EXHIBIT 23

March 27, 2018

VIA ELECTRONIC TRANSMISSION

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

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

Dear Secretary Azar and Director Severino:

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

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

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

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

Indeed, this proposed rule is unprecedented in its reach and harm, seeking to allow almost any worker in a health care setting to refuse services and information to a patient because of personal beliefs, which notably would include "religious, moral, ethical, or other reasons."[1] This means that under this proposed rule, a pharmacist could refuse to fill a prescription for birth control or antidepressants, a woman could be denied life-saving treatment for cancer, or a transgender patient could be denied hormone therapy. And while the proposed rule purports to be protecting the conscience rights and "personal freedom" of health care workers "with a variety of moral, religious, and philosophical backgrounds," it selectively ignores the many workers who are prevented from following their conscience by *restrictions* on care imposed by their employers.

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

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

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

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

The rule would erect more barriers to reproductive health care, transition-related services, and other services, and place women, LGBTQ people, and people living with HIV at greater risk of not getting the services they need. Access to comprehensive reproductive health care, including abortion, is already limited. According to a recent report, nearly half of the women of reproductive age have to travel between 10 to 79 miles, and some women have to travel 180 miles or more, to access an abortion.[2] Importantly, the proposed rule improperly expands upon

[1] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3923 (Jan. 26, 2018) (to be codified at 45 C.F.R. pt. 88).
[2] J. Mearak, et. al., Disparities and change over time in distance women would need to travel to have an abortion in the USA; spatial analysis, The Lancet (Nov. 2017), http://www.thelancet.com/pdfs/journals/lanpub/PIIS2468-2667(17)30158-5.pdf.

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

It is already the case that women with pregnancy complications who seek care at religiously-affiliated hospitals have been denied information or abortion care, even when that information is critical to their health. An often-cited case is that of Tamesha Means, who was rushed to Mercy Health Partners in Muskegon, Michigan after her water broke at 18 weeks of pregnancy. She was sent home twice in excruciating pain despite the fact that there was no chance that her pregnancy would survive and that continuing the pregnancy posed significant risks to her health. Due to the hospital's religious affiliation, Ms. Means was not informed that terminating her pregnancy was the safest course for her condition, and therefore her health was put at risk.[3] Another woman, Mikki Kendall, went to an emergency room after experiencing a placental abruption. Even though her pregnancy would not survive and Ms. Kendall could have died due to the amount of blood loss, the doctor on call refused to perform an abortion and refused to contact another physician to perform the procedure. Fortunately, Ms. Kendall was able to receive the care she needed after several risky and agonizing hours.[4] Unfortunately, many people are not even aware that they may be denied medically-appropriate care and information, even in emergency situations. For instance, nearly 40 percent of the people who regularly visit Catholic hospitals do not know of the religious affiliation, and even patients that are aware of the affiliation frequently do not know the hospital refuses to provide certain services.[5]

Certain communities are particularly affected by denials of care. Health care refusals disproportionately impact Black women, and the expansions outlined in this proposed rule would likewise disproportionately impact Black women. For example, according to a recent report, hospitals in neighborhoods that are predominately Black are more likely to be governed by ethical and religious directives for Catholic health care services.[6] Additionally, people living in rural areas are significantly impacted if their provider refuses to provide necessary or preventive care. Women living in in rural areas already experience provider shortages and have to travel long distances for health care, resulting in significant gaps in care and low health outcomes.[7] By making it easier for providers to refuse care, the proposed rule would further restrict these options or cut off access to care altogether, which would compromise patient health still further.

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

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

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

[5] *Id.*

[6] K. Shepherd, et. al., Bearing Faith: The Limits of Catholic Health Care for Women of Color, Columbia Law School (January 2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf?mc_cid=51db21f500&mc_eid=780170d2f0.

[7] The American College of Obstetricians and Gynecologists, Health Disparities in Rural Women (2014, reaffirmed 2016), https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co586.pdf?dmc=1&ts=20160402T0931414521.

people living with HIV. Discrimination in health care settings already prevents LGBTQ people from accessing the care they need. For instance, nearly one-third of transgender people surveyed said a doctor or health care provider refused to treat them due to their gender identity.[8] Related, people living with HIV frequently experience stigma in the health care system.[9] The proposed rule would increase this stigma and make it more likely that these communities are denied necessary health care.

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

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

The proposed rule itself notes that mainstream medical groups have recognized the negative effects refusing care can have on patients and that these organizations have called for patient protections when refusals may compromise health. For example, the American Congress of Obstetricians and Gynecologists (ACOG) ethics opinion states that "in an emergency in which referral is not possible or might negatively affect patient's physical or mental health, providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections."[10] The American Medical Association's (AMA) constitution and bylaws similarly note that physicians are required to be "moral agents" and "being a conscientious medical professional may well mean at times acting in ways contrary to one's personal ideals in order to adhere to a general professional obligation to serve patients' interests first." The constitution and bylaws further state that "having discretion to follow conscience with respect to specific interventions or services does not relieve the physician of the obligation to not abandon a patient."[11] The proposed rule would exacerbate these concerns by making it harder for medical organizations and providers to preserve existing access to reproductive health care.[12]

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[8] S. Mirza & C. Rooney, Discrimination Prevents LGBTQ people from Accessing Health Care, Ctr. for Amercian Progress (Jan. 18, 2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/.

[9] CDC, HIV Among Gay and Bisexual Men, https://www.cdc.gov/hiv/group/msm/index.htm; CDC, HIV Among African-Americans, https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/cdc-hiv-aa-508.pdf.

[10] 83 Fed. Reg. at 3888; ACOG, The Limits of Conscientious Refusal in Reproductive Medicine (Nov. 2007, reaffirmed 2016), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Ethics/The-Limits-of-Conscientious-Refusal-in-Reproductive-Medicine.

[11] American Medical Association, Physician Exercise of Conscience: Report of the Council on Ethical and Judicial Affairs, https://www.ama-assn.org/sites/default/files/media-browser/public/about-ama/councils/Council%20Reports/council-on-ethics-and-judicial-affairs/i14-ceja-physician-exercise-conscience.pdf.

