Nos. 20-15398, 20-15399, 20-16045 and 20-35044

IN THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

CITY AND COUNTY OF SAN FRANCISCO, *Plaintiff-Appellee*, v.

ALEX M. AZAR II, et al., *Defendants-Appellants*.

COUNTY OF SANTA CLARA, et al., *Plaintiffs-Appellees*, v.
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., *Defendants-Appellants*.

STATE OF CALIFORNIA, *Plaintiff-Appellee*, v.
ALEX M. AZAR, et al., *Defendants-Appellants*.

STATE OF WASHINGTON, *Plaintiff-Appellee*, v.
ALEX M. AZAR II, et al., *Defendants-Appellants*.

On Appeal from the United States District Courts for the Northern District of California and the Eastern District of Washington

SUPPLEMENTAL EXCERPTS OF RECORD VOLUME II OF X

XAVIER BECERRA
Attorney General of California
RENU R. GEORGE
Senior Assistant Attorney General
KATHLEEN BOERGERS
Supervising Deputy Attorney General
STEPHANIE T. YU
NICOLE RIES FOX
Deputy Attorneys General

October 8, 2020

NELI N. PALMA
Supervising Deputy Attorney General
State Bar No. 203374
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-7522
Fax: (916) 322-8288

Email: Neli.Palma@doj.ca.gov

Attorneys for the State of California

(additional counsel listed on inside cover)

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For the City and County of San Francisco

DENNIS J. HERRERA

City Attorney

JESSE C. SMITH

RONALD P. FLYNN YVONNE R. MERE

SARA J. EISENBERG

JAIME M. HULING DELAYE

Deputy City Attorneys

Office of the San Francisco City Attorney

City Hall, Room 234

1 Dr. Carlton B. Goodlett Place

San Francisco, CA 94102-4602

Telephone: (415) 554-3857 Facsimile: (415) 554-4715

Email: Sara.Eisenberg@sfcityatty.org

For the County of Santa Clara, et al.

JAMES R. WILLIAMS

GRETA S. HANSEN

LAURA S. TRICE

MARY E. HANNA-WEIR

SUSAN P. GREENBERG

H. LUKE EDWARDS

Office of the County Counsel,

County of Santa Clara

70 West Hedding St., East Wing

San José, CA 95110

Tel: (408) 299-5900

Counsel for County of Santa Clara

NICOLE A. SAHARSKY MIRIAM R. NEMETZ Mayer Brown LLP 1999 K Street NW Washington, DC 20006

Tel: (202) 263-3000

nsaharsky@mayerbrown.com

Counsel for all Plaintiffs

For the State of Washington

ROBERT W. FERGUSON

Attorney General of Washington

JEFFREY T. SPRUNG

LAURYN K. FRAAS

PAUL CRISALLI

R. JULY SIMPSON

NATHAN K. BAYS

Assistant Attorneys General

800 Fifth Avenue, Suite 2000

Seattle, WA 98104

Telephone: (206) 464-7744

Fax: (206) 464-6451

Email: jeff.sprung@atg.wa.gov Email: lauryn.fraas@atg.wa.gov Case: 20-15398, 10/12/2020, ID: 11855269, DktEntry: 46-2, Page 3 of 288

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475 Park Avenue South, Suite 2100 New York, NY 10016 tel 646.880.3005 fax 202.697.5058 info@familyequality.org

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 Rule, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03

To Whom it May Concern:

Family Equality Council submits the following comment in response to the request for public comment regarding the proposed rule entitled "Protecting Statutory Conscience Rights in Health Care," published January 26.

Family Equality Council connects, supports, and represents the three million parents who are lesbian, gay, bisexual, transgender and queer (LGBTQ) in this country and their six million children. We are a community of parents and children, grandparents and grandchildren that reaches across this country. For over 30 years we have raised our voices toward fairness for all families.

We thank you for the opportunity to comment on HHS' Proposed Rule, RIN 0945-ZA03, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" (Rule).

Every day too many LGBTQ people face discrimination and other barriers to accessing lifesaving care. These barriers are especially pronounced for transgender patients. The proposed rule ignores the prevalence of discrimination and damage it causes and will undoubtedly lead to increased discrimination and denials of care for some of the most vulnerable members of our community. We deeply value freedom of religion but sweeping exemptions that obstruct access to care are a fundamental distortion of that principle. American patients, particularly those already at heightened

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risk for discrimination in health care services as documented by HHS' own Office of Civil Rights, deserve better.¹

Family Equality Council and partner organizations have documented numerous instances of mistreatment, discrimination and denial of health care services to LGBTQ people and our children in amicus briefs to the Supreme Court and other courts. These stories illustrate not only the discrimination and degrading treatment LGBTQ individuals face when seeking medical care, but also the impact such treatment has on our families:

- Kinsey, a one-week old infant who had a life-threatening reaction to vaccine but was not immediately treated by hospital staff because the lesbian mother who had brought her could not prove she was her "real" mom.²
- M.C., a two-year old whose emergency treatment by a pediatric dentist was delayed because, as she was told, "a child cannot have two mothers."³
- A.S. and M.S., a married lesbian couple in Tennessee, who were denied service by multiple midwives and a birthing class provider during A.S.' pregnancy.⁴
- K.S., a transgender woman seeking mental health services who was subject to abusive treatment, inappropriate questioning and breaches of confidentiality, and who attempted to commit suicide twice while at the facility.⁵
- M.H., a gay man who checked into a New York City hospital with a severe infection and was treated roughly, called a 'faggot' multiple times, dragged down the hall in an office chair causing him to fall out of chair, and left on the ground where he had a seizure and convulsions.⁶

Expanding religious refusals can exacerbate the barriers to care that LGBTQ individuals and our family members already face.

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

² Brief of Amici Curiae Family Equality Council, Colage, and Kinsey Morrison in Support of Petitioners, Addressing the Merits and Supporting Reversal, Obergefell v. Hodges, 135 S. Ct. 2584, 2015, https://www.familyequality.org/ asset/mhfjym/VoCSCOTUS2015.pdf

³ Brief of Amici Curiae Lambda Legal Defense and Education Fund, Inc., Family Equality Council et al., in Support of Respondents, Masterpiece Cake Shop v. Colorado Civil Rights Commission, (S. Ct. 2017), https://www.familyequality.org/asset/5xtc7j/20171030-LambdaLegal-FamEq-Amicus-Brief-Masterpiece.pdf

⁴ Ibid.

⁵ Ibid.

⁶ Ibid.



Because of the broad language of the rule that goes beyond existing statutes and regulations, we are concerned it could embolden health care providers to claim protections for the kinds of harmful mistreatment and service denials such as those outlined in the examples above. Nearly 56% of lesbian, gay, and bisexual people have had at least one experience of mistreatment or service denials in health care and 31% of transgender people have faced such discrimination in the last year alone. 7

In a recent study, nearly one in five LGBTQ people, including 31% of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away. That rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider. For these patients, being turned away by a medical provider is not just an inconvenience: it often means being denied care entirely with nowhere else to go.

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

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

For example, section (d) of the Church Amendments refers to circumstances when a person may refuse to participate in any part of a health service program or research activity that "would be contrary to his religious beliefs or moral convictions." Even though longstanding legal interpretation applies this section singularly to participation in abortion and sterilization procedures, the proposed rule does not make this limitation clear. This ambiguity can encourage an overly broad interpretation of the statute that empowers a provider to refuse to provide any health care service or information for a religious or moral reason. Some providers may try to claim even broader refusal abilities, as a recent analysis of complaints to HHS showed that transgender patients are most often discriminated against simply for being who they are rather than for the medical care they are seeking.9

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Movement Advancement Project, LGBT Policy Spotlight: Public Accommodations Nondiscrimination Laws, 2018, http://www.lgbtmap.org/file/Spotlight-Public-Accommodations-FINAL.pdf

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

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



Medical staff may interpret the rule to indicate that they can not only refuse but decline to tell the patient where he would be able to obtain these lifesaving services or even inform patients of their treatment options. This puts the health of the patient, and potentially that of others, at risk. In addition, by unlawfully redefining the statutory term "assisting in the performance" of a procedure, the rule could encourage health care workers to obstruct or delay access to a health care service even when they have only a tangential connection to delivering that service, such as scheduling a procedure or running lab tests to monitor side-effects of a medication. The extension and broadening of this clause will impair LGBTQ patients' access to care services if interpreted—as the proposed rule improperly appears to do-to permit providers to choose patients based upon sexual orientation, gender identity, or family structure.

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

Expanding exemptions undermines the Department's mandate to protect the health and well-being of all Americans.

Reducing discrimination and other barriers to accessing health care services, as well as reducing the accompanying health disparities, is core to the Department's mission and its obligations under laws authorizing its programs. Weakening protections and limiting program access by expanding religionbased exemptions fundamentally runs contrary to this mission.

The Department's core mission is to "enhance and protect the health and well-being of all Americans...by providing for effective health and human services."10 Ensuring that beneficiaries of Department programs and other patients have fair and equal access to services and reducing barriers to those services is an inseparable and necessary component of this responsibility. The Department's ability to ensure equal, nondiscriminatory access to services would be significantly weakened by the proposed rule. In order to meet its legal obligations and its statutory mission, HHS must prioritize the needs and rights of patients over those of organizations seeking federal funds and individual health

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³⁰ Dep't, of Health & Human Servs., About HHS, 2017, https://www.hhs.gov/about/index.html.



care workers. Creating new or expanded exemptions for recipients of federal funds at the cost of patients' access to health services prevents the Department from meeting its responsibilities to HHS program beneficiaries and patients around the country.

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

The Department claims that its unwarranted new interpretations of federal law supersede laws passed by state and local governments to ensure patients' access to health care. By claiming to allow individuals and institutions to refuse care to patients based on the providers' religious or moral beliefs in such a sweeping way, the proposed rule creates conflicts with hundreds of state and local nondiscrimination laws around the country that apply to health care. It therefore is inaccurate 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.

Foster children face unique harms due to health care service refusals.

Allowing Such Refusals Undermines States' and Local Governments' Statutorily Required Efforts to Promote Safety, Permanency, and Well-Being of Foster Youth, Including Child-Welfare Specific Nondiscrimination Laws

Foster children, including LGBTQ foster youth, are particularly vulnerable to health care service refusals, and the rule could lead to unlawful service refusals and worsened outcomes for youth in care. The rule could undermine the core statutory objectives of those providing services in the child welfare context, who must act in the best interests of the child, with the objectives of child safety, permanency and well-being. Instead, a health care provider could prioritize personal religious beliefs over the best interests of the child. A broadening of the interpretation of the Church Amendment could lead to a medical professional funded by federal health programs who is providing health care services to foster children, including those in a restricted setting, to feel emboldened to refuse the child a range of services that are in his or her best interests such as reproductive health care for a girl in care, transition related care for a transgender foster youth, or counseling for an LGBTQ-identified foster youth that affirms her or his identity.

Foster children are uniquely dependent on those providing their care, including health care. For example, a child placed in a group home may not have access to the internet, phone service, email, or other means to communicate with health providers other than those entrusted with their care. This means if these children are refused needed health services, it may simply not be possible for them to find a viable alternative.

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LGBTQ and female foster youth are particularly vulnerable. HHS-funded research has shown that LGBTQ youth, who comprised 19% of foster youth over 12 in the study of Los Angeles foster care, suffer unacceptably high rates of mistreatment, hospitalizations, placements in group homes (instead of with loving families), serial placements, and homelessness. 11 A study conducted in New York City's child welfare system further found that more than half (56%) of the LGBTQ-identified youth who had been interviewed said that they had chosen living in the streets at one point as they felt safer there than living in group or foster homes. 12 Affirming care that supports LGBTQ foster youths' identities is essential for achieving the child welfare goals of safety, permanency, and well-being. This care includes affirming health care, including reproductive care, transition-related health care for transgender youth, and mental health care that helps LGBTQ foster youth address issues of trauma related to family rejection, violence, harassment, and discrimination due to their sexual orientation or gender identity or expression. Service refusals by medical professionals could greatly exacerbate the trauma these youth have already experienced, particularly as they face few options for accessing alternative providers.

It is impermissible to allow those who care for foster children to deny them access to reproductive health care.

The government is legally obligated to provide medical care and family planning services to the youth in its care, without exception. 13 Yet, the proposed Rule could allow foster parents and social service agencies that provide services to children and young people to refuse even minor assistance to a young person in foster care who needs reproductive health services, including birth control, testing or treatment for sexually transmitted infection, and abortion care. This means that a social service agency or even just one person at that agency could block a young person in foster care from making an appointment or getting to a doctor's office for reproductive health care. A bus driver who is supposed to take a foster child to a doctor's appointment, for example, could refuse to drive the young person to a family planning clinic, claiming that doing so would "assist in the performance" of providing birth control.

