.com/doi/pdf/10.1177/0098858816644717.

[91] AM. DIABETES ASS'N, STANDARDS OF MEDICAL CARE IN DIABETES-2017, 40 DIABETES CARE S115, S117 (2017), available at: http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf

[92] *Id.* at S114.

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

[94] Lawrence B. Finer & Stanley K. Henshaw, *Disparities in rates of unintended pregnancy in the United*

documented negative health effects of unwanted pregnancy for mothers and children. Unwanted pregnancy is associated with maternal morbidity and risky health behaviors as well as low-birth weight babies and insufficient prenatal care.[95]

b. Sexually transmitted infections (STIs)

Religious refusals also impact access to sexual health care more broadly. Contraceptives and access to preventative treatment for sexually transmitted infections are a critical aspect of health care. The CDC estimates that 20 million new sexually transmitted infections occur each year. Chlamydia remains the most commonly reported infectious disease in the U.S., while HIV/AIDS remains the most life threatening. Women, especially young women, and Black women, are hit hardest by Chlamydia—with rates of Chlamydia 5.6 times higher for Black than for white Americans.[96] Consistent use of condoms results in an 80 percent reduction of HIV transmission, and the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the World Health Organization all recommend the condom use be promoted by providers.[97]

c. Ending a Pregnancy

While there are numerous reasons for why a person would seek to end a pregnancy, there are many medical conditions in which ending a pregnancy is recommended as treatment. These conditions include: preeclampsia and eclampsia, certain forms of cardiovascular disease, and complications for chronic conditions. Significant racial disparities exist in rates of and complications associated with preeclampsia.[98] For example, the rate of preeclampsia is 61% higher for Black women than for white women, and 50% higher than women overall.[99] The American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics guidelines state

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States, 1994 and 2001, 38 PERSPECTIVES ON SEXUAL & REPROD. HEALTH 90-6 (2006).

[95] INSTITUTE OF MEDICINE COMMITTEE ON UNINTENDED PREGNANCY, THE BEST INTENTIONS: UNINTENDED PREGNANCY AND THE WELL-BEING OF CHILDREN AND FAMILIES (Sarah S. Brown & Leon Eisenberg eds.,1995).

[96] *Sexually Transmitted Disease Surveillance 2016*, CTR. FOR DISEASE CONTROL & PREVENTION (Sept. 2017), https://www.cdc.gov/std/stats16/CDC_2016_STDS_Report-for508WebSep21_2017_1644.pdf.

[97] American Academy of Pediatrics Committee on Adolescence, *Condom Use by Adolescents*, 132 PEDIATRICS (Nov. 2013), http://pediatrics.aappublications.org/content/132/5/973; American Academy of Pediatrics, American College of Obstetricians and Gynecologists, March of Dimes Birth Defects Foundation. Guidelines for perinatal care. 6th ed. Elk Grove Village, IL; Washington, DC: American Academy of Pediatrics; American College of Obstetricians and Gynecologists; 2007; American College of Obstetricians and Gynecologists. Barrier methods of contraception. Brochure (available at http://www.acog.org/publications/patient_education/bp022.cfm). Washington, DC: American College of Obstetricians and Gynecologists; 2008 July; World Health Organization, UNAIDS, UNFPA, *Position statement on condoms and HIV prevention*, UNICEF (2009), https://www.unicef.org/aids/files/2009_position_paper_condoms_en.pdf.

[98] Sajid Shahul et al., *Racial Disparities in Comorbidities, Complication, and Maternal and Fetal Outcomes in Women With Preeclampsia/eclampsia*, 34 HYPERTENSION PREGNANCY (Dec. 4, 2015), http://www.tandfonline.com/doi/abs/10.3109/10641955.2015.1090581?journalCode=ihip20.