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

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

The proposed rule could endanger women's lives because it fails to make sure that the protections of the Emergency Medical Treatment and Active Labor Act (EMTALA) apply and take precedence when a patient is facing a medical emergency. EMTALA requires virtually every hospital to provide an examination or treatment to individuals that come into the emergency room, including care for persons in active labor, and the hospital must provide an appropriate transfer if the hospital cannot stabilize the patient.[13] The proposed rule does not address EMTALA and the potential legal conflict between that Act and the proposed rule. In particular, it is unclear if the Department or a state or local government would be considered to have engaged in prohibited "discrimination" if it penalized a hospital for failing to comply with EMTALA when a pregnant woman needs an abortion in an emergency situation.[14] There is no dispute that some pregnant women develop serious medical complications for which the standard treatment is pregnancy termination.[15] The proposed rule's silence on medical emergencies could create confusion among health care institutions or even allow them to refuse to comply with existing federal requirements to treat patients with medical emergencies and thereby endanger women's lives.[16]

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

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

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

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

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[13] 42 U.S.C. § 1395dd.

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

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

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

ridiculously wide array of activities that go well beyond congressional intent. As an initial matter, although the Department purports to be bringing the refusal laws in line with other civil rights laws, the rule proposes to define "discrimination" contrary to how it is has been long understood in those laws. Under the Department's proposed rule, "discrimination" is more broadly defined to include a large number of activities, including denying a grant, employment, benefit or other privilege, as well an unspecified catch-all phrase "any activity reasonably regarded as discrimination." It also includes any laws or policies that would have the effect of defeating or substantially impairing accomplishment of a "health program or activity." The term, "health program or activity" is then defined to include, among other things, "health studies, or any other services related to health or wellness whether directly, through payments, grants contracts, or other instruments, through insurance, or otherwise."[17] The inclusion of any impairment of a "health program or activity," as defined, only adds to an unreasonably expansive definition of "discrimination" that could be applied to anything with a tangential connection to health or wellness. As set forth below, the rule's all-encompassing definition of "discrimination" fails to account for established anti-discrimination law that reflect a balancing of interests -- protecting against religious discrimination but recognizing it is not discriminatory to require an employee to perform functions that are essential to the position for which she applied and was hired.

The proposed rule also improperly stretches the definition of "refer" to include providing "any information … by any method … that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity or procedure."[18] This means that any health care entity, including both individuals and institutions, could refuse to provide any information that could help an individual to get the care they need, including even to provide patients with a standard pamphlet. The objecting entity would be able to refuse to provide that information even if they believe that a particular health care service is only the "possible outcome of the referral."[19] This definition would allow health care providers to deny patients full, accurate, and comprehensive information on health care options that allow people to make their own health care decisions.

The proposed rule also defines "assist in the performance of" far more broadly than its common meaning, to include participating in any program or activity with "an articulable connection" to a procedure, health service, health program, or research activity. The proposed rule specifically notes that this includes *but is not limited to* counseling, referral, training, and other arrangements.[20] Even though the Department claims to acknowledge "the rights in the statutes are not unlimited," this definition could in effect create an unlimited right to refuse services. For example, it is unclear if an employee whose task it is to mop the floors at a hospital that provides abortion would be considered to "assist in the performance" of the abortion under this proposed rule. A definition this limitless provides no functional guidance to health care providers as to what they can ask of their employees, and the refusals permitted by health care providers and non-medical staff.

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

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[17] 83 Fed. Reg. at 3924.
[18] Referral is defined far more narrowly elsewhere in federal law. *See, e.g.*, 42 U.S.C. § 1395nn(h)(5); 42 C.F.R. § 411.351.
[19] 83 Fed. Reg. at 3924.
[20] 83 Fed. Reg. at 3923.

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

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

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

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

The Department is exceeding its statutory authority by interpreting the Church Amendments far beyond what Congress intended. Each provision of the Church Amendments was enacted at a different point in time to address specific concerns. The first two provisions of the Church Amendments were enacted in 1973 during the public debate following the *Roe v. Wade* decision, and they clarify that receipt of certain federal funds does not require a health care entity to perform abortions or sterilizations or make its facilities available for abortions or sterlizations.[23] These provisions of the Church Amendments, codified at 42 U.S.C. § 300a-7(b) and (c)(1), permit individuals to refuse to perform or assist in the performance of a sterilization or abortion in certain federally funded programs if it is contrary to their religious or moral beliefs. Sections (d) and (e) of the Amendments were passed as a part of the National Research Act, which aimed at funding biomedical and behavioral research, and ensuring that research projects involving human subjects were performed in an ethical manner. [24] The Department's purported

[21] 83 Fed. Reg. at 3923–3924.
[22] 83 Fed. Reg. at 3924.
[23] The implicated funds are the Public Health Service Act [42 U.S.C. § 201 *et seq.*], the Community Mental Health Centers Act [42 U.S.C. § 2689 *et seq.*], and the Developmental Disabilities Services and Facilities Construction Act [42 U.S.C. § 6000 *et seq.*].
[24] See 119 Cong. Rec. 2917 (1973).

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

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

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

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

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

[25] 83 Fed. Reg. at 3925.
[26] 83 Fed. Reg. at 3894.

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

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

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

The Department has proposed a similarly broad -- and impermissible -- expansion of the Weldon Amendment. That amendment was added to the appropriations bill for the Departments of Labor, Health and Human Services, and Education in 2004 and each subsequent appropriations bill. It prohibits funds appropriated by those three agencies to be provided to a federal agency or program, or to a state or local government, if such agency, program, or government requires any institutional or individual health care entity to provide, pay for, provide coverage of, or refer for abortions.[28] While the text of the statute is limited to state and local governments and federal agencies or programs, the rule would apply the Weldon Amendment to "any entity that receives funds through a program administered by the Secretary or under an appropriations act [HHS]."[29] This interpretation of the Weldon Amendment would impermissibly turn private entities into "federal agencies or programs" by virtue of their receipt of HHS funding.

In addition to conflicting with the plain meaning of the statute, the Department's broad interpretation is also contrary to the legislative history of the Weldon Amendment. During final floor debates on the appropriations bill that included the first Weldon Amendment, one of its supporters explained: "The addition of conscience protection to the Hyde amendment remedies current gaps in Federal law and promotes the right of conscientious objection by forbidding federally funded government bodies to coerce the consciences of health care providers."[30] In other words, the Weldon Amendment's reference to "federal agency or program" was intended as a restriction on government bodies only, not on private entities that receive federal funds.

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

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

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

[29] 83 Fed. Reg. at 3925.