Comprehensive, non-judgmental, and trauma informed reproductive health care is critical for youth in foster care. Girls in foster care are twice as likely as girls not in foster care to have sex and less likely to use birth control when they do have sex. 14 As a result, girls in foster care are more likely to

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¹¹ Wilson, B.D.M., Cooper, K., Kastanis, A., & Nezhad, S. (2014). Sexual and Gender Minority Youth in Faster care: Assessing Disproportionality and Disparities in Los Angeles. Los Angeles: The Williams Institute, UCLA School of Law.

¹² G.P. Mallon, We don't exactly get the welcome wagon: The experience of gay and lesbian adolescents in North America's child welfare system, in Child Welfare League of America Best Practice Guidelines (Child Welfare League of America, 2006).

¹³ Flores v. Reno, No. CV 85-4544- RJK(Px) (C.D. Cal. Jan. 17, 1997).

Alison Stewart Ng & Kelleen Kaye, The National Campaign to Prevent Teen and Unplanned Pregnancy, Teen Childbearing and Child Welfare, 2013, 1, available at https://thenationalcampaign.org/sites/default/files/resourceprimary-download/childbearing-childwelfare.pdf.



become parents: A national study found that twice as many girls in foster care give birth compared to girls not in foster care. 15

It is critical, therefore, that young people in foster care be able to access comprehensive reproductive health care and counselling. Girls in foster care also experience higher rates of sexual violence. They are twice as likely as boys to be removed from their homes and placed in foster care because of sexual abuse (6 percent of girls versus 2.9 percent of boys), making it that much more crucial that they are provided timely, unimpeded access to a full range of reproductive health care services in a manner that is both respectful and non-stigmatizing.

Allowing young people to be placed in a setting with caregivers who are unwilling to allow a young person to access reproductive health care services would lead to discriminatory and substandard care. No young person in foster care should be denied access to needed health care services because the people or organizations who are supposed to care for the young person object to the care.

The proposed rule undermines states' and local governments' efforts to protect foster children's health and safety, including their nondiscrimination laws.

The Department claims that its new interpretations of federal law supersede laws passed by state and local governments to ensure patients' access to health care. Yet, by allowing health care providers to refuse care to patients based on the providers' religious or moral beliefs in such a sweeping way, the proposed rule conflicts with state and local nondiscrimination laws, regulations, and policies that provide protections to foster youth.

Thirty-seven states provide protections against discrimination based on sexual orientation for youth receiving foster care and adoption services by law, regulation, or policy, and twenty-four states provide such protections based on gender identity and expression. Further, "all States, the District of Columbia, American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands have statutes requiring that the child's best interests be considered whenever specified types of decisions are made regarding a child's custody, placement, or other critical life issues." (from HHS Children's Bureau website, with links to all statutes.)¹⁹

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¹⁵ Lois Thiessen Love et al., The National Campaign to Prevent Teen Pregnancy, Fostering Hope: Preventing Teen Pregnancy Among Youth in Foster Care, 2005, 7, available at

https://thenationalcampaign.org/sites/default/files/resource-primary-download/FosteringHope FINAL.pdf.

¹⁶ Karen Banes-Dunning & Karen Worthington, "Responding to the Needs of Girls in Foster Care," Georgetown Journal on Law & Poverty 20 no. 2, 2013, 321-49, available at

http://www.karenworthington.com/uploads/2/8/3/9/2839680/adolescent girls in foster care.pdf.

¹⁷ National Women's Law Center calculations of unpublished data by National Data Archive on Child Abuse and Neglect.

¹⁸ See https://www.lambdalegal.org/map/child-welfare for a map of sex, sexual orientation, and gender identity anti-discrimination statutes, regulations, and policies in place for foster youth by state.

¹⁹ Available at https://www.childwelfare.gov/pubPDFs/best interest.pdf



Two examples of state nondiscrimination laws and policies that protect LGBTQ foster youth from discrimination include (emphasis added):

California

Statute: Cal. Welf. & Inst. Code 16001.9

Rights of minors and non-minors in foster care.

"It is the policy of the state that all minors and nonminors in foster care shall have the following rights:

. . .

(23) To have fair and equal access to all available services, placement, care, treatment, and benefits, and to not be subjected to discrimination or harassment on the basis of actual or perceived race, ethnic group identification, ancestry, national origin, color, religion, sex, sexual orientation, gender identity, mental or physical disability, or HIV status.

(25) To have caregivers and child welfare personnel who have received instruction on cultural competency and sensitivity training relating to, and best practices for, providing adequate care to lesbian, gay, bisexual, and transgender youth in out-of-home care."

Idaho

Policy: Idaho Youth in Care Bill of Rights (Oct. 2015)

"Youth have the right to learn about their sexuality in a safe and supportive environment.

. . .

Youth have the most basic right to receive care and services that are free of discrimination based on race, color, national origin, ancestry, gender, gender identity and gender expression, religion, sexual orientation, physical and mental disability, and the fact that they are in foster care."

Because of explicit nondiscrimination protections in the provision of care and services to foster youth, including health care services, it is inaccurate 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. In fact, the rule could prove financially burdensome to states attempting to ameliorate the high costs of disproportionately negative outcomes for LGBTQ foster youth. An HHS-funded study found that LGBTQ foster youth had been hospitalized for emotional reasons at three times the rate of non-LGBTQ foster youth, and the report therefor recommended "address[ing] the needs of LGBTQ youth in care so their experience begins to approximate those of their non-LGBTQ counterparts. This will result in much needed cost avoidance for already over-burdened child welfare systems."²⁰

Love. Justice. Family. Equality.

www.familyequality.org

²⁰ Wilson, B.D.M., Cooper, K., Kastanis, A., & Nezhad, S., 2014. Sexual and Gender Minority Youth in Foster care: Assessing Disproportionality and Disparities in Los Angeles. Los Angeles: The Williams Institute, UCLA School of Law.



Conclusion

The proposed rule goes far beyond established law, improperly undermines state nondiscrimination laws, and most importantly will put the health and potentially even the lives of some of the most underserved and vulnerable patients at risk. We urge you to withdraw the proposed rule.

Should you have any questions about these comments, I would be happy to visit your offices in Washington, DC to discuss them, or you can reach me via telephone or email at 646.829.9314 or ssloan@familyequality.org.

Sincerely,

Rev. Stan J. Sloan

Chief Executive Officer

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Exhibit 73



March 26, 2018

Submitted via the Federal e-Rulemaking Portal

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

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

Dear Mr. Severino:

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

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

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

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

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

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

- HIV Prevention: Despite the availability of highly effective prevention tools including preexposure prophylaxis or (PrEP) -- a once-a-day pill recommended for individuals at higher risk for
 HIV the number of new HIV infections is around 40,000 annually. Allowing providers to ignore
 CDC clinical guidelinesⁱⁱⁱ for use of PrEP and other HIV prevention interventions will hinder our
 efforts to reduce new HIV infections, particularly for populations most at risk for HIV including
 gay men and transgender individuals. Individuals who turn to health care providers for HIV and
 STD testing, PrEP, HIV treatment, or prevention and treatment for any communicable disease,
 should never be denied access to these services because of a provider's religious beliefs. This is
 particularly important in underserved areas where health care provider access can be severely
 limited and travel to other providers can be prohibitive due lack of transportation and/or
 distance.
- LGBTQ Care, Particularly Transgender Care: LGBTQ individuals continue to face significant discrimination and stigma. Ensuring that this population has access to culturally competent and sensitive providers is critical to our efforts to address the HIV-related disparities faced by gay men and transgender individuals. IV Transgender individuals in particular are at high risk for HIV and have low rates of health coverage in the U.S. In many jurisdictions, transgender patients are already denied gender-affirming and medically necessary care. Denying transgender individuals the gender-related medical care they need will lead to fear and distrust of health care providers and of the health care system leaving them even more vulnerable to HIV and less likely to learn they are HIV-positive, to access care, and to effectively manage their HIV. Provider shortages in many areas will leave transgender individuals without viable alternatives for preventive and health care services if their local provider denies care.
- Women's Health Care: Women with HIV and all women have a right to reproductive health services including contraception and abortion. Granting health care providers and institutions the right to withhold medical information regarding prevention or treatment options or to deny women these services based on personal religious beliefs puts their health at risk.

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

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

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

Respectfully submitted by:

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

¹ HIV.gov.Activities Combating HIV Stigma and Discrimination. https://www.hiv.gov/federal-response/federal-activities-agencies/activities-combating-hiv-stigma-and-discrimination. Accessed 3/22/18.

^{II} Centers for Disease Control and Prevention. HIV Continuum of Care, U.S., 2014, Overall and by Age, Race/Ethnicity, Transmission Route and Sex. July 2017.

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

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

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

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

Exhibit 74



FEMINIST MAJORITY FOUNDATION

Working for Women's Equality

Eleanor Smeai President

Peg Yerkin Chair of the Board

Kamerine Spillar Executive Director

■ Washington DC. 1600 Wilson Favd Suite ±01 Arlington, VA 22299 703 522 2214 703 522 2219 fex

West Coast 433 S. Beverly D. Beverly H. Is, CA 90212 410 556 2500 310 556 2509 (a) March 24, 2018

VIA ELECTRONIC SUBMISSION

The Honorable Alex M. Azar
Director Roger Severino
U.S. Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building
200 Independence Avenue SW
Room 415F
Washington, DC 20201

ATTN: Conscience NPRM, RIN 0945-ZA03

Dear Secretary Azar and Director Severino,

The Feminist Majority Foundation (FMF), a national organization dedicated to women's equality, reproductive health, and the empowerment of women and girls in all spheres, writes in response to the Notice of Proposed Rulemaking regarding Protecting Statutory Conscience Rights in Health Care ("the Proposed Rule"), published in the Federal Register on January 26, 2018. FMF strongly opposes this Proposed Rule.

The Proposed Rule would unlawfully expand the reach of refusal laws, undermine access to care, and exacerbate already existing health disparities by allowing government-funded health care entities to impose their religious beliefs and moral convictions onto patients and other service recipients. Although the Department of Health and Human Services ("the Department") claims that the Proposed Rule is necessary to counter discrimination, the rule itself would allow individuals and health care entities who receive federal funding to use religion as a tool to discriminate, particularly against women, LGBTQ individuals, and gender nonconforming people.

For these reasons, the Feminist Majority Foundation calls on the Department and the Office for Civil Rights (OCR) to withdraw the Proposed Rule in its entirety.

The Proposed Rule is Unlawful

The Proposed Rule unlawfully seeks to expand the reach of federal refusal of care laws and create new refusals of care. As such, the Proposed Rule violates the Administrative Procedure Act (APA), which requires agency actions that are "not in accordance with

¹ Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (proposed Jan. 26, 2018) [hereinafter Proposed Rule].

law," "contrary to a constitutional right," or "in excess of statutory jurisdiction," to be set aside.²

One such unlawful expansion concerns the Church Amendments. The Church Amendments prevent healthcare personnel employed by federally-funded facilities or programs from being required to perform or "assist in the performance" of sterilization or abortion services to which they have a religious or moral objection.³ The statute does not contain a definition of "assist in the performance." The Proposed Rule would define this term, but the definition offered goes beyond the intent of the Church Amendments, as stated by Senator Frank Church himself. During debate on the amendments, Senator Church stated:

The amendment is meant to give protection the physicians, to the nurses, to the hospitals themselves, if they are religious affiliated institutions. So the fact [that] Federal funds may have been extended will not be used as an excuse for requiring physicians, nurses, or institutions to perform abortions or sterilizations that are contrary to their religious precepts. That is the objective of the amendment. There is no intention here to permit a frivolous objection from someone unconnected with the procedure to be the basis for a refusal to perform what would otherwise be a legal operation.⁴

The Proposed Rule, however, would create a broad definition of "assist in the performance," as meaning "to participate in *any* activity with an *articulable* connection to a procedure, health service or health service program, or research activity." It continues, "This includes but is not limited to counseling, referral, training, or other arrangements for the procedure, health service, health program, or research activity." This overly broad definition of "assist in the performance" greatly expands the types of services that can be refused—including making simple "arrangements for the procedure"—no matter how tangential. As a result, individuals who are not "assisting in the performance" of a procedure, under the ordinary meaning of the term, as suggested by Senator Church himself, could assert a new right to refuse, including the hospital room scheduler, the technician assigned to clean surgical instruments, and other hospital employees providing routine hospital services. The use of the term "articulable" does not cabin this overly broad definition; instead, it introduces yet another level of confusion and uncertainty. In defining this term, then, the Department broadened the scope of the Church Amendments far beyond what was envisioned when they were enacted.