[99] Richard Franki, *Preeclampsia/eclampsia rate highest in black women*, OB.GYN. NEWS (Apr. 29., 2017), http://www.mdedge.com/obgynnews/article/136887/obstetrics/preeclampsia/eclampsia-rate-highest-black-women.

that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually suggested regardless of fetal age or potential for survival.[100] ACOG and American Heart Association recommend that a pregnancy be avoided or ended for certain conditions such as severe pulmonary hypertension.[101] Many medications can cause significant fetal impairments, and therefore the Federal Food and Drug Administration and professional medical associations recommend that women use contraceptives to ensure that they do not become pregnant while taking these medications.[102] In addition, some medical guidelines counsel patients to end a pregnancy if they are taking certain medications for thyroid disease.[103]

d. Emergency contraception

The proposed rule will magnify the harm in circumstances where women are already denied the standard of care. Catholic hospitals have a record of providing substandard care or refusing care altogether to women for a range of medical conditions and crises that implicate reproductive health. For example, in a 2005 study of Catholic hospital emergency rooms by Ibis Reproductive Health for Catholics for Choice, it was found that 55 percent would not dispense emergency contraception under any circumstances.[104] Twenty three percent of the hospitals limited EC to victims of sexual assault.[105]

These hospitals violated the standards of care established by medical providers regarding treatment of sexual assault. Medical guidelines state that survivors of sexual assault should be provided emergency contraception subject to informed consent and that it should be immediately available where survivors are treated.[106] At the bare

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[100] AMERICAN ACADEMY OF PEDIATRICS & AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES FOR PERINATAL CARE 232 (7th ed. 2012).

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

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

[103] For example, the American College of Obstetricians and Gynecologists specifically recommends that if a woman taking Iodine 131 becomes pregnant, her physician should caution her to consider the serious risks to the fetus, and consider termination. American College of Obstetricians and Gynecologists, *ACOG Practice Bulletin No. 37: Thyroid disease in pregnancy* 100 OBSTETRICS & GYNECOLOGY 387-96 (2002).

[104] Teresa Harrison, *Availability of Emergency Contraception: A Survey of Hospital Emergency Department Staff*, 46 ANNALS EMERGENCY MED. 105-10 (Aug. 2005), http://www.annemergmed.com/article/S0196-0644(05)00083-1/pdf

[105] *Id.* at 105.

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

minimum, survivors should be given comprehensive information regarding emergency contraception.[107]

e. Artificial Reproductive Technology (ART)

Refusals to provide the standard of care to LGBTQ individuals because of their sexual orientation or gender identity can impact access to care across a broad spectrum of health concerns, which includes primary and specialty care settings. One example of refusals that impacts LGBTQ patients, as well as non-LGBTQ patients, is refusals to educate about, provide, or cover ART procedures for religious reasons. For individuals with cancer, the standard of care includes education and informed consent around fertility preservation, according to the American Society for Clinical Oncology and the Oncology Nursing Society.[108] Refusals to educate patients about or to provide ART occur for two reasons: refusal based on religious beliefs about ART itself and refusals to provide ART to LGBTQ individuals because of their LGBTQ identity. In both situations, refusals to educate patients about ART and fertility preservation, and to facilitate ART when requested, are against the standard of care.

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

f. HIV Health

For HIV, in addition to consistent condom use, pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) are an important part of prevention for those at high risk for contracting HIV. The American College of Obstetricians and Gynecologists recommends that PrEP be considered for individuals at high risk of contracting HIV.[109] Under the proposed rule, an insurance company could refuse to cover PrEP or PEP

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

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

[109] ACOG *Committee Opinion 595: Preexposure Prophylaxis for the Prevention of Human Immunodeficiency Virus*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (May 2014), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Preexposure-Prophylaxis-for-the-Prevention-of-Human-Immunodeficiency-Virus.

because of a religious belief. Refusals to promote and facilitate condom use because of religious beliefs and refusals to prescribe PrEP or PEP because of a patient's perceived or actual sexual orientation, gender identity, or perceived or actual sexual behaviors is in violation of the standards of care and harms patients already at risk for experiencing health disparities. Both PrEP and PEP have been shown to be highly effective in preventing HIV infection. Denying access to this treatment would adversely impact vulnerable, highest risk populations including gay and bisexual men.