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

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

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

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

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

The proposed rule's broad definitions of "health care entity," "refer," and "discrimination" would also expand the applicability of the Coats Amendment beyond its statutory language and intent. The Coats Amendment was adopted in 1996 in response to a new standard adopted by the Accrediting Council for Graduate Medical Education, requiring all obstetrics and gynecology residency programs to provide induced abortion training.[32] Senator Coats offered the amendment to "prevent any government, Federal or State, from discriminating against hospitals or residents that do not perform, train, or make arrangements for abortions."[33]

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

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

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

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

[34] *See* 42 U.S.C. § 238n.

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

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

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

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

The Department would seemingly allow entities to apply for and receive federal funds while exempting them from the core legal and programmatic duties upon which such funds are generally conditioned. We find this particularly concerning in the context of federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for people with low-incomes. When it comes to Title X, the proposed rule would not only sanction conduct at odds with pre-existing legal requirements, but could also undermine the program's fundamental objective of expanding access to reproductive health care to underserved communities.

Several of the Department's proposed provisions and definitions appear to exempt recipients of federal funds from following the rules that govern federal programs if they have an objection to doing so. As discussed above, the proposed rule's expansion of the Weldon Amendment turns private entities into "federal agencies or programs" and then bars them (as well as the Department) from "discriminating" against a "health care entity" based on its refusal to provide "referrals" for abortion.[36] "Discrimination" includes, among other things, denying federal awards or sub-awards to objectors.[37] Similarly, the proposed rule provides that the Department cannot require recipients of grants provided under the Public Health Service Act to "assist in the performance of an abortion."[38] Such "assistance" includes an unreasonably broad range of conduct, including "counseling, referral, training, and other arrangements." Also, the proposed rule provides that entities receiving Public Health Service Act grants cannot be required to

[35] 42 USC § 238n(c)(2).
[36] 83 Fed. Reg. at 3925.
[37] 83 Fed. Reg. at 3923–3924.
[38] 83 Fed. Reg. at 3925.

provide personnel for "the performance or assistance in the performance of any . . . abortion;" the overbroad definition of "assistance" again applies here.[39]

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

The proposed rule's defects come into clear focus in the context of Title X, the nation's program for birth control and reproductive health. Title X of the Public Health Service Act empowers the Department to make grants to public and not-for-profit entities for the purpose of providing confidential family planning and related preventive services.[40] Title X gives priority to services for people with low incomes and, depending on their income and insurance status, patients may be eligible for free or discounted Title X services.[41] In 2016, Title X-funded providers served over 4 million people.[42] This total includes a disproportionate share of individuals from groups that face longstanding racial and ethnic inequities; for example, 32 percent of Title X patients identified as Hispanic or Latino, and 21 percent identified as Black in 2016.[43] Title X-funded projects offer a range of reproductive health care and information, including counseling and services related to a broad range of contraceptive methods, HIV/STI services, cancer screenings, and other care.

The Department's proposal appears to sanction conduct that would interfere with Title X's legal requirements. For example, although Title X funds are barred from going toward abortion, the program's regulations expressly require providers to offer non-directive options counseling to patients, including abortion counseling and referrals upon request.[44] Even before its codification in regulation, longstanding Departmental interpretations held that non-directive options counseling was a basic and necessary Title X service.[45] The centrality of non-directive options counseling in Title X is reinforced every year through legislative mandates in annual appropriations measures.[46] These prescriptions reflect well-settled principles of medical ethics: patients are entitled to prompt, accurate, and complete information to enable them to make informed decisions about their health. And, especially when an entity does not offer a desired

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[39] 83 Fed. Reg. at 3925.
[40] 42 U.S.C. §§ 300 - 300a-8.
[41] 42 U.S.C. § 300a–4(c).
[42] Christina Fowler, et al., RTI International, *Family Planning Annual Report: 2016 national summary* (2017), available at https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf.
[43] *Id.*
[44] 42 U.S.C. § 300a-6 (prohibiting funding for abortion); 42 C.F.R. § 59.5(a)(5) (requiring non-directive options counseling and referral).
[45] *See* Comptroller General of the United States, "Restrictions on Abortion and Lobbying Activities In Family Planning Programs Need Clarification" (Sept. 1982), available at http://www.gao.gov/assets/140/138760.pdf.
[46] *See, e.g.*, Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, 131 Stat 135 (2017).

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

On top of interfering with counseling and referrals under Title X, the proposed rule could also override other program requirements. For instance, Title X requires projects to provide medical services, including "a broad range of acceptable and effective medically approved family planning methods."[47] This unquestionably includes long-acting reversible contraceptive methods such as intrauterine devices (IUDs). The central place of IUDs, which are exceptionally effective, in the family planning repertoire is cemented by the Centers for Disease Control and Prevention's (CDC) Quality Family Planning recommendations. These recommendations provide, for example, that "[c]ontraceptive services should include consideration of a full range of FDA-approved contraceptive methods," and a "broad range of methods, including long-acting reversible contraception (i.e., intrauterine devices [IUDs] and implants), should be discussed with all women and adolescents."[48] Despite these national clinical standards of care, some individuals are opposed to contraception or certain forms of contraception, and under the proposed impermissible expansion of Church (d) discussed above, any individual working for an entity participating in Title X could claim a right to refuse to provide information or services related to contraception for Title X patients.

If allowed by the Department, such exemptions not only would overtake pre-existing legal rules, but could also thwart the critical health care objectives that federal programs are meant to advance. For example, Congress's purpose in passing Title X was, in part, "to assist in making comprehensive voluntary family planning services readily available to all persons desiring such services," and "to enable public and nonprofit private entities to plan and develop comprehensive programs of family planning services."[49] Permitting health care entities to withhold vital counseling, referrals, and services is hardly conducive to the "comprehensive" approach that was contemplated by Congress. In practical terms, such policies could cut off access to basic, preventive health care and information for the low-income and uninsured people who turn to Title X-funded providers.

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

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

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

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[47] 42 C.F.R. § 59.5(a)(1).
[48] Centers for Disease Control and Prevention, *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs*, 7, 8, (2014), available at https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf.
[49] Act of Dec. 24, 1970, Pub. L. No. 91-572, § 2, 84 Stat. 1504 (1970).

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

We strongly oppose the statutory prohibition on the use of foreign aid funding for abortion as a method of family planning, known as the Helms Amendment, both as it is written and the broader manner in which it is applied, and the broad and harmful refusal provision contained within the statute governing PEPFAR, which are both cited in the proposed regulation.[50] The Helms Amendment effectively coerces women into continuing unwanted pregnancies because the health care they are able to access is provided with U.S. funding. The outcome of this harmful policy is increased unwanted pregnancies and maternal morbidity and mortality.