The Proposed Rule's definition of "referral" also goes beyond an ordinary understanding of the term, allowing individuals, hospitals, and other health care entities to refuse to provide *any* information that could help an individual get access to care, even if that care is criticallyneeded. The Department would even allow an individual to refuse to provide any "guidance"

² 5 U.S.C. § 706(2)(A)-(C).

³ 42 U.S.C. § 300a-7.

⁴ 155 Cong. Rec. S9597 (1973) (statement of Sen. Church) (emphasis added).

⁵ Proposed Rule, *supra* note 1, at 3923 (emphasis added).

⁶ Id.

⁷ Id. at 3895. Note that the Proposed Rule would also appear to conflict with the Emergency Medical Treatment and Active Labor Act (EMTALA) which requires hospitals that have a Medicare provider agreement and an

likely to assist a patient" in obtaining abortion care, including providing information for "a physician or clinic that may provide an abortion." Such a broad definition that gives no direction on when information becomes "likely" to assist and provides no limiting principle for denying referrals to a healthcare provider who may provide abortion, is an invitation to abuse, potentially at the cost of women's health and lives.

Similarly, the Proposed Rule creates a new definition of the term "health care entity" that appears to be much broader than what is allowed under the Coats and Weldon Amendments.

The Department argues that the Weldon Amendment's inclusion of "any other kind of health care facility, organization, or plan," in its definition of "health care entity" justifies the Department's broad definition of the term in the Proposed Rule; however, the Proposed Rule does not set any parameters for its definition at all. In fact, the Department notes that in its attempt to create a definition, it is merely creating an "illustrative" list.

Such an approach, which disregards the statutory definitions of the term for an open-ended laundry list, would not only create confusion, it would undermine Congressional intent and not be in accordance with the law, in violation of the APA.

In addition to the Proposed Rule being an unlawful expansion of refusal of care provisions, the rule also conflicts with Title VII of the Civil Rights Act of 1964, which provides the legal framework for religious accommodations in the workplace.¹²

With respect to religion, Title VII requires an employer to provide a reasonable accommodation of an employee's or an applicant's sincerely held religious belief, practice, or observance, unless doing so would pose an undue hardship. ¹³ In considering whether an accommodation would pose an undue hardship, employers may consider not only the cost of the accommodation, but also the burden it would impose on patients and coworkers and the impact on overall safety. Employers can also consider the type of workplace it runs as well as the nature of the

emergency room or department to provide anyone requesting treatment an appropriate medical screening to determine whether an emergency exists, to stabilize the patient, and to determine whether a transfer to another facility is warranted. 42 U.S.C. § 1395dd(a)-(c). Hospitals must comply with the EMTALA, even those who are religiously affiliated. The Proposed Rule, however does not create an exception for emergencies, or even acknowledge EMTALA, suggesting once again, that the Department has engaged in overreach through its Proposed Rule.

Id (emphasis added).

³ See 42 U.S.C. § 238n (c)(2) (defining "health care entity" to include "an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions); The Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009) (defining "health care entity" to include "an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan").

¹⁰ ld.

¹¹ Proposed Rule, supra note 1, at 3893.

^{12 42} U.S.C. § 2000e-2.

¹³ Questions and Answers: Religious Discrimination in the Workplace, U.S. EQUAL EMP'T, OPPORTUNITY COMM'N (Jan. 31, 2011), https://www.eeoc.gov/policy/docs/qanda_religion.html.

employee's duties to determine whether the accommodation would be an undue hardship.¹⁴ The Proposed Rule, however, not only makes no mention of Title VII, it would appear to conflict with the law in that the Proposed Rule, as written, could require health care entities to hire people, whether or not the applicants' religious or moral objections posed an undue hardship, who intend to refuse to provide services that would otherwise be performed.

To illustrate the problem created by the Proposed Rule, consider a Title X funded health clinic. Title X of the Public Health Service Act is the only domestic federal grant program dedicated solely to providing family planning and related healthcare services. Under the Proposed Rule, the Department would appear to allow a situation in which a Title X grantee could receive federal funds while being exempt from providing necessary services required by law—including the provision of non-directive pregnancy counseling options and referrals, upon request, for a range of services, including pregnancy termination¹⁵—if the grantee had a religious or moral objection. Even if grantees did generally provide these services, the Proposed Rule offers no guidance on whether it would be impermissible for a Title X funded health clinic *not* to hire a counselor or clinician if that person would refuse to provide these required services, something that Title VII would not mandate.¹⁶ The Proposed Rule is therefore not only at odds with preexisting legal and regulatory requirements, but it could also undermine the entire purpose of the Title X program, which is to provide low-income people with affordable family planning services and health care information they can use to make the best health care decisions for themselves, free from government interference or coercion.

Finally, the Proposed Rule would also appear to violate the First Amendment. Although the U.S. Constitution recognizes that freedom of religion is a fundamental right, the First Amendment does not allow the government to use religious liberty as a weapon to harm others. To the contrary, the U.S. Constitution forbids the government from creating religious accommodations to generally applicable laws when the accommodation would harm a third party. As the Proposed Rule would allow individuals and health care entities to use their personal religious beliefs or moral convictions—instead of medical standards of care—to dictate patient care, the Proposed Rule, as described in more detail below, would create substantial harm to patients who may be denied care and therefore incur additional economic costs, experience adverse health outcomes, and/or suffer social or emotional harm.

¹⁴ See id.

¹⁵ See Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017); 42 C.F.R. § 59.5(a)(5).

¹⁶ It is also of note that Congress specifically rejected the House Conscience Protection Act in the FY 2018 omnibus spending bill passed on March 23, 2018, which continues to fund Title X programs.

¹⁷ See e.g., Estate of Thornton v. Caldor, 472 U.S. 703, 709 (1985) (finding that a Connecticut law that gave workers an absolute and unqualified right not to work on their chosen Sabbath violated the Establishment Clause of the First Amendment because "the State commands that Sabbath religious concerns automatically control over all secular interests at the workplace; the statute takes no account of the convenience or interests of the employer or those of other employees who do not observe a Sabbath. The employer and others must adjust their affairs to the command of the State whenever the statute is invoked by an employee.").

The Proposed Rule Will Impose Substantial Harm to Patients & Exacerbate Health Disparities

Far from improving access to health care and expanding care and service options, when healthcare providers are allowed to let religion or moral convictions dictate care, patients often have fewer options, resulting in poorer health outcomes that can have devastating and long-lasting consequences. Religious directives, for example, have led certain hospitals to refuse to provide appropriate, life-saving treatment to women following miscarriage, putting women at greater risk of death. Not only have women been denied treatment and services—including family planning services and sterilization procedures—women have even been prevented from receiving appropriate referrals or have been outright denied information about their own health condition. Citing religious beliefs and/or moral convictions, medical providers have also denied care to LGBTQ individuals and persons with HIV. Religious and/or moral beliefs could also be used as a license to discriminate against young people seeking sexuality and sexual health information, older adults seeking end-of-life care, and victims of intimate partner violence seeking care and support, among other populations.

Refusals of care can have devastating consequences for patients who are denied access to healthcare information and services. Withholding care during miscarriage, for example, caused women at a religiously-affiliated hospital to suffer from potentially life-threatening infections, including sepsis. This experience mirrors what was learned in a 2008 study in which providers disclosed how some women at Catholic hospitals were being denied care consistent with prevailing medical standards and transferred to other facilities, sometimes at a great distance, thereby delaying care and increasing risks to their health. 22

Refusals also increase the economic cost of care to patients—sometimes preventing them from accessing health care at all. 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 to travel, or where there is no transportation available, then refusals can amount to an outright bar on access to health care. This is especially true for individuals in rural areas where there may be severely limited healthcare options. Allowing providers and health care entities to discriminate against patients by refusing care therefore exacerbates healthcare disparities for low-income people.

Expanding already harmful refusal laws will also have a substantial impact on women of color who already face increased barriers to access care, generally receive poorer quality care, and

¹⁸ Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide, NAT'L WOMEN'S LAW CNTR, (Aug. 30, 2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/.

¹⁹ Id.

²⁰ Id.

Molly Redden, Abortion Ban Linked to Dangerous Miscarriages at Catholic Hospital, Report Claims, THE GUARDIAN (Feb. 18, 2016), https://www.theguardian.com/us-news/2016/feb/18/michigan-catholic-hospital-women-miscarriage-abortion-mercy-health-partners.

²² Lori R. Freedman, Uta Landy and Jody Steinauer, When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals, Am. J. Pub. HEALTH (2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.

experience worse health outcomes.²³ For example, Black women in the U.S. are up to four times more likely than white women to die during or after childbirth, a disparity that is growing not decreasing.²⁴ The shocking rates of maternal mortality for Black women are likely related to discrimination Black women face accessing health care or when interacting with healthcare providers.²⁵ Creating more opportunities for Black women to be discriminated against or denied information, treatment, or care only adds to these disparities, especially at a time when the Department should be focusing its resources on lowering sky high rates of Black maternal death.

For transgender individuals, refusals can also block access to care with devastating consequences. A recent survey of over 20,000 transgender individuals in the U.S. found that one-third of those who saw a healthcare provider had at least one negative experience related to being transgender, such as being verbally harassed or refused treatment because of their gender identity, with higher rates for people of color and people with disabilities. Additionally, nearly one-quarter of respondents reported that they did not seek the health care they needed in the year prior to completing the survey due to fear of being mistreated as a transgender person. Creating expanded protections for those who would deny health care to transgender individuals based on religious or moral beliefs, would only aggravate these existing problems.

The Proposed Rule also harms patients by threatening informed consent, a bedrock principle of patient-centered decision-making that is a hallmark of the patient-provider relationship. Informed consent requires that a provider give patients relevant and medically accurate information so that patients can make the best healthcare decisions for themselves. Existing refusals of care based on religious or other personal beliefs already undermine open communication between providers and patients. Although the Department argues that the Proposed Rule would improve communication between patients and providers, ²⁸ that argument simply rings hollow. In truth, the Proposed Rule broadens protection for refusals and allows providers, including hospitals and other health care institutions, to refuse to provide patients with information. By its very nature, then, the Proposed Rule allows providers to block information, curtail meaningful communication, and make it impossible for patients to make informed healthcare decisions, undermining their right to dignity and bodily autonomy.

The consequences of undermining informed consent were captured by one woman who, after being denied information and access to care following a miscarriage, reported to a health

²³ See generally, Petry Ubri and Samantha Artiga, Disparities in Health Care: Five Key Questions and Answers, HENRY J. KAISER FAMILY FOUND. (Aug. 12 2016), https://www.kff.org/disparities-policy/issue-brief/disparities-in-health-and-health-care-five-key-questions-and-answers/#endnote_link_195310-17.

²⁴ See Nina Martin and Renee Montagne, Nothing Protects Black Women from Dying in Childbirth, PROPUBLICA AND NPR NEWS (Dec. 7, 2017), https://www.propublica.org/article/nothing-protects-black-women-from-dying-in-pregnancy-and-childbirth.

See id.

The Report of the 2015 U.S. Transgender Survey, NAT'L CTR FOR TRANSGENDER EQUALITY (2015), http://www.ustranssurvey.org/reports.

²⁸ Proposed Rule, supra note 1, at XX.

official "her anger at being given false hope that her infant would survive and at the hospital's decision to risk her life for a pregnancy that staff knew was no longer viable."²⁹ Had she had all of the facts, this woman may have chosen very different care, but her healthcare providers, acting on religious directives, imposed their religious and moral view onto her and robbed her of all of her choices, without her knowledge.

Conclusion

Healthcare providers should not be able to use their own personal religious or moral beliefs to determine the care a person may receive. Moreover, the government has an obligation to prevent its partners from imposing their own religious beliefs onto patients or other service recipients.

If the Department is serious about its mission "to enhance and protect the health and well-being of all Americans," then the Feminist Majority Foundation has grave concerns about the current Proposed Rule. In developing this Proposed Rule, it does not appear that the Department considered how patients denied care—especially those who already face barriers to access, those suffering from large healthcare disparities, or those who live in medically under-served areas—would be able to access the healthcare information and services they need and want. Instead, on its face, the Proposed Rule is specifically designed to expand the category of entities that can deny care to specific populations of people, especially women, LGBTQ people, gender nonconforming people, pregnant people, and the elderly, as well as the categories of care that can be denied. It is a reckless rule that privileges religion and moral convictions over standards of care, public health, and the lives of some of the most vulnerable, not only in the U.S. but also globally as the Proposed Rule also purports to reach global health programs.

As the Proposed Rule is discriminatory, violates multiple statues and the U.S. Constitution, ignores Congressional intent, and would create confusion while harming patients and the public, the Feminist Majority Foundation calls on the Department to withdraw the Proposed Rule in its entirety.