VI. The proposed rule violates the Establishment Clause

The Establishment Clause of the First Amendment bars the government from granting religious and moral exemptions that would harm any third party.[110] It requires the Department to "take adequate account of the burdens" that an exemption "may impose on nonbeneficiaries" and must ensure that any exemption is "measured so that it does not override other significant interests."[111]

The Supreme Court acknowledged the limitations imposed by the Establishment Clause in *Burwell v. Hobby Lobby Stores, Inc.*, declaring the effect on employees of an accommodation provided to employers under the Religious Freedom Restoration Act (RFRA) "would be precisely zero."[112] Justice Kennedy emphasized that an accommodation must not "unduly restrict other persons, such as employees, in protecting their own interests."[113] The proposed exemptions clearly impose burdens on and harm others and thus, violate the clear mandate of the Establishment Clause.

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

The regulations dangerously expand the application of the underlying statutes by offering an extremely broad definition who can refuse and what they can refuse to do. Under the proposed rule, any one engaged in the health care system could refuse services or care. The proposed rule defines workforce to include "volunteers, trainees or other members or agents of a covered entity, broadly defined when the conduct of the person is under the control of such entity."[114] Under this definition, could any member of the health care workforce refuse to serve a patient in any way – could a nurse assistant refuse to serve lunch to a transgender patient, could a billing specialist refuse to help a patient who had sought contraceptive counseling?

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[110] E.g., *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Cutter v. Wilkinson*, 544 U.S.709, 720, 726 (2005); *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 n.8 (1989).
[111] *Cutter*, 544 U.S. at 720, 722; see also *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 709-10 (1985).
[112] *Hobby Lobby*, 134 S. Ct. 2751, 2760 (2014).
[113] *Id.* at 2786-87 (Kennedy, J., concurring).
[114] 83 Fed. Reg. 3894.

a. Discrimination

The failure to define the term "discrimination" will cause confusion for providers, and as employers, expose them to liability. Title VII already requires that employers accommodate employees' religious beliefs to the extent there is no undue hardship on the employer.[115] The regulations make no reference to Title VII or current EEOC guidance, which prohibits discrimination against an employee based on that employee's race, color, religion, sex, and national origin.[116] The proposed rule should be read to ensure that the long-standing balance set in Title VII between the right of individuals to enjoy reasonable accommodation of their religious beliefs and the right of employers to conduct their businesses without undue interference is to be maintained.

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

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

Finally, the proposed rule's lack of clarity regarding what constitutes discrimination, may undermine non-discrimination laws. Because of the potential harm to individuals if religious refusals were allowed, courts have long rejected arguments that religiously affiliated organizations can opt out of anti-discrimination requirements.[117] Instead, courts have held that the government has a compelling interest in ending discrimination

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[115] 42 U.S.C. § 2000e-2.; *Title VII of the Civil Rights Act of 1964*, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.

[116] *Id.*

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

and that anti-discrimination statutes are the least restrictive means of doing so. Indeed, the majority opinion in *Burwell v. Hobby Lobby Stores, Inc.* makes it clear that the decision should not be used as a "shield" to escape legal sanction for discrimination in hiring on the basis of race, because such prohibitions further a "compelling interest in providing an equal opportunity to participate in the workforce without regard to race," and are narrowly tailored to meet that "critical goal."[118] The uncertainty regarding how the proposed rule will interact with non-discrimination laws is extremely concerning.

b. Assist in the performance

The definition of "assist in the performance" greatly expands the types of services that can be refused beyond any reasonable stretch of the imagination. The proposed rule defines "assistance" to include participation "in any activity with an *articulable connection* to a procedure, health service or health service program, or research activity."[119] In addition, the Department includes activities such as "making arrangements for the procedure."[120] If workers in very tangential positions, such as schedulers, are able to refuse to do their jobs based on personal beliefs, the ability of any health system or entity to plan, to properly staff, and to deliver quality care will be undermined. Employers and medical staff may be stymied in their ability to establish protocols, policies and procedures under these vague and broad definitions. The proposed rule creates the potential for a wide range of workers to interfere with and interrupt the delivery of health care in accordance with the standard of care.