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

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

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

[50] 83 Fed. Reg. at 3926–3927.

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

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

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

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

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

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

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

Additionally, Title VI clearly requires that an agency must engage in a concerted effort to obtain voluntary compliance *before* it may begin enforcement proceedings against an entity found to be in violation.[52] Specifically, federal law states that "effective enforcement of Title VI requires that agencies take prompt action to achieve voluntary compliance in all instances in which noncompliance is found."[53] The proposed rule loosely states that "OCR will inform relevant parties and the matter will be resolved informally wherever possible," and notes that while attempting to obtain this informal compliance, OCR can simultaneous engage in a range of enforcement actions.[54] This is not consistent with Title VI as it does not require the Department to attempt to achieve voluntary compliance from an entity *before* enforcement actions are taken.

Further, no guidance is given about the actions that would trigger each enforcement mechanism. For instance, would failure to meet the rule's requirement to post a notice result in millions of dollars of funds being withheld? Can failure to certify intention to comply with the rule result in a referral to DOJ? This proposed rule seems to allow OCR unlimited discretion to choose its enforcement mechanism -- including withdrawal of all federal funding and/or a referral to DOJ within any assurance that the Department's actions are proportionate to the violation. The Supreme Court has found government overreach when Congress authorized the Department to utilize federal financial assistance to control recipients' actions. Specifically, in *National Federation of Independent Business v. Sebelius*, the Supreme Court held that Congress exceeded its authority when it authorized the Department to withhold federal financial assistance from a state's Medicaid program if the state failed to expand the program's eligibility.[55] The Court explained if the Department withheld all federal funding from a state for failing to comply with conditions attached to the funding, then States would not have a "genuine choice whether to accept the offer" for funding.[56] Such financial inducement was found to be akin to a "gun to the head."[57] Therefore, the Department does not have unbridled authority to withhold federal financial assistance, and the Department's actions must be proportionate to the violation.

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

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[51] 42 U.S.C. § 2000d-1.

[52] 42 U.S.C. § 2000d-1.

[53] 28 C.F.R. § 42.411(a).

[54] 83 Fed. Reg. at 3930.

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

[56] *Id.* at 584.

[57] *Id.* at 582.

review, investigation, or complaint.[58] This disclosure must be done even if the compliance reviews or investigations are found frivolous or do not lead to a finding of violation. The Department can conduct compliance reviews "whether or not a formal complaint has been filed." The Department is also "explicitly authorized to investigate 'whistleblower' complaints, or complaints made on behalf of others, whether or not the particular complainant is a person or entity protected by" the refusal laws.

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

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

For more than 50 years, Title VII has provided protections against religious discrimination.[59] In defining "discrimination" in a way that can be understood as both different from and far broader than it has long been understood, the Department has both exceeded its authority and caused confusion. In particular, the proposed rule does not clearly state that "discrimination" has the same limits as it does in the context of religious discrimination under Title VII and in particular that the "reasonable accommodation/undue hardship" framework for assessing if there has been "discrimination" also applies under the proposed rule. On its face, it is unclear if the proposed rule adopts Title VII's reasonable accommodation/undue hardship standard, or rather, creates a *per se* rule that allows employees' beliefs to take precedence over the needs and interests of health care providers and their patients under any circumstance.

Under Title VII and the case law interpreting it: [A]n employer, once on notice, [must] reasonably accommodate an employee whose sincerely held religious belief, practice or observance conflicts with a work requirement, *unless providing the accommodation would create an undue hardship, . . . [meaning] that the proposed accommodation in a particular case poses a "more than de minimis" cost or burden.*[60] Court cases that have addressed the issue of religious refusal have found that there are limits to what employers must do to accommodate refusals, and specifically that it is legal and appropriate for employers to prioritize maintaining patient access to care.[61] Additionally, years of case law interpreting religious accommodation

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[58] 83 Fed. Reg. at 3929–3930.

[59] 42 U.S.C. § 2000e(j).

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

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

provisions of Title VII has made clear that an accommodation should not place an unfair load on co-workers.[62] Finally, case law has made it clear that "Title VII does not require an employer to reasonably accommodate an employee's religious beliefs if such accommodation would violate a federal statute."[63] The proposed rule fails to give any consideration to this binding precedent or suggest why "discrimination" should be given any different meaning in the context of the refusal laws.

By requiring a balancing of interests between the employee, the employer, and the employer's clients, Title VII ensures that accommodating the religious beliefs of an employee in the health care field does not harm patients by denying them health care and/or health care information. Title VII also avoids placing employers in the untenable position of having employees on staff who will not fulfill core job functions. The Department has ignored that balancing, undermining its stated goal to "ensure knowledge, compliance, and enforcement of the Federal health care conscience and associated antidiscrimination laws."[64] In so doing, the Department should bear in mind that a decision not to incorporate the Title VII reasonable accommodation/undue hardship balancing would lead to absurd and disastrous results. For example, a health care provider could be forced to hire employees who refuse to be involved in medical services that form the core of the medical care it offers. The Department should also bear in mind Executive Order 13563's injunction, which as the Department notes requires it to "avoid creating redundant, inconsistent, or overlapping requirements applicable to already highly-regulated industries and sectors."

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

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

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

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

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

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

[64] 83 Fed. Reg. at 3887.

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

The Department makes it clear that there are certain types of state laws that they seek to eliminate by reinterpreting the federal refusal laws. For example, the Department clearly wants to undermine state laws that require coverage of abortion. To do so, the Department not only reverses their position on the application of the Weldon amendment, but actually changes the existing (and statutory) definition of "health care entity" so as to include plan sponsors and third party administrators. This will mean more individuals are covered under the statute. The Department has previously rejected this interpretation noting "by its plain terms, the Weldon Amendment's protections extend only to health care entities and not individuals who are patients of, or institutions, or individuals that are insured by such entities."[65]

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

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

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

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

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

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

comprehensive medical information, impeded ability for patients to make their own health care choices, and interference with provider-patient relationships.[67] Also contrary to Executive Order 12866, it fails to account for how these costs are distributed, e.g. whether they will fall disproportionately on women, rural residents, individuals with low incomes, people of color, LGBTQ people, and people living with HIV. It fails to account for the public health costs associated with reduced patient access to medical information, contraception, abortion, and other reproductive health care, or delays in accessing care due to refusals. Thus, it clearly fails multiple requirements under Executive Order 12866, including the requirement that the Department analyze "any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs."