Thank you for your attention to these comments. If you have any questions or need any further information, please email gburroughs@feminist.org.

Sincerely,

Gaylynn Burroughs

Lagriburge.

Director of Policy and Research

29 Redden, supra note 21.

Exhibit 77



March 27, 2018

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

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

To Whom It May Concern:

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

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

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

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

GLBTQ Legal Advocates & Defenders | 30 Winter Street, STE 800 Boston, MA 02108

glad beg

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

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

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

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

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

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

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

Z Id.

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

⁴ Id.

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

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

For example, section (d) of the Church Amendments refers to circumstances when a person may refuse to participate in any part of a health service program or research activity that "would be contrary to his religious beliefs or moral convictions." Even though longstanding legal interpretation applies this section singularly to participation in abortion and sterilization procedures, the proposed rule does not make this limitation clear. This ambiguity can encourage an overly broad interpretation of the statute that empowers a provider to refuse to provide *any* health care service or information for a religious or moral reason—potentially including not just sterilization and abortion procedures, but also Pre-Exposure Prophylaxis (PrEP), infertility care, treatments related to gender dysphoria, and even HIV treatment. Some providers may try to claim even broader refusal abilities, as a recent analysis of complaints to HHS showed that transgender patients are most often discriminated against simply for being who they are rather than for the medical care they are seeking.⁵

Doctors may be misled into believing they may refuse on religious grounds to administer an HIV test or prescribe PrEP to a gay or bisexual man, or refuse screening for a urinary tract infection for a transgender man.⁶ In fact, medical staff may interpret the regulation to indicate that they can not only refuse, but decline to tell the patient where he would be able to obtain these lifesaving services or even inform patients of their treatment options. This puts the health of the patient, and potentially that of others, at risk. The regulation could lead a physician to refuse to provide fertility treatments to a same-sex couple, or a pharmacist to refuse to fill a prescription for hormone replacement therapy for a transgender customer. In addition, by unlawfully redefining the statutory term "assisting in the performance" of a procedure, the rule could encourage health care workers to obstruct or delay access to a health care service even when they have only a tangential connection to delivering that service, such as scheduling a procedure or running lab tests to monitor side-effects of a medication. The extension and broadening of this clause will impair LGBTQ patients' access to care services if interpreted—as the proposed rule improperly appears to do—to permit providers to choose patients based upon sexual orientation, gender identity, or family structure.

We are particularly concerned that the proposed rule will be used to refuse medically necessary care to transgender patients. We are concerned that the rule's sweeping terms and HHS's troubling discussions of a case involving a transgender patient will encourage the mistaken belief that treatments that have an incidental impact on fertility, such as some procedures used to treat gender dysphoria, are sterilization procedures. Treatments for serious medical conditions may have the incidental effect of causing or contributing to infertility: for example, a hysterectomy to treat gender dysphoria, chemotherapy to treat

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

⁶ https://www.americanprogress.org/issues/lght/reports/2018/03/07/447414/acas-lghtq-nondiscrimination-regulations-prove-crucial/

cancer, and a wide range of medications can have the incidental effect of temporarily or permanently causing infertility. The primary purpose of such procedures, however, is not to sterilize, but to treat an unrelated medical condition. If religious or moral exemptions related to sterilization are misinterpreted to include treatments that have simply an incidental effect on fertility—as the vague and sweeping language of this rule encourages—it can lead to refusals that go even further beyond what federal law allows and unlawfully encourages individuals and institutions to refuse a dangerously broad range of medically needed treatments.

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

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

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

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

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

The expanded religious exemptions in the proposed regulations also conflict with many patient protections in federal laws like the Affordable Care Act and the Emergency Medical Treatment and Active Labor Act. While protections under these laws are subject to religious exemptions provided under federal statute, they are not subject to exemptions whose scope goes beyond federal law—including many of the exemptions expanded in this rule. Additionally, the proposed regulation's approach to religious exemptions—which appears to allow for no limitations even when those exemptions unjustifiably harm patients or employers—conflict with the well-established standard under other federal laws, like Title VII of the Civil Rights Act. Title VII ensures that employers can consider the effect that providing a religious accommodation would have on coworkers, customers, and patients, as well as factors like public safety, public health, and other legal obligations. A standard that appears to allow for none of these considerations, and instead appears to require broad, automatic exemptions, would create confusion and undermine the federal government's ability to properly enforce federal laws.

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

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

The timing of the proposed rule also illustrates a lack of sufficient consideration. The proposed rule was published just two months after the close of a public comment period for a Request for Information closely related to this rule. The 12,000-plus public comments were not all posted until mid-December, a month before this proposed rule was released. Nearly all of the comments submitted at that time related to the subjects covered by the proposed rule—namely, the refusal of care by federally funded health care institutions or their employees on the basis of personal beliefs. This short period of time calls into question the comprehensiveness of the review of the Request for Information and whether the proposed rule was developed in an arbitrary and capricious manner.

Conclusion

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

Sincerely

Allison Wright, Esq.

GLBTQ Legal Advocates & Defenders

617-426-1350 x. 6961 awright@glad.org

Exhibit 78



March 27, 2018

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

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

To Whom it May Concern:

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

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

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

Health care providers refusing to touch them or using excessive precautions

1133 19th St., NW, Suite 302 | Washington, DC 20036 | 202-600-8037 | Fax: 202-478-1500 | info@glma.org | www.glma.org

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

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

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

These encounters with discrimination have serious negative consequences for the health and wellbeing of LGBT individuals. They also exacerbate the significant health disparities that affect the LGBT population at large. Sources such as the National Academy of Medicine³ (formerly the Institute of Medicine), the Centers for Disease Control and Prevention, and Healthy People 2020 report that discrimination threatens the health of the LGBT population in ways that include:⁴

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

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

² Sandy E. James et al., The Report of the 2015 US Transgender Survey (2016), available at http://www.transequality.org/sites/default/files/docs/usts/USTS%20Full%20Report%20-%20FINAL%201.6.17.pdf.
³ Institute of Medicine, The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding (2011), available at http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx.

U.S. Department of Health and Human Services, Healthy People 2020: LGBT Health Topic Area (2015), available at http://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health.
 Center for Disease Control and Prevention, Lesbian, Gay, Bisexual, and Transgender Health (2014), available at http://www.cdc.gov/lgbthealth/about.htm.

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

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

Fenway Institute, Promoting Cervical Cancer Screening Among Lesbians and Bisexual Women (2013), available at http://www.lgbthealtheducation.org/wp-content/uploads/Cahill PolicyFocus cervicalcancer web.pdf.

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

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

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

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

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

LGBT people, women, and other vulnerable groups around the country already face enormous barriers to getting the care they need. ¹⁰ Accessing quality, culturally competent care and overcoming outright discrimination is even a greater challenge for those living in areas with already limited access to health providers. The proposed regulation threatens to make access even harder and for some people nearly impossible.

Patients living in less densely populated areas already face a myriad of barriers to care including less access to health insurance coverage, lower incomes, and lower rates of paid sick leave. This is in addition to the universal costs of transportation, taking time from work, and other incidentals that go along with obtaining care in the first place. For many, the sheer distance to a healthcare facility can be a significant barrier to getting care. For example, more than half of

¹⁰ Institute of Medicine, The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding; Sandy E. James et al., The Report of the 2015 US Transgender Survey 93–126; Lambda Legal, When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV; Shabab Ahmed Mirza & Caitlin Rooney, Discrimination Prevents LGBTQ People from Accessing Health Care (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

rural women live more than 30 minutes away from a hospital that provides basic obstetric care.
Patients seeking more specialized care like that required for fertility treatments, endocrinology, or HIV treatment or prevention are often hours away from the closest facility offering these services. For example, a 2015 survey of nearly 28,000 transgender adults nationwide found that respondents needed to travel much further to seek care for gender dysphoria as for other kinds of care.

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

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

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

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

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¹¹ American College of Obstetrics and Gynecologists, *Health Disparities in Rural Women* (2014), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Disparities-in-Rural-Women#17.

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

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

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

Healthcare providers may be misled into believing they may refuse on religious grounds to administer an HIV test or an HIV prevention regimen to a gay or bisexual man, or refuse screening for a urinary tract infection for a transgender man. ¹⁵ In fact, medical staff may interpret the regulation to indicate that they can not only refuse, but decline to tell the patient where he would be able to obtain these lifesaving services or even inform patients of their treatment options. This puts the health of the patient, and potentially that of others, at risk. The regulation could lead a physician to refuse to provide fertility treatments to a same-sex couple, or a pharmacist to refuse to fill a prescription for hormone replacement therapy for a transgender customer. In addition, by unlawfully redefining the statutory term "assisting in the performance" of a procedure, the rule could encourage healthcare workers to obstruct or delay access to a healthcare service even when they have only a tangential connection to delivering that service, such as scheduling a procedure or running lab tests to monitor side-effects of a medication. The extension and broadening of this clause will impair LGBT patients' access to care services if interpreted—as the proposed rule improperly appears to do—to permit providers to choose patients based upon sexual orientation, gender identity, or family structure.

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

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

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

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

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

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

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

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

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

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

The expanded religious exemptions in the proposed regulations also conflict with many patient protections in federal laws like the Affordable Care Act and the Emergency Medical Treatment and Active Labor Act. While protections under these laws are subject to religious exemptions

provided under federal statute, they are not subject to exemptions whose scope goes beyond federal law—including many of the exemptions expanded in this rule. Additionally, the proposed regulation's approach to religious exemptions—which appears to allow for no limitations even when those exemptions unjustifiably harm patients or employers—conflict with the well-established standards under other federal laws, like Title VII of the Civil Rights Act. Title VII ensures that employers can consider the effect that providing a religious accommodation would have on coworkers, customers, and patients, as well as factors like public safety, public health, and other legal obligations. A standard that appears to allow for none of these considerations, and instead appears to require broad, automatic exemptions, would create confusion and undermine the federal government's ability to properly enforce federal laws.

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

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

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

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

The timing of the proposed rule also illustrates a lack of sufficient consideration. The proposed rule was published just two months after the close of a public comment period for a Request for Information closely related to this rule. The 12,000-plus public comments were not all posted

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

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

¹⁸ Id. at 3895.

until mid-December, a month before this proposed rule was released. Nearly all of the comments submitted at that time related to the subjects covered by the proposed rule—namely, the refusal of care by federally funded healthcare institutions or their employees on the basis of personal beliefs. This short period of time calls into question the comprehensiveness of the review of the Request for Information and whether the proposed rule was developed in an arbitrary and capricious manner.

Conclusion

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

Sincerely.

Gal Mayer, MD, MS

GLMA President

Hector Vargas, JD

GLMA Executive Director

Exhibit 79

GREATER NEW YORK HOSPITAL ASSOCIATION

555 WEST 57TH STREET, NEW YORK, NY 10019 • T (212) 246-7100 • F (212) 262-6350 • WWW.GNYHA.ORG • PRESIDENT, KENNETH E. RASKE

March 27, 2018

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

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

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

Dear Mr. Severino:

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

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

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



GNYHA is a dynamic, constantly evolving center for health care advocacy and expertise, but our core mission—helping hospitals deliver the finest patient care in the most cost-effective way—never changes.

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

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

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

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

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

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

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

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

^{[1] &}quot;The Limits of Conscientious Refusal in Reproductive Medicine," ACOG Committee Opinion, no. 385 (November 2007; reaffirmed 2016)

^[2] N. Berlinger, B. Jennings, S. Wolf, <u>The Hastings Center Guidelines for Decisions on Life Sustaining Treatment and Care Near the End of Life</u> (Oxford University Press, 2013), 17.
[3] Total

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

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

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

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

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

Comments on Specific Regulatory Proposals

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

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

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

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

^{[7] &}quot;EEOC Compliance Manual, Religious Discrimination, Section 12-I(A)(1)—Definition of Religion," (July 22, 2008). https://www.ccoc.gov/policy/docs/religion.html, (accessed March 26, 2018).

"Assist in the Performance"

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

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

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

"Discriminate" or "Discrimination"

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

Compliance Requirements

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

Enforcement Authority

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

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

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

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

Thank you for taking our comments into consideration.