The regulations also leave unclear whether a worker can assert his or her moral belief in refusing to treat patients on the basis of their identity or deny care for reasons outside of religious or moral beliefs. Even though women living with disabilities report engaging in sexual activities at the same rate as women who do not live with disabilities, they often do not receive the reproductive health care they need for multiple reasons, including lack of accessible provider offices and misconceptions about their reproductive health needs.[121] Biased counseling can contribute to unwanted health outcomes and exacerbate health disparities.[122] The proposed rule is especially alarming as it does not articulate a definition of moral beliefs. The prejudices of a health care professional could easily inform their beliefs and consequently, serve as the basis of denying care to an individual based on characteristics alone. The proposed rule will foster discriminatory health care settings and interactions between patients and

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[118] *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, slip op. at 46 (2014).
[119] 83 Fed. Reg. 3892.
[120] *Id.*
[121] RM Haynes et al., *Contraceptive Use at Last Intercourse Among Reproductive-Aged Women with Disabilities: An Analysis of Population-Based Data from Seven States*, CONTRACEPTION (2017), https://www.ncbi.nlm.nih.gov/pubmed/29253580; *See generally* Alex Zielinski, *Why Reproductive Health Can Be A Special Struggle for Women with Disabilities*, THINKPROGRESS, Oct. 1, 2015, https://thinkprogress.org/why-reproductive-health-can-be-a-special-struggle-for-women-with-disabilities-73ececea23c4/.
[122] In one study in Massachusetts, women living with intellectual and developmental disabilities, including those who were Black and Latina, faced increased risks of preterm delivery and very low and low birth weight babies. M. Mitra et al., *Pregnancy Outcomes Among Women with Intellectual and Developmental Disabilities*, AM. J. PREV. MED. (2015), https://www.ncbi.nlm.nih.gov/pubmed/25547927.

providers that are informed by bias instead of medically accurate, evidence-based, patient-centered care.

Moreover, in the preamble, the proposed rule states that the exemptions that Weldon provides is not limited to refusals of abortion care on the basis of religious or moral beliefs.[123] Due to this, health care professionals may think they can deny abortion care and other health services just because they do not want to provide the service. The preamble uses language such as "those who choose not to provide" or "Would rather not" as justification for a refusal. This is more concerning because the proposed rule contains no mechanism to ensure that patients receive the care they need if their provider refuses to furnish a service. The onus will be on the patient to question whether her hospital, medical doctor, or health care professional has religious, moral, or other beliefs that would lead them to deny services or if services were denied, the basis for refusal. This is likely to occur as the proposed rule does not have any provisions that stipulate that patients must be given notice that they may be refused certain health care services on the basis of religious or moral beliefs.

c. Referral

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

d. Health Care Entity

The proposed rule's definition of "health care entity" conflicts with Federal religious refusal laws such as the Coats and Weldon Amendments, thus fostering confusion regarding which entities are required to comply with the proposed rule and existing Federal religious refusals. Specifically, under the Coats and Weldon Amendments a "health care entity" is defined to encompass a limited and specific range of individuals and entities involved in health care delivery. Under the proposed rule, a plan sponsor "not primarily engaged in the business of health care" would be deemed a "health care entity."[125] This definition would mean that an employer acting as a third party administrator or sponsor could count as a "health care entity" and deny coverage. In

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[123] 83 Fed. Reg. 3890-91.
[124] *Id.* at 3895.
[125] *Id.* at 3893.