Second, the Department's estimate of costs that the rule imposes on health care providers is far too low. Given the new burdensome notice and attestation policies, it is unrealistic to think that health care providers -- who as of 2015, employed more than 12 million employees -- would be able to adjust all of their policies, train all of their hiring managers, and ensure and document compliance with the proposed rules, for less than $1000 the first year and less than $900 in subsequent years.[68] Moreover, the Department's cost analysis ignores entirely the enormous cost imposed on health care providers if they were required to employ people unwilling to fulfill job functions necessary to deliver care.

Therefore, the Department's estimate that the proposed rule would cost over $812 million dollars within the first five years is inadequate.[69] But even if it would *only* cost the amount estimated by the Department (which it would not), that sum could be far better used to *provide* health care to individuals and correct inequities in the health care system. While the Department claims the rule is required to "vindicate" the religious or moral conscience of health care providers, significant portions of the proposed rule have nothing to do with the Department's purported motivation. Rather, certain sections give license to HMOs, health insurance plans, or any other kind of health care organization to refuse to pay for, or provide coverage of necessary abortion services for any reason—even financial.[70] These provisions do not protect anyone's conscience, they simply undercut providers' ability to deliver care and consumers' ability to obtain and pay for medical services. The limited resources of the Department and health care providers should be better spent.

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

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

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

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

[70] 83 Fed. Reg. at 3925.

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

Respectfully,

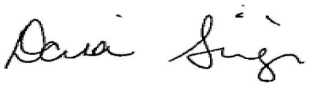

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EXHIBIT 24

PUBLIC SUBMISSION

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

Document:HHS-OCR-2018-0002-71117
Comment on FR Doc # 2018-01226

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General Comment

See attached file(s)

Attachments

Mazzoni Center Coments to RIN 0945-ZA03 HHS-OCR-2018-0002 Proposed Rule - FINAL

MAZZONI CENTER
LGBTQ HEALTH AND WELL-BEING

March 27, 2018

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

RE: Department of Health and Human Services, Office for Civil Rights RIN 0945-ZA03
Public Comments of Mazzoni Center in Response to the Proposed Regulation,
Protecting Statutory Conscience Rights in Health Care
Docket ID Number HHS-OCR-2018-002

To Whom It May Concern:

I am writing on behalf of Mazzoni Center in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26, 2018. For the reasons that follow, Mazzoni Center urges you to withdraw the proposed rule.

Mazzoni Center is a Philadelphia-based nonprofit organization, which focuses on the health, wellness, and legal needs of the lesbian, gay, bisexual, transgender, and queer (LGBTQ) community. Our mission is to provide quality comprehensive health and wellness services in an LGBTQ-focused environment, while preserving the dignity and improving the quality of life of the individuals we serve. With more than 35,000 individuals benefiting annually from our services, we have proven ourselves a leader among community-based organizations in the greater Philadelphia area.

As providers to the LGBTQ community across a broad range of services, we at Mazzoni Center know firsthand the discrimination and other barriers preventing these individuals from accessing lifesaving and life affirming care. These barriers exist for all members of the LGBTQ community, but are especially pronounced for transgender patients. The proposed regulation ignores the prevalence of discrimination and the damage it causes, and will undoubtedly lead to increased discrimination and flat-out denials of care for some of the most vulnerable members of our community. We all deeply value freedom of religion, but sweeping exemptions that obstruct access to care are a fundamental distortion of that principle. Americans deserve better.

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

LGBTQ people, as with people needing access to obstetric care, and as with many other vulnerable groups around the country, already face enormous barriers to getting the care they need.[1] According to the 2015 U.S. Transgender Survey—prepared by the National Center for Transgender Equality—one third of respondents who had visited a doctor's office in the last year reported having "at least one negative experience related to being transgender," like being denied treatment or experiencing verbal harassment.[2] As a 2017 survey from the Center for American Progress confirms, discrimination in the doctor's office remains a problem for the LGBT community more broadly, not just for transgender people.[3] That nationally representative survey found that eight percent of lesbian, gay, bisexual, and queer respondents reported that a health care provider had "refused to see them because of their actual or perceived sexual orientation."[4] In addition, nine percent said they had been on the receiving end of "harsh or abusive language" while receiving medical treatment.[5]

Accessing quality, culturally competent care and overcoming outright discrimination is even a greater challenge for people, including LGBTQ people, living in areas with already limited access to health providers. The proposed regulation threatens to make access even harder, and for some people nearly impossible.

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

[2] *Id.*

[3] Sejal Singh and Laura Durso, "Widespread Discrimination Continues to Shape LGBT People's Lives in Both Subtle and Significant Ways," Center for American Progress, May 2, 2017, available at https://www.americanprogress.org/issues/lgbt/news/2017/05/02/429529/widespread-discrimination-continues-shape-lgbt-peoples-lives-subtle-significant-ways.

[4] *Id.*

[5] Sharita Gruberg, The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial, (hereafter "*ACA's LGBT Nondiscrimination Provisions Prove Crucial*"), available at https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/#.WrO2IsMYDvA.email.

Patients living in less densely populated areas already face a myriad of barriers to care including less access to health insurance coverage, lower incomes, and lower rates of paid sick leave. This is in addition to the universal costs of transportation, taking time from work, and other incidentals that go along with obtaining care in the first place. For many, the sheer distance to a healthcare facility can be a significant barrier to getting care. For example, more than half of rural individuals who need basic obstetric care live more than 30 minutes away from a hospital that provides that important care.[6] Patients seeking more specialized care, like that required for fertility treatments, endocrinology, or HIV treatment or prevention, are often hours away from the closest facility offering these services. For example, a 2015 survey of nearly 28,000 transgender adults nationwide found that respondents needed to travel much further to seek care for gender dysphoria than for other kinds of care.[7]

This means that if these patients are turned away or refused treatment, it is much harder—and sometimes simply not possible—for them to find a viable alternative. In a recent study, nearly one in five LGBTQ people, including 31% of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away. That rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider.[8] While some people may go to LGBTQ-focused community health centers to avoid such discrimination, such centers are not widely available across the United States, and many do not provide comprehensive services. "A total of 13 states—mainly those in the central United States—do not have any LGBTQ community health centers."[9] For patients in these areas, being turned away by a medical provider is not just an inconvenience: it often means being denied care entirely with nowhere else to go.