Very Truly Yours,

KAFE PL

Kenneth E. Raske

President

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

Exhibit 83



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

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Executive Director Andrea Weddle, MSW March 27, 2018

Submitted via the Federal e-Rulemaking Portal

Roger Severino

Director, Office for Civil Rights

U.S. Department of Health and Human Services

200 Independence Avenue SW

Washington, DC 20201

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

Dear Mr. Severino:

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

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

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

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

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

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

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

- HIV Prevention: Among medical providers nationwide, lack of education on scientifically accurate and modern HIV prevention tools such as pre-exposure prophylaxis (PrEP) is already a barrier to accessing them for many people at risk of HIV infection. Health care providers should be required to follow widely accepted care standards including the CDC's clinical guidelines⁸ for use of PrEP. The proposed rule may mislead providers into believing that refusal to administer an HIV or STD test, offer sexual risk reduction counseling including recommending condom use, or prescribing PrEP to a gay or bisexual patient is allowable on religious grounds. No individual who seeks prevention or treatment services for any communicable disease should ever be refused treatment by a health care provider based on the provider's religious views.
- LGBTQ Transgender Care: LGBTQ individuals continue to face significant discrimination and stigma. Ensuring that this population has access to culturally competent and quality health care services is an essential part of addressing the HIV-related disparities faced by gay men and transgender individuals. ⁹ ¹⁰ Transgender women face the highest rates of HIV and low rates of health coverage in the U.S. ¹¹ In most jurisdictions, transgender patients are already denied gender-affirming and medically necessary care. Denying transgender people the gender-related medical care they need will lead to fear and distrust of health care providers and the health care system, leaving them even more vulnerable to HIV infection and less likely to be diagnosed and effectively managed with HIV treatment. Provider shortages in many areas will leave transgender individuals without viable alternatives for preventive and health care services.
- Women's Health Care: All women, including women living with HIV, have a right to
 reproductive health services including contraception and abortion. Granting health care
 providers and institutions the right to withhold medical information regarding prevention or
 treatment options or to deny women these services based on personal religious beliefs puts
 their health at risk. In addition, denial of contraceptive services to women with HIV could lead to
 an increase in the rate of perinatal HIV infection, which we seek to eliminate in the U.S.

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

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

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

Sincerely,

Melanie Thompson, MD Chair, Board of Directors

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

² 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.

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

⁴ American College of Obstetrics and Gynecologists, Health Disparities in Rural Women. 2014. https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Disparities-in-Rural-Women#17.

Senter for American Progress. 2016. Discrimination Prevents LGBTQ People from Accessing Health Care, https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

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

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

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

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

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

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

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

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

Exhibit 85



March 27, 2018

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

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

To Whom It May Concern:

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

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

Discrimination against LGBTQ People is Real and Causes Irreparable Harm.

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

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

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

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

HHS has Consistently Found LGBTQ People to be Vulnerable to Discrimination

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

¹ Lambda Legal, When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People ² Id

³ S.E. James, C. Brown, & I. Wilson, 2015 U.S. Transgender Survey, 97 (National Center for Transgender Equality 2017).

⁴ *Id.* at 98.

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

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

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

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

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

⁵ Healthy People 2020, *Disparities*, https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities (last visited Mar. 26, 2017).

⁶ Healthy People 2020, *About Healthy People*, https://www.healthypeople.gov/2020/About-Healthy-People (last visited Mar. 26, 2017).

Id.
 Disparities, https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities (last visited Mar. 26, 2017).

⁹ Eliseo J. Pérez-Stable, M.D., *Director's Message: Sexual and Gender Minorities Formally Designated as a Health Disparity Population for Research Purposes*, National Institute on Minority Health and Health Disparities (Oct. 6, 2016) https://www.nimhd.nih.gov/about/directors-corner/message.html.

¹¹ *Id*.

goes far beyond what longstanding legal tradition and public policy understanding have understood the statutes permit.

For example, section (d) of the Church Amendments refers to circumstances when a person may refuse to participate in any part of a health service program or research activity that "would be contrary to his religious beliefs or moral convictions." Even though longstanding legal interpretation has applied this section singularly to participation in abortion and sterilization procedures, the proposed rule does not make this limitation clear. This ambiguity can encourage an overly broad interpretation of the statute that empowers a provider to refuse to provide any health care service or information for a religious or moral reason—potentially including not just sterilization and abortion procedures, but also Pre-Exposure Prophylaxis (PrEP), infertility care, treatments related to gender dysphoria, and even HIV treatment. Some providers may try to claim even broader refusal abilities, as a recent analysis of complaints to HHS showed that transgender patients are most often discriminated against simply for being who they are rather than for the medical care they are seeking.¹³

Doctors may be misled into believing they may refuse to administer an HIV test or prescribe PrEP to a gay or bisexual man, or refuse screening for a urinary tract infection for a transgender man. 14 In fact, medical staff may interpret the regulation to indicate that they can not only refuse, but decline to tell the patient where he would be able to obtain these lifesaving services or even inform patients of their treatment options. This puts the health of the patient, and potentially that of others, at risk. The regulation could lead a physician to refuse to provide fertility treatments to a same-sex couple, or a pharmacist to refuse to fill a prescription for hormone replacement therapy for a transgender customer. In addition, by unlawfully redefining the statutory term "assisting in the performance" of a procedure, the rule could encourage health care workers to obstruct or delay access to a health care service even when they have only a tangential connection to delivering that service, such as scheduling a procedure or running lab tests to monitor side-effects of a medication. The extension and broadening of this clause will impair LGBTO patients' access to care services if interpreted—as the proposed rule improperly appears to do—to permit providers to choose patients based upon sexual orientation, gender identity, or family structure.

We are particularly concerned that the proposed rule will be used to refuse medically necessary care to transgender patients. We are concerned that the rule's sweeping terms and HHS's troubling discussions of a case involving a transgender patient will encourage the mistaken belief that treatments that have an incidental impact on fertility, such as some procedures used to treat

^{12 42} U.S. Code § 300a-7(d).

¹³ Sharita Gruberg and Frank J. Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial*, Center for American Progress (Mar. 7, 2018)

https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulationsprove-crucial/. ¹⁴ *Id*.

gender dysphoria, are sterilization procedures. Treatments for serious medical conditions may have the incidental effect of causing or contributing to infertility: for example, a hysterectomy to treat gender dysphoria, chemotherapy to treat cancer, and a wide range of medications can have the incidental effect of temporarily or permanently causing infertility. The primary purpose of such procedures, however, is not to sterilize, but to treat an unrelated medical condition. If religious or moral exemptions related to sterilization are misinterpreted to include treatments that have simply an incidental effect on fertility—as the vague and sweeping language of this rule encourages—it can lead to refusals that go even further beyond what federal law allows and unlawfully encourages individuals and institutions to refuse a dangerously broad range of medically needed treatments.

The Regulation Lacks Safeguards to Protect Patients from Harmful Refusals of Care.

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

The expanded religious exemptions in the proposed regulations also conflict with many patient protections in federal laws like the Affordable Care Act and the Emergency Medical Treatment and Active Labor Act. While protections under these laws are subject to religious exemptions provided under federal statute, they are not subject to exemptions whose scope goes beyond federal law—including many of the exemptions expanded in this rule. Additionally, the proposed regulation's approach to religious exemptions—which appears to allow for no limitations even when those exemptions unjustifiably harm patients or employers—conflict with the well-established standard under other federal laws, like Title VII of the Civil Rights Act.

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

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

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

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

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

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

¹⁵ Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e.

¹⁶ Letter in response to request for public comment from Reed L. Russell, Legal Counsel, EEOC, to Brenda Destro, Department of Health and Human Services (Sept. 24, 2008) https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii religious hhsprovider reg.html.

 $^{^{17}} Id$.

Department of Health and Human Services, *Mission Statement*, https://www.hhs.gov/about/strategic-plan/introduction/index.html (last visited Mar. 26, 2017).

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

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

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

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

¹⁹ Protecting Statutory Conscience Rights in Health Care, 83 Fed. Reg. 18, 3916 (proposed Jan. 26, 2018).

²⁰ Ancillary, Merriam-Webster.com. Accessed March 26, 2018. https://www.merriam-webster.com/dictionary/ancillary.

²¹ Protecting Statutory Conscience Rights in Health Care, 83 Fed. Reg. at 3917.

²² *Id.* at 3916.

Exhibit 87



March 27, 2018

VIA ELECTRONIC SUBMISSION

U.S. Department of Health and Human Services

Attn: Office for Civil Rights

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83

Fed. Reg. 3880 (Jan. 26, 2018); RIN 0945-ZA03

The Institute for Policy Integrity ("Policy Integrity") at New York University School of Law¹ respectfully submits the following comments to the Department of Health and Human Services ("HHS" or "the Department") regarding its proposed rule on statutory conscience protections in health care ("Proposed Rule").² Policy Integrity is a non-partisan think tank dedicated to improving the quality of government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy.

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

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

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

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

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

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

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

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

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

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

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

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

^{6 2011} Rule, 76 Fed. Reg. at 9973.

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

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

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

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

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

⁷ *Id.*

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

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

 $^{^{\}rm 10}$ 2011 Rule, 76 Fed. Reg. at 9973.

¹¹ *Id.*

¹² *Id.*

^{13 2008} Rule, 73 Fed. Reg. at 78,097.

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

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

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

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

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

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

^{15 2011} Rule, 76 Fed. Reg. at 9973-74.

¹⁶ Id. at 9973.

¹⁷ Id. at 9974.

¹⁸ E.O. 12,866 § 6(a)(3)(C)(ii).

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

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

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

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

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

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

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

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

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

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

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

HHS Fails to Consider Indirect Personnel Costs for Providers

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

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

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

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

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

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

- Immigrant Women: Recent immigrants may be less well informed on the availability
 of reproductive health care in the U.S., and therefore in greater need of the counselling
 and referral services that the Proposed Rule covers.
- Rural Women: Increasing the incidence of health care providers refusing to provide counseling or referrals may create a greater problem for women who live in rural areas than for women at large, due to the increased search and travel costs associated with finding an alternative provider in rural areas.
- Low-Income Women: Women with lower incomes have fewer resources available to allocate to transportation and child care. If refused counseling or referral services, these women may suffer greater costs when seeking alternative health care providers. The refusal may even result in an insurmountable obstacle to obtaining the health service sought.
- Women of Color: Women of color disproportionately earn lower incomes and live in underserved areas. If refused counseling or referrals, these women may experience greater burdens to seek alternative health care providers.

²³ E.O. 12,866 § 6(b)(5).

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

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

- LGBTQ Individuals: As discussed in Section I, the Proposed Rule, like the 2008 Rule, may lead health care workers to believe they can permissibly refuse to provide any type of medical service to gay or transgender individuals (or their families) based on moral or religious objections. Such refusals would decrease the quantity and quality of health care available to that population.
- Individuals with HIV/AIDS: Similarly, the Proposed Rule may lead health care workers to believe that they can permissibly refuse to provide any type of medical service to individuals with HIV/AIDS. Again, such refusals would decrease the quantity and quality of health care available to that population.
- Interracial/Interfaith Families: Finally, the Proposed Rule may lead health care
 workers to believe that they can permissibly refuse to provide any type of medical
 services to interracial or interfaith families because they morally object to such
 relationships. As with LGBTQ patients and HIV-positive patients, this misimpression
 could result in reduced access to health care for interracial and interfaith families.

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

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

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

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

²⁷ Id. at 3910.

²⁸ Id. at 3910, 3915.

²⁹ Id. at 3909-10.

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

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

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

Respectfully,

Michael Domanico Theodore Gifford Jack Lienke Jason A. Schwartz

³⁰ Id. at 3929.

³¹ Id. at 3910.

Exhibit 89



A BOLD AND INDEPENDENT VOICE FOR THE RIGHTS OF WOMEN AND GIRLS

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

Health care is a human right, and a health care provider's personal beliefs should never determine the care a patient receives. That is why the International Women's Health Coalition strongly opposes the Department of Health and Human Services' (the "Department") proposed rule ("Proposed Rule"). If enacted, this rule will effectively permit discrimination in all aspects of health care.

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

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

INTERNATIONAL WOMEN'S HEALTH COALITION

333 7th Avenue, 6th Floor New York, NY 10001

T (+1) 212.801.1272 F (+1) 212.979.9009

New York San Francisco Washington, DC

IWHC.org

involved in patient care to use their personal beliefs to deny people the care they need. For these reasons, the International Women's Health Coalition calls on the Department and OCR to withdraw the Proposed Rule in its entirety.

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

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

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

The Proposed Rule will exacerbate health inequities by expanding the ability to refuse critical services, including abortion and transition-related care. Specifically, the Department and OCR are attempting to require a broad swath of entities to allow individuals to refuse "any lawful health service or activity based on religious beliefs or moral convictions (emphasis added)."

Read in conjunction with the rest of the Proposed Rule, it is clear this is intended to allow any entity involved in a patient's care—from a hospital board of directors to the receptionist that schedules procedures—to use their personal beliefs to determine a patient's access to care.