2016, OCR found that religiously affiliated employers were not health care entities under the Weldon amendment.[126]

Moreover, the Department states that their definition of "health care entity" is "not an exhaustive list" for concern that the Department would "inadvertently omit[ting] certain types of health care professionals or health care personnel."[127] Additionally, the proposed rule incorporates entities as defined in 1 USC 1 which includes corporations, firms, societies, etc.[128] States and public agencies and institutions are also deemed to be entities.[129] The Department's inclusion of entities who are primarily not engaged in the health care delivery system highlights the true purpose of the proposed rule, to permit a greater number of entities to interfere in the provider-patient relationship and deter a patient from making the best decision based on their circumstances, preferences, and beliefs.

Conclusion

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

Thank you for your attention to our comments. If you have any questions, please reach out to Erin Prangley, Public Policy Director at EPrangley@nacdd.org.

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[126] Office for Civil Rights, Decision Re: OCR Transaction Numbers: 14-193604, 15-193782 & 15-195665, 4 (Jun. 21, 2016) (letter on file with NHeLP-DC office).
[127] 83 Fed. Reg. 3893.
[128] *Id.*
[129] *Id.*

Exhibit 76

AAMC

Association of
American Medical Colleges
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400
www.aamc.org

Via Electronic Submission *(www.regulations.gov)*

March 26, 2018

Roger Severino
Director, Office of Civil Rights
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Protecting Statutory Conscience Rights in Health Care, HHS (HHS-OCR-2018-0002)

Dear Mr. Severino:

The Association of American Medical Colleges (AAMC or Association) welcomes the opportunity to comment on the Department of Health and Human Services (HHS' or the Agency's) proposed rule titled *Protecting Statutory Conscience Rights in Health Care, HHS*, 83 *Fed. Reg.* 3880 (January 26, 2018).

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Our members are all 151 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, we serve the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences. As will be described in detail below, should the rule be finalized as proposed, it will result in harm to patients, undermine standards of medical professionalism, and raise serious concerns regarding individuals' rights that are protected by other federal and state laws. **Therefore, we urge the Department to withdraw the proposed regulation.**

The Needs of Patients Should Be Put First

Ethical and moral issues within the context of health care are among the most challenging that we face. They require a careful balance between the rights of the health care professional to avoid behavior that violates his/her moral or ethical code, and the rights of a patient to receive lawful health care services that are safe and medically appropriate. In some circumstances, it is difficult to maintain this balance. When that happens, the health and the rights of the patient, who is in the more vulnerable position, must be given precedence. Those who choose the profession of medicine are taught repeatedly during their medical school and residency training that, in the end, their duty to care for the patient must come first, before self. For example, the American Medical Association *Principles of Medical Ethics* state, "A physician shall, while caring for a patient, regard responsibility to the patient as paramount." This does not mean that a physician or other health care provider must act in violation of his or her own moral code,

but it does mean that a physician has the duty to provide information and to refer the patient to other caregivers without judgment.[1]

Julie Cantor wrote about the need for a balance towards professionalism in her article, "Conscientious Objection Gone Awry – Restoring Selfless Professionalism in Medicine" (New England Journal of Medicine, April 9, 2009), which is cited in this proposed rule instead as evidence of rampant discrimination against those who wish to practice women's health. Rather than promote discrimination against health care professionals, Dr. Cantor calls on those who "freely choose their field" to evaluate their beliefs in relation to their specialties and whether they are able to provide all legal options for care. "As gatekeepers to medicine, physicians and other health care providers have an obligation to choose specialties that are not moral minefields for them. … Conscience is a burden that belongs to that individual professional; patients should not have to shoulder it."

There Is No Demonstrable Need for the Proposed Rule

As we stated when we commented on the original 2008 Federal Health Care Conscience Rule, no individual or entity in this country has the option to pick and choose the laws to which he/she will adhere. Every health care provider and entity already has the obligation to comply with all applicable federal laws. The Department has offered little evidence that this has not been the case. The Office of Civil Rights has received just forty-four complaints since it was designated with authority to enforce the Church, Coats-Snow, and Weldon Amendments. The paucity of complaints does not provide compelling evidence of a need for the expansion of OCR's authority, or the need for changes in the current regulations.