2. Health care providers often discriminate against LGBTQ individuals simply for being who they are—not based on the care they need.

Although the proposed rule purports to "ensure that persons or entities are not subjected to certain *practices or policies* that violate conscience, coerce, or discriminate, in violation of such Federal laws[10]," this proposed rule addresses a problem that does not exist at the expense of

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

[7] *U.S. Transgender Survey, supra* note 1.

[8] Discrimination Denies Health Care to LGBTQ People, *supra* note 1.

[9] Alexander J. Martos, Patrick A. Wilson, Ilan H. Meyer, Lesbian, Gay, Bisexual, and Transgender (LGBT) Health Services in the United States: Origins, Evolution, and Contemporary Landscape (2017), available at https://williamsinstitute.law.ucla.edu/research/lgbt-health-services/.

[10] U.S. Department of Health and Human Services, Summary of Proposed rule "Protecting Statutory Conscience Rights in Health Care (Hereafter "Summary of Proposed Rule"), available at https://www.federalregister.gov/documents/2018/01/26/2018-01226/protecting-statutory-conscience-rights-in-health-care-delegations-of-authority.

LGBTQ people and other marginalized communities. In fact, the stated reason for the proposed rule is undermined by HHS's own records, which suggest that, if anything, there is a need for greater, not lesser, protection of LGBTQ people against discriminatory denials of care.

A report by the Center for American Progress (CAP) — that reviewed a total of 34 complaints to the Department — explains that the majority of discrimination complaints filed by transgender people were related to medical care that had ***nothing to do with gender transition.***[11]

Among the complaints, some with more than one issue claim, "were 31 claims involving gender identity discrimination and six involving sexual orientation discrimination."[12] In two cases, HHS completed its investigation and issued actual findings of discrimination. In one of those complaints, a receptionist told a transgender person the clinic would not perform surgery because the "Lord does not approve."[13] After the Department investigated, the clinic offered to proceed with the surgery, revised its nondiscrimination policy and providing training for its staff.[14]

Five of the reviewed complaints involved patients who alleged receiving substandard care because of their sexual orientation or gender identity.[15] These claims involved instances were someone's care was delayed or they were released from a hospital prematurely.[16] In two complaints, two individuals alleged being treated differently because their spouse was the same sex.[17] Additionally, CAP reviewed one case were an individual was denied a flu shot because they were HIV-positive.[18]

These complaints show that in 22 cases, the Department often worked with the subject of the complaint to amend policies and implement trainings to teach personnel how to treat transgender patients without discrimination, in lieu of taking them to court.[19] This occurred in all cases "involving the misgendering of patients—seven of the 37 closed issue claims CAP reviewed—and for nearly all cases involving coverage or provision of transition-related care."

Having carried out these investigations and even having found discrimination against LGBTQ people, it is unconscionable that the Department is now attempting to promulgate a regulation

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[11] https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/#.WrO2IsMYDvA.email. These complaints were accessed through a January 24, 2017, Freedom of Information Act request to the Department for copies of complaints of discrimination based on gender identity, sexual orientation, and sexual orientation-related sex stereotyping under Section 1557 of the Affordable Care Act from March 23, 2010 to January 20, 2017. *Id.*

[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] *Id.*

that will likely encourage providers to continue or begin discriminating against the LGBTQ community.

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

The proposed regulation purports, among other things, to clarify current "religious refusal clauses" related to abortion and sterilization in three federal statutes.[20] Each of these three statutes refers to specific, limited circumstances in which health care providers or health care entities may not be required to participate in abortion and sterilization procedures. The newly proposed regulation, however, creates ambiguity about these limited circumstances and encourages an overly broad misinterpretation that goes far beyond what the statutes permit.

For example, section (d) of the Church Amendments refers to circumstances when a person may refuse to participate in any part of a health service program or research activity that "would be contrary to his religious beliefs or moral convictions."[21] Even though longstanding legal interpretation applies this section singularly to participation in abortion and sterilization procedures, the proposed rule does not make this limitation clear. This ambiguity can encourage an overly broad interpretation of the statute that empowers a provider to refuse to provide *any* health care service or information for a religious or moral reason—potentially including not just sterilization and abortion procedures, but also Pre-Exposure Prophylaxis (PrEP), infertility care, treatments related to gender dysphoria, and even HIV treatment. Some providers may try to claim even broader refusal abilities, as shown by the previously-mentioned analysis of complaints to HHS showed that transgender patients are most often discriminated against simply for being who they are rather than for the medical care they are seeking.[22]

Doctors may be misled into believing they may refuse on religious grounds to administer an HIV test or prescribe PrEP to a gay or bisexual man, or refuse screening for a urinary tract infection for a transgender man.[23] In fact, medical staff may interpret the regulation to indicate that they can not only refuse in those instances, but also decline to tell patients where they would be able to obtain these lifesaving services or even inform patients of their treatment options. This puts the health of the patient, and potentially that of others, at risk. The proposed regulation could encourage a physician to refuse to provide fertility treatments to a same-sex couple, or a pharmacist to refuse to fill a prescription for hormone replacement therapy for a transgender customer. In addition, by unlawfully redefining the statutory term "assisting in the performance" of a procedure, the proposed rule could encourage health care workers to obstruct or delay access to a health care service even when they have only a tangential connection to delivering that service, such as scheduling a procedure or running lab tests to monitor side effects of a

[20] Summary of Proposed Rule, *supra* note 10.
[21] 42 U.S.C. 300a-7 (the Church Amendments).
[22] ACA's LGBTQ Nondiscrimination Regulations Prove Crucial, *supra* note 5.
[23] *Id.*

medication. The expansion and broadening of this clause will impair LGBTQ patients' access to care services if interpreted—as the proposed rule improperly appears to do—to permit providers to choose patients based upon sexual orientation, gender identity, or family structure.

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

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

Under Executive Order 13132, an agency that is proposing a regulation with federalism implications, which either preempt State law or impose non-statutory unfunded substantial direct compliance costs on State and local governments, must consult with State and local officials early in the process of developing the regulation.[24]

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

[24] Exec. Order No. 13132, 64 Fed. Reg. 43255 (August 4, 1999).