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

Already existing refusal of care laws are used across the country to deny patients the care they need.² The Proposed Rule attempts to expand these laws in numerous ways that are directly contrary to the stated purpose of the existing laws. For example, one provision of the Church Amendments allows individuals who work for or with entities receiving grants or contracts for biomedical or behavioral research entities to refuse to participate in "any lawful health services or research activity" based on religious beliefs or moral convictions specifically related to the service or research activity to which they object.³ But the Proposed Rule attempts to broaden this provision to allow individuals to refuse to perform aspects of their jobs based on a mere

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/; Catherine Weiss, et al., Religious Refusals and Reproductive Rights, AM. CIVIL LIBERTIES UNION (2002), https://www.aclu.org/report/religious-refusals-and-reproductive-rights-report; Julia Kaye, et al., Health Care Denied, AM. CIVIL LIBERTIES UNION 1 (2016),

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

¹ See id. at 12.

³ The Church Amendments, 42 U.S.C. § 300a-7 (2018).

reference to a religious or moral belief regardless of whether it relates to the specific biomedical or behavioral service or research activity they are working on.⁴ Such an attempted expansion goes beyond what the statute enacted by Congress allows. Furthermore, the Proposed Rule would expansively apply other provisions of the Church Amendments to, among other things, individuals working under global health programs funded by the Department thereby allowing global health providers and entities to refuse individuals the care they need contrary to the very purpose of such programs.

Similarly, the Proposed Rule defines common phrases and words used throughout existing refusals of care laws and civil rights laws in ways that stretch their intended meaning beyond recognition. For example, the definition of "assist in the performance" greatly expands the types of services that can be refused to include merely "making arrangements for the procedure" no matter how tangential.⁵ This means individuals not "assisting in the performance" of a procedure within the ordinary meaning of the term, such as the hospital room scheduler, the technician charged with cleaning surgical instruments, and other hospital employees, can now assert a new right to refuse. The Proposed Rule's definition of "referral" similarly goes beyond any understanding of the term, allowing refusals to provide any information, including location or funding, that could help an individual to get the care they need.⁶

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

When these impermissibly broad definitions are combined with the expansive interpretations of the underlying statutes, they work together to further expand refusals of care to allow more individuals and entities to refuse to provide access to health care. For example, one way the Weldon Amendment is expanded under the Proposed Rule is through the definition of

⁴ See Rule supra note 1, at 185.

⁵ *Id.* at 180.

⁶ Id. at 183.

⁷ The Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009); Public Health Service Act, 42 U.S.C. § 238n (2018).

⁸ See Rule supra note 1, at 182.

⁹ The doctrine of expression unius est exclusion alterius (the expression of one thing implies the exclusion of others) as applied to statutory interpretation creates a presumption that when a statute designates certain persons, things, or manners of operation, all omissions should be understood as exclusions.

"discrimination." ¹⁰ In particular, the Proposed Rule defines "discrimination" against a health care entity broadly to include a number of activities, including denying a grant or employment as well as an unspecified catch-all phrase "any activity reasonably regarded as discrimination." ¹¹ In a Proposed Rule that seeks to protect those who want to discriminate, this broad definition is nonsensical and inappropriate. Further such a vague and inappropriate definition provides no functional guidance to entities on how to comply with the applicable requirements, thereby fostering confusion.

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

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

The refusal of sexual and reproductive health care, including abortion and contraception, hurts people who are denied the care that they want and need, and it particularly affects those who already face disadvantages and discrimination. A woman denied services might have no choice but to continue an unintended pregnancy. She may resort to a clandestine, unsafe abortion, with severe consequences for her health or even risk of death. She might be forced to seek out another provider, which can be costly in time and expense, or not even a possibility. All of these scenarios can cause health problems, mental anguish and economic hardship.

Across the country refusals of care based on personal beliefs have been invoked in countless ways to deny patients the care they need. One woman experiencing pregnancy complications rushed to the only hospital in her community, a religiously affiliated facility, where she was denied the miscarriage management she needed because the hospital objected to this care. Another woman experiencing pregnancy loss was denied care for ten days at a religiously affiliated hospital outside Chicago, Illinois. In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy. Another patient in Arkansas endured a number of dangerous pregnancy complications and could not risk becoming pregnant again. She requested a sterilization procedure at the time of her Cesarean delivery, but her Catholic hospital provider refused to give her the procedure. Another woman was sent home by a religiously affiliated hospital with

¹⁰ See Rule supra note 1, at 180.

¹¹ Id.

¹² See, e.g., supra note 3.

¹³ 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.

¹⁴ 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.

¹⁵ See Kira Shepherd, et al., Bearing Faith The Limits of Catholic Health Care for Women of Color, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 29 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

¹⁶ See The Patient Should Come First: Refusals to Provide Reproductive Health Care, NAT'L WOMEN'S L. CTR. (2017), https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/05/Refusals-FS.pdf; Sandhya

two Tylenol after her water broke at 18 weeks of pregnancy. Although she returned to the hospital twice in the following days, the hospital did not give her full information about her condition and treatment options.¹⁷

Globally, we see the same thing: for example, a woman in Spain learned late in her pregnancy that the fetus had an anomaly incompatible with life. She was unable to find anyone in her region who would terminate the pregnancy. The public health service declared that "in order to respect the professionals' right to objection on moral grounds," she would have to travel to Madrid. By the time she arrived at the clinic, she was bleeding heavily and had to go to a hospital for an emergency caesarean section to remove the fetus, which died soon after. They removed her uterus to stop the bleeding. She nearly died and is now unable to have any more children. Research into the experiences of women who face denial of abortion shows that they are more likely to face long term harm to their physical and psychological health, socioeconomic outcomes, and life trajectories.

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

Refusals of care based on personal beliefs already make it difficult for many individuals to access health care and have real consequences for those denied the care they need because of a provider or hospital's religious beliefs. When women and families are uninsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services or travel to another location, refusals bar access to necessary care. ¹⁸ This is especially true for immigrant patients who often lack access to transportation and may have to travel great distances to get the care they need. ¹⁹ In rural areas there may be no other sources of health and life preserving medical care. ²⁰ In developing countries where many health systems

Somashekhar, A Pregnant Woman Wanted her Tubes Tied. Her Catholic Hospital Said No., WASH. POST (Sept. 13, 2015), https://www.washingtonpost.com/national/a-pregnant-woman-wanted-her-tubes-tied-her-catholic-hospital-said-no/2015/09/13/bd2038ca-57ef-11e5-8bb1-b488d231bba2 story.html?utm_term=.8c022b364b75.

¹⁷ See Kira Shepherd, et al., Bearing Faith The Limits of Catholic Health Care for Women of Color, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 27 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

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

²⁰ Since 2010, eighty-three rural hospitals have closed. *See Rural Hospital Closures: January 2010 – Present*, THE CECIL G. SHEPS CTR FOR HEALTH SERVS. RES. (2018), http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.

are weak, health care options and supplies are often unavailable.21 When these individuals encounter refusals of care, they may have nowhere else to go.

This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals. For example, new research shows that women of color in many states disproportionately receive their care at Catholic hospitals. In nineteen states, women of color are more likely than white women to give birth in Catholic hospitals.²² These hospitals as well as many Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provides guidance on a wide range of hospital matters, including reproductive health care and can keep providers from offering the standard of care. 23 Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals, and as a result, women were delayed care or transferred to other facilities at great risk to their health.²⁴ The reach of this type of religious refusal of care is growing with the proliferation of both the types of entities using religious beliefs to discriminate and the number of religiously affiliated entities that provide health care and related services.²⁵

On an international level, refusals have the gravest consequences for women who are already the most vulnerable. In Uruguay, for example, the highest levels of refusal based on conscience claims - above 60 percent and even reaching 80 percent - are concentrated in the more remote areas of the west and the north, where access to services is already limited. In addition, in many of the countries where the Department implements global AIDS programs, many of the patients served already face numerous barriers to care, including a broad and harmful refusal provision contained within the statute governing such programs.²⁶

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

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

²¹ See Nurith Aizenman, Health Care Costs Push a Staggering Number of People into Extreme Poverty, NPR (Dec. 14, 2017), https://www.npr.org/sections/goatsandsoda/2017/12/14/569893722/health-care-costs-push-a-staggeringnumber-of-people-into-extreme-poverty; Tracking Universal Health Coverage: 2017 Global Monitoring Report, WORLD HEALTH ORG. & THE WORLD BANK (2017),

http://documents.worldbank.org/curated/en/640121513095868125/pdf/122029-WP-REVISED-PUBLIC.pdf. ²² See Kira Shepherd, et al., Bearing Faith The Limits of Catholic Health Care for Women of Color, PUB, RIGHTS PRIVATE CONSCIENCE PROJECT 1, 12 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gendersexuality/PRPCP/bearingfaith.pdf. ²³ See id. at 10-13.

²⁵ See, e.g., Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care, AM, CIVIL LIBERTIES UNION & MERGER WATCH (2013), https://www.aclu.org/files/assets/growth-of-catholichospitals-2013.pdf.

²⁶ See The Mexico City Policy: An Explainer, KAISER FAMILY FOUND. (June 1, 2017), https://www.kff.org/globalhealth-policy/fact-sheet/mexico-city-policy-explainer/.

LGBTQ people already face enormous barriers to getting the care they need.²⁷ Accessing quality, culturally competent care and overcoming outright discrimination is even a greater challenge for those living in areas with already limited access to health providers. The proposed regulation threatens to make access even harder and for some people nearly impossible.

LGBTQ 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 – in addition to the universal costs of transportation, taking time from work, and other incidentals. For many, the sheer distance to a healthcare facility can be a significant barrier to getting care. For example, more than half of rural women live more than 30 minutes away from a hospital that provides basic obstetric care.²⁸ Patients seeking more specialized care like that required for fertility treatments, endocrinology, or HIV treatment or prevention are often hours away from the closest facility offering these services. For example, a 2015 survey of nearly 28,000 transgender adults nationwide found that respondents needed to travel much further to seek care for gender dysphoria as for other kinds of care.²⁹

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

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

By expanding refusals of care the Proposed Rule will exacerbate the barriers to health care services patients need. It is evident that the harm caused by this Proposed Rule will fall hardest

²⁷ See, e.g., Institute of Medicine, The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding (2011), http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx; Sandy E. James et al., The Report of the U.S. Transgender Survey 93–126 (2016), www.ustranssurvey.org/report; Lambda Legal, When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV (2010), http://www.lambdalegal.org/publications/when-health-care-isnt-caring; Shabab Ahmed Mirza & Caitlin Rooney,

Discrimination Prevents LGBTQ People from Accessing Health Care (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-

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

²⁸ American College of Obstetrics and Gynecologists, Health Disparities in Rural Women (2014), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Disparities-in-Rural-Women#17.

²⁹ Sandy E. James et al., *The Report of the U.S. Transgender Survey* 99 (2016), www.ustranssurvey.org/report
³⁰ Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

on those most in need of care by allowing individuals and health care entities to use their personal beliefs to dictate patient care. The Department should remember, under Executive Order 13563, an agency may only propose regulations where it has made a reasoned determination that the benefits justify the costs and where the regulations are tailored "to impose the least burden on society."³¹ The Proposed Rule plainly fails on both counts. Although the Proposed Rule attempts to quantify the costs of compliance, it completely fails to address the costs and burdens to patients who may be denied care and who then may incur and experience even greater social and medical costs.³²

Moreover, the Establishment Clause of the First Amendment requires the government to adequately account for just these sorts of consequences when considering whether to grant religious exemptions and, in fact, bars granting an exemption when it would detrimentally affect any third party.³³ Because the Proposed Rule would cause substantial harm, including to patients, it would violate the Establishment Clause.³⁴

e. The Proposed Rule would violate international human rights standards, which do not recognize a right to conscience claims in health care and require states to guarantee access to services

International human rights standards, to date, do not require states to guarantee a right to "conscientious objection" for health care providers. On the contrary, human rights treaty monitoring bodies have called for limitations on the exercise of conscience claims, when states allow for such claims, in order to ensure that providers do not hinder access to services and thus infringe on the rights of others. They call out states' insufficient regulation of the use of "conscientious objection," and in most cases, direct states to take steps to guarantee access to services. They also affirm clearly that claims of "conscientious objection" must never be exercised by institutions.

The European human rights systems have repeatedly stated that if domestic law allows health care providers to refuse to provide legal reproductive health services on grounds of conscience, states must ensure that they do not hinder access to care and must put mechanisms in place to

³¹ Improving Regulation and Regulatory Review, Executive Order 13563 (Jan. 18, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review.