Accreditation Organizations Require Medical Students and Residents to Be Taught to Respond to the Many Health Care Needs of a Diverse Patient Population and Respect a Medical Student or Resident's Decision to Not Receive Training in Abortions

Starting with undergraduate medical education and continuing through residency training, physicians are taught that they will be practicing medicine in a multi-cultural, multi-ethnic world in which patients and their families hold diverse viewpoints on many complex ethical issues that affect health care. Their education also occurs in an atmosphere that acknowledges that as health care providers, physicians themselves bring a diversity of religious and moral views on health care issues to their work. Such disparate views are examined during the educational process during a physician's initial training and throughout the individual's professional development.

Belying the concern that medical schools and training program are discriminating against medical students and residents for their religious views are the accreditation requirements of the Liaison Committee for Medical Education (LCME), which accredits all US medical education programs leading to the MD degree, and the Accreditation Council for Graduate Medical Education (ACGME), which accredits residency programs that seek to attract a wide variety of individuals into medicine. Both organizations have standards that are designed to ensure that the education of physicians provides an environment that embraces diversity of views and values for both health care providers and patients. For instance, the LCME requires that "[t]he selection of individual [medical] students must not be influenced by any political or financial factors."

[1] American Medical Association Council on Ethical & Judicial Affairs, "Code of Medical Ethics Opinion 1.1.7" https://www.ama-assn.org/delivering-care/physician-exercise-conscience

Additional requirements include the following:

> A medical school does not discriminate on the basis of age, creed, gender identity, national origin, race, sex, or sexual orientation.
>
> A medical school ensures that the learning environment of its medical education program is conducive to the ongoing development of explicit and appropriate professional behaviors in its medical students, faculty, and staff at all locations and is one in which all individuals are treated with respect. The medical school and its clinical affiliates share the responsibility for periodic evaluation of the learning environment in order to identify positive and negative influences on the maintenance of professional standards, develop and conduct appropriate strategies to enhance positive and mitigate negative influences, and identify and promptly correct violations of professional standards.
>
> A medical school develops effective written policies that address violations of the code, has effective mechanisms in place for a prompt response to any complaints, and supports educational activities aimed at preventing inappropriate behavior. Mechanisms for reporting violations of the code of professional conduct are understood by medical students, including visiting medical students, and ensure that any violations can be registered and investigated without fear of retaliation. (Standards, Publications, & Notification Forms. LCME. lcme.org/publications. Accessed March 2018).

Further, the LCME's June 2017 Rules of Procedure regarding medical school accreditation state that:

> Medical education programs are reviewed solely to determine compliance with LCME accreditation standards. LCME accreditation standards and their related elements are stated in terms that respect the diversity of mission of U.S. medical schools, including religious missions.

The LCME also recognizes the need for medical students to learn how to care for a diverse patient population. For example,

> The faculty of a medical school ensure that the medical curriculum provides opportunities for medical students to learn to recognize and appropriately address gender and cultural biases in themselves, in others, and in the health care delivery process. The medical curriculum includes instruction regarding the following:
>
> - The manner in which people of diverse cultures and belief systems perceive health and illness and respond to various symptoms, diseases, and treatments
> - The basic principles of culturally competent health care
> - The recognition and development of solutions for health care disparities
> - The importance of meeting the health care needs of medically underserved populations
> - The development of core professional attributes (e.g., altruism, accountability) needed to provide effective care in a multidimensional and diverse society

Similarly, the ACGME states that:

> Residents are expected to demonstrate sensitivity and responsiveness to a diverse patient population, including but not limited to diversity in gender, age, culture, race, religion, disabilities, and sexual orientation.