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

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

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

The expanded religious exemptions in the proposed regulations also conflict with patient protections in federal laws like the Affordable Care Act and the Emergency Medical Treatment and Active Labor Act. While protections under these laws are subject to religious exemptions provided under federal statute, those protections are not subject to exemptions beyond the scope set forth in federal law—including many of the exemptions as they would be expanded by this proposed rule. Additionally, the proposed regulation's approach to religious exemptions—which appears to allow for no limitations even when conduct based on those asserted exemptions would unjustifiably harm patients or employers—conflict with the well-established standard under other federal laws, like Title VII of the Civil Rights Act. Title VII ensures that employers can consider the effect that providing a religious accommodation would have on coworkers, customers, and patients, as well as factors like public safety, public health, and other legal obligations. A proposed standard that appears to forego acknowledgement or even consideration of those effects, and instead appears to require broad, automatic exemptions, would create confusion and undermine the federal government's ability to properly enforce federal laws.

6. The Department's proposed rule would increase the burden of providing care to underserved populations and its Notice requirement would undermine the ability of Mazzoni Center and entities with similar missions to provide services to these communities.

Nearly 40 years ago, Mazzoni Center was founded by members of the LGBTQ community for the very purpose of ensuring access to life- and identity-affirming health and wellness care – care that was denied to them by others. If adopted, the proposed rule will erode the progress that has been made, and will cause, rather than prevent, behavior that is harmful to patients. Moreover, the notice and reporting requirements set forth in the proposed rule would unjustifiably and unnecessarily impede the ability of LGBTQ-focused health and wellness providers to meet the

needs of the underserved and vulnerable population that desperately needs those services, and will cause confusion as patients try to understand whether they will receive the medically necessary care they need in an environment that preserves their dignity and improves their quality of life. They would be given conflicting information about whether providers will treat them with respect that aligns with the organization's mission. Nor would the Department's stated interest in considering whether to exempt entities from the notice requirement offer more than superficial comfort; exemptions could not adequately address the resulting confusion, and would do nothing to address the ability of patients to access the care they need, including people facing the additional barriers and geographical limitations described above. Instead, the Department should focus on ways to increase capacity of organizations and individual providers to provide medically necessary care and treatment to underserved populations, rather than seeking to create a regulatory patchwork that encourages discriminatory denials of treatment to patients. Even with exemptions, the proposed rule would increase or create confusion among LGBTQ and other vulnerable, underserved patients, many of whom are already reluctant to access care because they fear mistreatment based on past experience.

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

The Federal Government enacted Executive Order 12866 to reform and optimize the regulatory process.[25] The objectives of this Executive order are "to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public."[26] The Order emphasizes the use of the semiannual Unified Regulatory Agenda, as a way of identifying significant issues early in the process so that whenever coordination or collaboration is appropriate it can be achieved at the beginning of the regulatory development process rather than at the end.[27]

Despite the Federal Government enacting this Order to make the regulatory process more efficient, HHS rushed to publish this rule without first publishing any notice in its Unified Regulatory Agenda. The failure to follow proper procedure reflects an inadequate consideration of the rule's impact on patients' health and completely undermines the Federal Government's intention of utilizing this requirement to safeguard the rulemaking process.

The timing of the proposed rule also illustrates a lack of sufficient consideration. The proposed rule was published just two months after the close of a public comment period for a Request for

[25] Exec. Order No. 12866, 58 Fed. Reg. 51735 (October 4, 1993).
[26] *Id.*
[27] Memorandum for Heads of Executive Departments and Agencies, and Independent Regulatory Agencies, 94 Pub. Papers 3 (October 12, 1993), available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/inforeg/eo12866_implementation_guidance.pdf

Information closely related to this rule. The 12,000-plus public comments were not all posted until mid-December, a month before this proposed rule was released. Nearly all of the comments submitted at that time related to the subjects covered by the proposed rule—namely, the refusal of care by federally funded health care institutions or their employees because of personal beliefs. Such a short period of time calls into question the comprehensiveness of the review of the Request for Information and whether the proposed rule was developed in an arbitrary and capricious manner.

Conclusion

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

Thank you for your attention to these comments. If you would like clarification or additional information, please contact Iveliz R. Crespo, Esq., by email to icrespo@mazzonicenter.org, or by telephone at 215-563-0652.

Sincerely,

Mazzoni Center

By Iveliz R. Crespo
Staff Attorney

EXHIBIT 25

March 27, 2018

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

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

To Whom It May Concern:

New Voices for Reproductive Justice is a Human Rights and Reproductive Justice advocacy organization with a mission to build a social change movement dedicated to the full health and well-being of Black women, femmes, and girls in Pennsylvania and Ohio. Since 2004 the organization has served over 75,000 women of color and LGBTQ+ people of color through community organizing, grassroots activism, civic engagement, youth mentorship, leadership development, culture change, public policy advocacy and political education.

New Voices defines Reproductive Justice as the human right of all people to have full agency over their bodies, gender identity and expression, sexuality, work, reproduction and the ability to form families. New Voices for Reproductive Justice opposes efforts by the Federal Administration and the U.S. Department of Health and Human Services to make it easier for a wide range of institutions and entities, including hospitals, pharmacies, doctors, nurses, even receptionists, to deny patients the critical care they need via the proposed rule entitled "Protecting Statutory Conscience Rights in Health Care" published January 26.[1]

In allowing unprecedented discretion of providers on religious, ethical, or moral grounds, the proposed conscience and religious freedom provisions make it easier for patients to be denied crucial healthcare and to encounter harmful provider bias. Women of color and LGBTQ+ people of color, in particular, already face disproportionate and systemic barriers to accessing care. Under these newly proposed rules, blatant racism, homophobia, transphobia, and gender discrimination are given the opportunity to run rampant in the health care system without consequence.

This proposed regulation would exacerbate the challenges that many patients -- especially women, LGBTQ people, people of color, immigrants and low-income people -- already face in getting the health care they need in a timely manner and at an affordable cost. The rule would expose vulnerable patients to increased discrimination and denials of medically indicated care by broadening religious health care provider exemptions beyond the existing limited circumstances allowed by law. Moreover, while

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

protecting health providers who deny care, the rule would provide *no protections for patients who are being denied care – even in emergencies*. As drafted, the rule would not even require that patients be informed of all their potential treatment options and referred to alternative providers of needed care.

We urge the administration to put patients first, and withdraw the proposed regulation because of the serious problems enumerated below.

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

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

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

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

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

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

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[2] *See, e.g., Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/; Uttley, L., et al, *Miscarriage of Medicine,* MergerWatch and the ACLU (2013), https://www.aclu.org/report/miscarriage-medicine.