 ³² See Rule supra note 1, at 94-177.
 ³³ U.S. Const. amend. I; Cutter v. Wilkinson, 554 U.S. 709, 720, 722 (2005) (to comply with the Establishment

Clause, courts "must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries" and must ensure that the accommodation is "measured so that it does not override other significant interests") (citing *Estate of Thornton v. Caldor*, 472 U.S. 703, 710 (1985)); *see also Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).

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

guarantee access to lawful services. Two bodies of the European human rights system have each heard three cases related to the exercise of "conscientious objection" and neither has recognized it as right in the case of health care.

For example, in the 2012 case of P and S v. Poland, a 14-year-old victim of rape was denied emergency contraception, despite reporting to the police the next day and having an examination at a health clinic, as required by law. She became pregnant as a result of the rape, but encountered numerous barriers to obtaining a lawful abortion, in part due to the use of "conscientious objection." She was subjected to coercive and biased counseling by a priest and was removed from the custody of her mother, who supported her decision to have an abortion. She also discovered that confidential information about her pregnancy had been divulged to the press. Eventually, she was able to have the abortion, but clandestinely, far from her home, and without proper post-abortion care. In this and another case from Poland, the European Court of Human Rights ("the Court"), found the practice of conscientious refusal to be in violation of the European Convention on Human Rights. It determined that Poland – by obstructing access to lawful reproductive health care information and services – had violated the individuals' right to be free from inhuman and degrading treatment, and the right to privacy. Furthermore, for the first time, the Court recognized that states have an obligation under the Convention to regulate the exercise of "conscientious objection," in order to guarantee patients access to lawful reproductive health care services.

In the 2001 Pichon and Sajous v. France case of two French pharmacists who refused to sell contraceptives, the Court decided that the right to freedom of religion does not entitle someone to follow their individual beliefs in the public sphere, especially in a situation such as this, where the product cannot be purchased other than in a pharmacy.

The European Committee on Social Rights ("the Committee"), also part of the European human rights systems, has ruled similarly as the Court, but gone a step further to say international human rights obligations—specifically the right to health, which the Charter guarantees—do not give rise to an entitlement to refuse to provide health services. In a collective complaint case, FAFCE v. Sweden, the Federation of Catholic Families in Europe (FAFCE) argued that Sweden had failed to protect the right to health, asserting that the guarantee to claim "conscientious objection" is necessary to promote the health of health care workers. They also argued that Sweden was violating the rights of health care workers' to non-discrimination, because the government had not established a regulatory framework allowing them to refuse to provide abortion services on grounds of conscience. Under Swedish law, health care providers have a duty to provide abortions; although health care institutions may choose to exempt an employee from performing abortions, exemption is not an entitlement.

The Committee found that under the Charter, neither the right to health nor the right to non-discrimination entitles health professionals to refuse to perform abortion services on grounds of personal conscience. The Committee stated that the purpose of the right to health is to guarantee individuals' access to adequate health care, not to protect the interests of health care

providers. When it comes to reproductive health care, the Committee said that the primary rights holders under the Charter are women, not their doctors.

Importantly, the Committee also went on to underscore that the Charter, "does not impose on states a positive obligation to provide a right to conscientious objection for health care workers." This is the most explicit finding yet that international human rights standards do not give rise to an entitlement to refuse health services on grounds of conscience.

In another important 2014 case, IPPF EN v. Italy, the Committee determined that the government of Italy was violating the rights to health and to nondiscrimination of women. The shortage of providers due to refusals based on conscience forced women to wait long periods or travel long distances, placing an undue burden, especially on those with fewer resources. The Committee upheld this judgment in another case in 2016, finding that the government of Italy had failed to rectify this situation.

Unlike the European Court of Human Rights, the Inter-American Court of Human Rights (IACHR has not yet had the opportunity to rule on conscience claims in health care contexts. Given the lack of rulings on the issue in the Inter-American system to date, the Inter-American Commission on Human Rights uses the standards established by the decisions from the Colombian Constitutional Court, which limited the use of conscience to refuse services. In 2006, the Colombian Constitutional Court partially decriminalized abortion. In 2008, the Court clarified the law with a ruling on the case of a 13-year-old girl who was refused an abortion by a health facility and subsequently was forced to complete her pregnancy resulting from rape. The Court tightened limitations on the use of "conscientious objection," importantly stating that the law does not permit institutional objection to abortion. They also restricted conscience claims to the individual directly involved with the procedure, which would not include administrative staff, and required the provider refusing care to make a written statement. Notably, the Court fined the health facility that denied this girl an abortion, also mandating that they provide compensation to her.

In 2014, the African Commission on Human and Peoples' Rights ("the African Commission"), charged with protecting and promoting the Maputo Protocol (Africa's main legal instrument for the protection of women and girls' rights), issued general comment number 2 on article 14. The general comment brings specific attention to conscience claims, saying "state parties should particularly ensure that health services and health care providers do not deny women access to contraception/family planning and safe abortion information and services because of, for example, requirements of third parties or for reasons of conscientious objection."

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

The Proposed Rule would seemingly allow health care entities to receive grants and contracts under HHS-funded programs or other federal health programs, such as Title X, the only domestic family planning program, while refusing to provide key services required by those

programs.³⁵ For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling³⁶ and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.³⁷ Under the Proposed Rule, the Department would seemingly allow entities to apply for and receive federal funds while exempting them from the core legal and programmatic duties upon which such funds are generally conditioned.³⁸ The Proposed Rule creates uncertainty about whether Title X grantees may ensure that the subrecipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. Such actions are particularly concerning in the context of federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for low-income populations.³⁹ When it comes to Title X, the Proposed Rule would not only sanction conduct at odds with pre-existing legal requirements, but could also undermine the program's fundamental objectives. Every year millions of low-income, including under-insured, and uninsured individuals, rely on Title X clinics to access services they otherwise might not be able to afford.⁴⁰

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

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

The Proposed Rule threatens informed consent, a necessary principle of patient-centered decision-making intended to help balance the power dynamics between health providers and patients and ensure patient-centered decision-making.⁴² Informed consent requires providers disclose relevant and medically accurate information about treatment choices and alternatives

³⁵ See Rule supra note 1, at 180-181, 183. See also Title X Family Planning, U.S. DEP'T OF HEALTH & HUMAN SERVS. (2018), https://www.hhs.gov/opa/title-x-family-planning/index.html; Title X an Introduction to the Nation's Family Planning Program, NAT'L FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOC. (2017) (hereinafter NFPRHA), https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf.

³⁶ See, e.g., Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).

³⁷ See What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).

³⁸ See, e.g., Rule supra note 1, at 180-185.

³⁹ See NFPRHA supra note 34.

⁴⁰ See id.

⁴¹ 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.

⁴² See Tom Beauchamp & James Childress, Principles of Biomedical Ethics (4th ed. 1994); Charles Lidz et Al., Informed Consent: A Study of Decisionmaking in Psychiatry (1984).

so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether. ⁴³ By allowing providers, including hospital and health care institutions, to refuse to provide patients with information, the Proposed Rule makes it impossible for patients to have full information regarding treatment options. While the Department claims the Proposed Rule improves communication between patients and providers, in truth it will deter open, honest conversations that are vital to ensuring that a patient can control their medical circumstances. ⁴⁴

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

Specifically, medical ethics guidelines require providers to prioritize patient care over conscience claims. Current guidelines by the International Federation of Gynecology and Obstetrics (FIGO) state that a doctor objecting to abortion based on conscience "has an obligation to refer the woman to a colleague who is not in principle opposed to termination." The current World Health Organization (WHO) safe abortion guidance further stipulates that the referral must be to someone in the same or another easily accessible health care facility. If a referral is not possible, the objecting provider is obligated to provide safe abortion to save the woman's life and to prevent risks to her health. Any woman who presents with complications due to abortion must receive treatment with urgency and respect, as with any other emergency case.

⁴³ See id.

⁴⁴ See Rule supra note 1, at 150-151.

⁴⁵ For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care. Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant. Am. DIABETES ASS'N, STANDARDS OF MEDICAL CARE IN DIABETES-2017, 40 DIABETES CARE § 114-15, S117 (2017), available at

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

Health care providers or institutions that claim personal or religious beliefs to justify refusal of services undermine the objectives of their profession, which is to provide health care to all those who need it. Furthermore, providers represent a monopoly, because they offer a sought-after, specialized, and finite service. Patients are the weaker party in this situation and providers prioritizing their own consciences over the needs and rights of those they are supposed to serve shifts even more power into their hands. The more marginalized the person seeking services, the more likely they will face difficulty overcoming the power imbalance to demand and access the services they need.

In the case of the refusal of health care based on conscience claims, others pay the price. The most severely affected is, of course, the person denied care. But that is not all. Health care providers or institutions that refuse to deliver a service also increase the workloads of their peers who choose to uphold their professional obligations to deliver comprehensive sexual and reproductive health care. It also causes costly disruptions and inefficiencies in the health care system. Precious resources go to making adjustments for those who refuse to provide care. In addition to the direct costs of making accommodations, allowing providers to refuse care can distort resource allocation and create costly inefficiencies in health care systems that often are already strained.

In addition, the Proposed Rule ignores the many providers with deeply held moral convictions that affirmatively motivate them to provide patients with health care, including abortion, transition-related care, and end-of-life care. Moreover, the Proposed Rule fails to acknowledge the Church Amendments' protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce. 46 No health care professional should face discrimination from their employer because they treated or provided information to a patient seeking an abortion.

The Department is Abdicating its Responsibility to Patients

The Proposed Rule exceeds OCR's authority by abandoning OCR's mission to address health disparities and discrimination that harms patients. 47 Instead, the Proposed Rule appropriates language from civil rights statutes and regulations that were intended to improve access to health care and applies that language to situations for which it was not intended. By taking the language of civil rights laws and regulations out of context, the Proposed Rule creates a regulatory scheme that is not only nonsensical but is affirmatively harmful. For example, the notice and certification of compliance and assurance requirements simply do not make sense when applied to the laws the Proposed Rule seeks to enforce. 48 They will place a significant and

⁴⁶ See The Church Amendments, 42 U.S.C. § 300a-7(c) (2018).

⁴⁷ OCR's Mission and Vision, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/ocr/about-us/leadership/mission-and-vision/index.html ("The mission of the Office for Civil Rights is to improve the health and well-being of people across the nation; to ensure that people have equal access to and the opportunity to participate in and receive services from HHS programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").

⁴⁸ See Rule supra note 1, at 203-214.

burdensome requirement on health care providers and impose unique challenges for those working in other countries by taking resources away from patient care without adding any benefit.

The Department, including OCR, has an important role to play in ensuring equal opportunity to access health care and ending discriminatory practices that contribute to poor health outcomes and health disparities. ⁴⁹ If finalized, however, the Proposed Rule will represent a radical departure from the Department's mission to combat discrimination, protect patient access to care, and eliminate health disparities. Through robust enforcement of civil rights laws, OCR has worked to reduce discrimination in health care by ending overtly discriminatory practices such as race segregation in health care facilities, segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things. ⁵⁰

Nevertheless, there is still work to be done, and the Proposed Rule seeks to divert limited resources away from ending discrimination. De facto segregation, for example, continues to contribute to poorer health outcomes for Black people. According to one study, over half of the racial disparity in survival for heart attack patients can be attributed to the lower performance of hospitals that serve predominantly people of color.⁵¹ And these disparities do not occur in isolation. Black women, for example, are three to four times more likely than white women to die during or after childbirth.⁵² Further, the disparity in maternal mortality is growing rather than decreasing.⁵³ which in part may be due to the reality that women have long been the subject of

⁴⁹ As one of its first official acts in 1967, the Office of Equal Health Opportunity undertook the massive effort of inspecting 3,000 hospitals to ensure they were complying with Title VI's prohibition against discrimination on the basis of race, color, or national origin. 42. U.S.C. § 2000d (1964). After this auspicious start, the Office of Equal Health Opportunity which would eventually become OCR would go on to ensure that health programs and activities it regulated complied with key anti-discrimination laws including Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 (1973), Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 (1972), the Age Discrimination Act of 1976, 42 U.S.C. § 6101 (1976), and Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116 (2010), among others. Through robust enforcement of these laws, OCR has worked to reduce discrimination in health care.

⁵⁰ See, e.g., Serving People with Disabilities in the Most Integrated Setting: Community Living and Olmstead, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/community-living-and-olmstead/index.html; Protecting the Civil Rights and Health Information Privacy Rights of People Living with HIV/AIDS, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/hiv/index.html; National Origin Discrimination, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/health-disparities/index.html.

⁵¹ See Skinner et al., Mortality after Acute Myocardial Infarction in Hospitals that Disproportionately Treat African-Americans, NAT'L INSTIT. OF HEALTH 1 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1626584/pdf/nihms13060.pdf.

⁵² 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-dving-after-giving-birth-shalon-irvings-story-explains-why.