> Clinical learning environments (CLEs) need to ensure that their residents and fellows learn to recognize health care disparities and strive for optimal outcomes for all patients, especially those in potentially vulnerable populations. As front-line caregivers, residents and fellows are a valuable resource for formulating strategies on these matters. They can assist the CLEs in addressing not only low-income populations, but also those that experience differences in access or outcome based on gender, race, ethnicity, sexual orientation, health literacy, primary language, disability, geography, and other factors.
>
> The diverse, often vulnerable, patient populations served by CLEs also provide an important opportunity for teaching residents and fellows to be respectful of patients' cultural differences and beliefs, and the social determinants of health.
>
> In considering patient outcomes, it is important to note that patients at risk for disparities are likely to require differences in care that are tailored to their specific needs—based not only on their biological differences, but also on other social determinants of health (e.g., personal social support networks, economic factors, cultural factors, safe housing, local food markets, etc.).

The ACGME's Common Program Requirements state that "Programs must provide a professional, respectful, and civil environment that is free from mistreatment, abuse, or coercion of students, residents, faculty and staff. Programs, in partnership with their Sponsoring Institutions, should have a process for education of residents and faculty regarding unprofessional behavior and a confidential process for reporting, investigating, and addressing such concerns. (Standard VI.B.6)

In regard to women's healthcare, both accrediting organizations are clear that a program cannot require training in abortion procedures. The ACGME's Program requirements specific to obstetrics and gynecology state "Residents who have a religious or moral objection may opt-out and must not be required to participate in training in or performing induced abortions." The profession of medicine seeks to embrace within its ranks individuals from diverse racial/ethnic, cultural, religious and socioeconomic backgrounds. Such diversity of backgrounds helps to ensure that physicians will understand and be sympathetic to the traditions, values, and beliefs of their patients and provide competent care.

The Proposed Rule Is Overly Expansive In Its Reach and Is Incongruous with Medical Professionalism

The proposed rule is overly expansive, allowing physicians and others to avoid engaging in any activity "with an articulable connection" to the objectionable procedure, "include[ing] counseling, referral, training, and other arrangements for the procedure." It then proposes a definition of referral that expands the general understanding of referral to include "the provision of *any* information…when the entity or health care entity making the referral sincerely understands that particular health care service, activity, or procedure to be a purpose or *possible outcome of the referral*." (emphasis added). The refusal of a physician or other health care professional to provide a patient with information, or to give a patient a referral to a provider where the desired care is available, risks limiting the patient's access to health care. Allowing health care professionals to engage in behavior that could harm patients is incongruous with the standards of medical professionalism that are the core of a physician's education and the practice of medicine.

Similarly, the proposed regulation would interpret the term "assist in the performance" to include "any activity with an articulable connection to a procedure, health service, or research activity[.]" The proposed regulation states that this definition is intended to be broad, and not limited to direct involvement with a procedure, health service, or research activity. For example, this broader definition could apply to an employee whose task is to clean a room where a particular procedure took place. Such a

broad view is unnecessary particularly since the employee has the option to seek employment elsewhere while the patient may have only one place where he/she can receive care.

The Proposed Rule Will Do Harm to Lower Income Americans, Racial and Ethnic Minorities, the LGBTQ Community, and Patients in Rural Areas

The proposed rule would allow physicians and others to avoid engaging in any activity "with an articulable connection" to the objectionable procedure, "includ[ing] counseling, referral, training, and other arrangements for the procedure." This broad reach will create or exacerbate inequities in health care access for Americans whose access may already be limited due to their geographic residence or financial means. For rural- and frontier-dwelling Americans who reside in a health professional shortage area, access to certain services might functionally cease to exist as a result of this proposed rule: seeking care in distant locales might be too burdensome or expensive. This holds, too, for lower income Americans who lack the financial means to seek out care for procedures when their primary physicians decline to provide services.

Racial and ethnic minority women have reported experiencing race-based discrimination when receiving family planning care.[2] The proposed rule may exacerbate this problem and the consequences that follow for women and their children. Research has associated unintended pregnancy with several adverse maternal and child health outcomes, such as delayed prenatal care, tobacco and alcohol use during pregnancy, delivery of low birthweight babies[3], and poor maternal mental health.[4] These negative health outcomes are more prevalent in racial and ethnic minority communities likely would worsen under the proposed rule.