[3] *See* Rule *supra* note 1, at 12.

[4] Hardaway, Lisa, *Settlement Reached in Case of Lambda Legal Lesbian Client Denied Infertility Treatment by Christian Fundamentalist Doctors,* Lambda Legal, September 29, 2009, accessed at https://www.lambdalegal.org/news/ca_20090929_settlement-reached.

[5] Erdely, Sabrina, *Doctors' beliefs can hinder patient care*, SELF magazine, June 22, 2007, accessed at http://www.nbcnews.com/id/19190916/print/1/displaymode/1098/

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

On an institutional level, the right to refuse to "assist in the performance of" a service could mean *a* religiously-affiliated hospital or clinic could deny care, and *then also refuse to provide a patient with a referral or transfer to a willing provider* of the needed service.

The proposed rule thus could be read as allowing health providers to refuse to inform patients of all potential treatment options. A 2010 publication of the National Health Law Program, "Health Care Refusals: Undermining Quality of Care for Women," noted "refusal clauses and institutional restrictions can operate to deprive patients of the complete and accurate information necessary to give informed consent."[6]

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

There have been reported instances in which pregnant women suffering medical emergencies – including premature rupture of membranes (PPROM) and ectopic pregnancies[7] -- have gone to hospital emergency departments and been denied prompt, medically-indicated care because of institutional religious restrictions.[8] The proposed rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person to another facility.[9] Under EMTALA every hospital is required to comply – even those that are religiously affiliated.[10] Because the proposed rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

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

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

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

[9] 42 U.S.C. § 1295dd(a)-(c) (2003).

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

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

The rule sets forth extensive requirements for health care institutions, such as hospitals, to notify employees about their refusal rights, including how to file a discrimination complaint with OCR. The rule requires posting of such notices on the employer's website and in prescribed physical locations within the employer's building. The rule also sets forth the expectation that OCR would investigate or do compliance reviews of whether health care institutions are following the posting rule.[11]

By contrast, the rule contains no requirement that patients be notified of institutional restrictions on provision of certain types of care. Such notification is essential because research has found that patients often are unaware of service restrictions at religiously sponsored health care institutions.[12]

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

The Proposed Rule generates chaos through its failure to account for existing laws that conflict with the refusals of care it would create. For example, the proposed rule makes no mention of Title VII,[13] the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[14] Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer.[15] The proposed rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both.

6. The proposed rule carries severe consequences for patients and will exacerbate existing inequities.

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

Across the country, refusals of care based on personal beliefs have been invoked in countless ways to deny patients the care they need.[16] One woman experiencing pregnancy complications rushed to the only hospital in her community, a religiously affiliated facility, where she was denied the miscarriage

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[11] The notice requirement is spelled out in section 88.5 of the proposed rule.
[12] *See*, for example, Freedman, Lori R., Luciana E. Hebert, Molly F. Battistelli, and Debra B. Stulberg, *Religious hospital policies on reproductive care: what do patients want to know?* American Journal of Obstetrics & Gynecology 218, no. 2 (2018): 251-e1, accessed here: http://www.ajog.org/article/S0002-9378(17)32444-4/fulltext; also Guiahi, Maryam, Jeanelle Sheeder, and Stephanie Teal, *Are women aware of religious restrictions on reproductive health at Catholic hospitals? A survey of women's expectations and preferences for family planning care*, Contraception and Stulberg, D., et all, accessed here: http://www.contraceptionjournal.org/article/S0010-7824(14)00358-8/fulltext; *Do women know when their hospital is Catholic and how this affects their care? Restrictions in Catholic Hospitals (PARRCH) national survey*, Contraception, Volume 96, Issue 4, 268-269,accessed here: http://www.contraceptionjournal.org/article/S0010-7824(17)30235-4/fulltext; a
[13] 42 U.S.C. § 2000e-2 (1964).
[14] *Title VII of the Civil Rights Act of 1964*, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.
[15] *See id.*
[16] *See, e.g.*, *supra* note 2.

management she needed because the hospital objected to this care.[17] Another woman experiencing pregnancy loss was denied care for 10 days at a religiously affiliated hospital outside Chicago, Illinois.[18] In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital, which refused to provide him a hysterectomy.[19] 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.[20] 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.[21]

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

Refusals of care based on personal beliefs already make it difficult for many individuals to access health care and have real consequences for those denied the care they need because of a provider or hospital's religious beliefs. When women and families are uninsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services or travel to another location, refusals bar access to necessary care.[22] 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.[23] In rural areas there may be no other sources of health and life preserving medical care.[24] When these individuals encounter refusals of care, they may have nowhere else to go.

This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals. For example, new research shows that In 19 states, women of color are more likely than white women to give birth in Catholic hospitals.[25] Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provide guidance on a wide range of hospital matters, including reproductive health care, and can keep providers from offering the standard of care.[26] The reach of this type of religious refusal of care is growing with the proliferation

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[17] *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.

[18] *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.

[19] *See* Kira Shepherd, et al., *supra* note 19, at 29.

[20] *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.

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

[22] 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.

[23] 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.

[24] 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/.

[25] *See* Kira Shepherd, et al., *supra* note 19, at 12.

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

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]

7. The Department is abdicating its responsibility to patients

If finalized, the proposed rule will represent a radical departure from the Department's mission to combat discrimination, protect patient access to care, and eliminate health disparities

The proposed rule seeks to divert limited resources away from ending discrimination. De facto segregation, for example, continues to contribute to poorer health outcomes for Black people. For example, Black women are three to four times more likely than white women to die during or after childbirth.[28] Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.[29] Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a health care provider had refused to see them because of their actual or perceived sexual orientation or gender identity in the year before the survey.[30] OCR must work to address these disparities, yet the proposed rule is antithetical to OCR's mission.

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

The proposed rule will have a chilling effect on the enforcement and passage of state laws that protect access to health care and prevent discrimination against individuals seeking medical care. Moreover, the proposed rule invites states to further expand refusals of care by making clear that this expansive rule is a floor, and not a ceiling, for religious exemption laws.[31]

Conclusion

The proposed pule will allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care. The proposed rule is discriminatory, violates multiple federal statutes and the Constitution, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons New Voices for Reproductive Justice calls on the Department to withdraw the proposed rule in its entirety.

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[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.
[28] *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.
[29] *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.
[30] *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.
[31] *See, e.g.*, Rule, *Supra* note 1, at 3888-89.