For the lesbian, gay, bisexual, transgender, and queer (LGBTQ) communities, the proposed rule may further exacerbate heath care access disparities. It is well documented that LGBTQ Americans currently experience discrimination in health care settings, erecting a barrier to accessing health care services.[5] This proposed rule would codify what many within and beyond the LGBTQ communities will view as state-sanctioned discrimination, and allow providers to refuse care or appropriate referrals solely on the basis of their patients' sexual orientation or gender identity. This stands in stark opposition to OCR's stated goal to "protect fundamental rights of nondiscrimination."

The Proposed Rule Adds Burdensome Requirements That Have No Commensurate Benefit

The Department and this Administration have undertaken major efforts to reduce regulatory burden, such as "Reducing Regulation and Controlling Regulatory Costs" (Executive Order 13771, issued January 30, 2017), "Enforcing the Regulatory Reform Agenda" (Executive Order 13777, issued February 24, 2017), the Centers for Medicare & Medicaid's "Patient over Paperwork" initiative (launched October 2017, in an effort to reduce unnecessary burden), and several Requests for Information regarding administrative burden. The burden associated with complying with the proposed rule runs counter to this goal. Moreover, the investment in resources that would be required for a large teaching health care system to

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[2] Thorburn S, Bogart LM. "African American women and family planning services: perceptions of discrimination," *Women Health*. 2005;42(1):23–39.
[3] Institute of Medicine (US) Committee on Unintended Pregnancy; Brown SS, Eisenberg L, editors. "The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families. National Academies Press (US); 1995. 3, *Consequences of Unintended Pregnancy*. Available from: https://www.ncbi.nlm.nih.gov/books/NBK232137/
[4] Herd P et al., "The implications of unintended pregnancies for mental health in later life," *American Journal of Public Health*, 2016, 106(3):421–429.
[5] Cahill, S. "LGBT Experiences with Health Care," *Health Affairs* Vol. 36, No.4. 2017. Available from: https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.0277

ensure compliance and monitoring of all of the proposed requirements would be even more onerous and reduce funds available for the core missions of teaching, patient care, and research.

The Department proposes to modify existing civil rights clearance forms (or develop similar forms in the future), and notes that it might require submission of these documents annually and incorporate by reference in all other applications submitted that year. The receipt of any federal funds already requires the compliance with all federal laws and regulations; assurances and attestations to compliance are routine. OCR has not made clear why there is a need for additional assurance and certification.

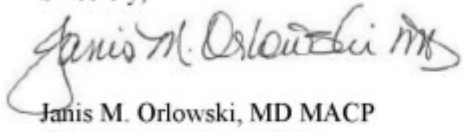
The Department also proposes notice requirements, which includes notice on the funding recipient's website, in prominent and conspicuous physical locations where other notices to the public and notices to the recipient's workforce are customarily posted. The notice is to be posted by April 26, 2018, or for new recipients, within 90 days of becoming a recipient. Even if the rule is finalized by April 26, and no changes are made in the notice requirement, it is unreasonable to expect current recipients to comply by that date.

The rule also proposes that if a sub-recipient is found to have violated federal health care conscience and associated anti-discrimination laws, the recipients "shall be subject to the imposition of funding restrictions and other appropriate remedies." Requiring the imposition of funding restrictions should be dependent on the facts and circumstances of a particular case; however, by using the word "shall" there seems to be no discretion in whether this penalty is appropriate. If the rule is finalized, the AAMC asks that OCR clearly make the penalty optional by using "may" instead of "shall."

The AAMC strongly urges the Department to withdraw the proposed rule. Alternatively, the rule should be re-proposed and narrowed in scope to, at a minimum, appropriately balance the needs of patients with the needs of health care providers who have freely chosen their profession.

If you would like additional information, please contact Ivy Baer, Senior Director and Regulatory Counsel, at 202-828-0499 or ibaer@aamc.org.

Sincerely,



Janis M. Orlowski, MD MACP
Chief, Health Care Affairs