⁵³ See id.

discrimination in health care and the resulting health disparities. For example, women's pain is routinely undertreated and often dismissed.⁵⁴ And due to gender biases and disparities in research, doctors often offer women less aggressive treatment, or even no treatment, for conditions such as heart disease.⁵⁵ Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.⁵⁶ Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a doctor or other health care provider had refused to see them because of their actual or perceived sexual orientation or gender identity in the year before the survey.⁵⁷

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

The Proposed Rule Conflicts with Other Existing Federal Law

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

For example, the Proposed Rule makes no mention of Title VII,⁵⁹ the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.⁶⁰ With respect to religion, Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer.⁶¹ For decades, Title VII has established the legal framework for religious accommodations in the

⁵⁴ See, e.g., Diane E. Hoffmann & Anita J. Tarzian, The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain, 29:1 J. OF L., MED., & ETHICS 13, 13-27 (2001).

⁵⁵ See, e.g., Judith H. Lichtman et al., Symptom Recognition and Healthcare Experiences of Young Women with Acute Myocardial Infarction, 10 J. of the Am. Heart Ass'n 1 (2015).

⁵⁶ See, e.g., When Health Care Isn't Caring, LAMBDA LEGAL 5 (2010),

https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring_1.pdf. A survey examining discrimination against LGBTQ people in health care more than half of respondents reported that they have experienced at least one of the following types of discrimination in care: being refused needed care; health care professionals refusing to touch them or using excessive precautions; health care professionals using harsh or abusive language; being blamed for their health care status; or health care professionals being physically rough or abusive.

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

⁵⁸ See supra note 46.

^{59 42} U.S.C. § 2000e-2 (1964).

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

⁶¹ See id.

workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on patients, coworkers, public safety, and other legal obligations. The Proposed Rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both. Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.⁶²

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

In addition, the Proposed Rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person to another facility. ⁶⁴ Under EMTALA every hospital is required to comply – even those that are religiously affiliated. ⁶⁵ Because the Proposed Rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

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

⁶² Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), available at https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii religious hhsprovider reg.html.

⁶³ See Rule supra note 1, at 180-181.

^{64 42} U.S.C. § 1295dd(a)-(c) (2003).

⁶⁵ In order to effectuate the important legislative purpose, institutions claiming a religious or moral objection to treatment must comply with EMTALA, and courts agree. *See, e.g., Shelton v. University of Medicine and Dentistry of New Jersey*, 223 F.3d 220, 228 (3rd Cir. 2000); In In re Baby K, 16 F.3d 590, 597 (4th Cir. 1994); *Nonsen v. Medical Staffing Network, Inc.* 2006 WL 1529664 (W.D. Wis.); *Grant v. Fairview Hosp.*, 2004 WL 326694, 93 Fair Empl. Prac. Cas. (BNA) 685 (D. Minn. 2006); *Brownfield v. Daniel Freeman Marina Hosp.*, 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); *Barris v. County of Los Angeles*, 972 P.2d 966, 972 (Cal. 1999).

The Proposed Rule will have a chilling effect on the enforcement of and passage of state laws that protect access to health care and prevent discrimination against individuals seeking medical care. The preamble of the Proposed Rule discusses at length state laws that the Department finds objectionable, such as state laws that require anti-abortion counseling centers to provide information about where reproductive health care services can be obtained or whether facilities have licensed medical staff, as well as state laws that require health insurance plans to cover abortion. Moreover, the Proposed Rule invites states to further expand refusals of care by making clear that this expansive rule is a floor, and not a ceiling, for religious exemption laws.

Conclusion

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

Sincerely,

Nina Besser Doorley

Senior Program Officer

⁶⁶ See, e.g., Rule, Supra note 1, at 3888-89.

⁶⁷ See id.

Exhibit 91

Jacobs Institute of Women's Health

THE GEORGE WASHINGTON UNIVERSITY

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

The Jacobs Institute of Women's Health appreciates the opportunity to comment on the proposed rule "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority." The Jacobs Institute of Women's Health's mission is to identify and study aspects of healthcare and public health, including legal and policy issues, that affect women's health at different life stages; to foster awareness of and facilitate dialogue around issues that affect women's health; and to promote interdisciplinary research, coordination, and information dissemination, including publishing the peer-reviewed journal Women's Health Issues.

We urge you to withdraw this rule due to the harm it will cause the patient-provider relationship and the quality of patient care. Its impact on women and LGBTQ individuals will be particularly detrimental, and it will exacerbate the disparities already affecting those who face discrimination and limited access to care. The rule's broad definitions invite a wide range of individuals and organizations to deny appropriate care to patients.

Threats to Informed Consent and Standards of Care

Informed consent is a core tenet of healthcare, and requires that patients be fully informed of all options and their risks and benefits. A provider who fails to describe a medically appropriate option based on a personal objection to it prevents a patient from being fully informed – yet that is exactly what this rule would invite. Failure to assure informed consent has characterized shameful episodes in this country's history, including the forced or coerced sterilization of thousands of low-income women of color.¹

https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf

Milken Institute of Public Health 950 New Hampshire Ave. NW, 6th Floor Washington, DC 20052 202-994-0034 whieditor@gwu.edu

¹ Shepherd K, Platt ER, Franke K, Boylan E. (2018). Bearing Faith: The Limits of Catholic Health Care for Women of Color. Public Rights, Private Conscience Project. Available:

The proposed rule also disregards standards of care established by the medical community by allowing providers to opt out of providing medical care. Medical practice guidelines and standards of care establish the boundaries of medical services that patients can expect to receive and that providers should be expected to deliver. Yet, the proposed rule seeks to allow providers and institutions to ignore the standards of care, particularly surrounding reproductive and sexual health.

Research into services provided or withheld at Catholic hospitals demonstrates the kinds of impacts patients can suffer when their providers fail to uphold the standard of care. The Ethical and Religious Directives (ERDs) that Catholic-affiliated hospitals must follow effectively prohibit the provision of some forms of contraception and some treatments for miscarriages and ectopic pregnancies. Interviews with obstetrician-gynecologists working in Catholic-owned hospitals revealed that they could not provide the standard of care for managing miscarriages (uterine evacuation) when fetal heart tones were present; as a result, women's medically indicated care was delayed and their health placed at risk.² A study conducted by Ibis Reproductive Health in emergency rooms of Catholic hospitals in 2002 found more than half would not dispense emergency contraception under any circumstances, even if a woman had been sexually assaulted.³

In addition, the proposed rule ignores the many providers with deeply held moral convictions that affirmatively motivate them to provide patients with health care, including abortion, transition-related care, and end-of-life care.⁴

Exacerbating Existing Disparities

Allowing healthcare providers and their staff to refuse to provide certain types of healthcare will exacerbate existing health disparities. Women of color, LGBTQ individuals, and rural residents are already at greater risk of several poor health outcomes, and will see their options for comprehensive medical care further constrained if this rule is finalized.

In many states, women of color disproportionately receive their care at Catholic hospitals. A recent analysis from authors at Columbia Law School found that in 19 states, women of color are more likely than white women to give birth at Catholic hospitals. They are then less likely to have access to postpartum tubal ligations or insertion of long-acting contraception (LARC). Policies that impede women's access to postpartum LARC or sterilization contribute to unwanted rapid repeat pregnancies,

² Freedman LR, Landy U, Steinauer J. (2008). When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals. *American Journal of Public Health*, 98(10): 1774-1778.

³ Harrison T. Availability of Emergency Contraception: A Survey of Hospital Emergency Department Staff. (2002). *Annals of Emergency Medicine*, 46(2): 105-110.

⁴ Fernandez Lynch H & Stahl RY. (2018). Protecting Conscientious Providers of Health Care. *The New York Times*. Available: https://www.nytimes.com/2018/01/26/opinion/protecting-conscientious-providers-of-health-care.html

^{5,6} which place women and their children at higher risk of poor outcomes. Given that the maternal mortality rate for black women is more than three times the rate for white women, ⁷ improving the quality of maternal healthcare that black women receive – including provision of any FDA-approved form of contraception they select – should be a priority. Broadening providers' ability to refuse to provide certain forms of care will further reduce access to interventions that women desire and that can improve their health outcomes.

In a recent study, nearly one in five LGBTQ people, including 31% of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away. That rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider. For these patients, being turned away by a medical provider is not just an inconvenience: it often means being denied care entirely with nowhere else to go. Some providers may try to claim even broader refusal abilities, as a recent analysis of complaints to HHS showed that transgender patients are most often discriminated against simply for being who they are rather than for the medical care they are seeking. 9

Rural residents may find it especially difficult to locate an alternative provider if their nearest provider refuses to provide the care they seek. For instance, more than half of rural women live more than 30 minutes from hospital providing basic obstetrics care; ¹⁰ finding a second provider will require even more travel and care delay.

Expansive Definitions Allow Extensive Discrimination

Broad definitions of several key terms in the proposed rule raise the possibility of widespread refusals by many individuals, leading to chaotic environments in which all patients' care suffers. For example, the definition of "assist in the performance" greatly expands the types of services that can be refused to

⁵ Potter JE, Hubert C, Stevenson AJ, Hopkins K, Aiken ARA, White K, Grossman D. (2016). Barriers to Postpartum Contraception in Texas and Pregnancy within 2 Years of Delivery. *Obstetrics & Gynecology*, 127(2): 289-296.

⁶ Folit-Weinberg S, Harney C, Dude A, Haider S. (2014). Have we failed them? Rapid repeat pregnancy rates and contraceptive methods in a highly motivated population. *Contraception*, 90(3): 327.

⁷ Louis JM, Menard KM, Gee RE. (2015). Racial and Ethnic Disparities in Maternal Morbidity and Mortality. *Obstetrics & Gynecology*, 125(3): 690-694.

⁸ Mirza SA & Rooney C. (2016). Discrimination Prevents LGBTQ People from Accessing Health Care. Center for American Progress. Available:

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

⁹ Gruberg S & Bewkes F. The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial. Center for American Progress. Available: https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/

¹⁰ American College of Obstetricians & Gynecologists, Committee on Health Care for Underserved Women. (2014). Health Disparities for Rural Women, Committee Opinion Number 586. Available: https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Disparities-in-Rural-Women#17

include merely "making arrangements for the procedure" no matter how tangential. This means individuals not "assisting in the performance" of a procedure within the ordinary meaning of the term, such as the hospital room scheduler, the technician charged with cleaning surgical instruments, and other hospital employees, can now assert a new right to refuse. The Proposed Rule's definition of "referral" similarly goes beyond any understanding of the term, allowing refusals to provide any information, including location or funding, that could help an individual to get the care they need.

Harmful Impact on Title X Program

The proposed rule would seemingly allow health care entities to receive grants and contracts under HHS-funded programs or other federal health programs, such as Title X, the only domestic family planning program, while refusing to provide key services required by those programs. For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling¹¹ and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination. 12 Under the Proposed Rule, the Department would seemingly allow entities to apply for and receive federal funds while exempting them from the core legal and programmatic duties upon which such funds are generally conditioned. The proposed rule creates uncertainty about whether Title X grantees may ensure that the subrecipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. Such actions are particularly concerning in the context of federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for low-income populations.¹³ When it comes to Title X, the proposed rule would not only sanction conduct at odds with pre-existing legal requirements, but could also undermine the program's fundamental objectives. Every year millions of low-income, including under-insured, and uninsured individuals rely on Title X clinics to access services they otherwise might not be able to afford. 13

Lack of Safeguards

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. It includes no limitations to its sweeping exemptions that would protect patients' rights under the law and ensures that they receive medically warranted treatment. Any extension of religious accommodation should always be accompanied by equally extensive protections for patients to ensure that their medical needs remain paramount, and that they are able to receive both accurate information and quality health services.

¹¹ Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).

¹² What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).

¹³ National Family Planning and Reproductive Health Association. (2017). Title X: An Introduction to the Nation's Family Planning Program. Available: https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf

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

The expanded religious exemptions in the proposed regulations also conflict with many patient protections in federal laws like the Affordable Care Act and the Emergency Medical Treatment and Active Labor Act. While protections under these laws are subject to religious exemptions provided under federal statute, they are not subject to exemptions whose scope goes beyond federal law—including many of the exemptions expanded in this rule. Additionally, the proposed regulation's approach to religious exemptions—which appears to allow for no limitations even when those exemptions unjustifiably harm patients or employers—conflict with the well-established standard under other federal laws, like Title VII of the Civil Rights Act. Title VII ensures that employers can consider the effect that providing a religious accommodation would have on coworkers, customers, and patients, as well as factors like public safety, public health, and other legal obligations. A standard that appears to allow for none of these considerations, and instead appears to require broad, automatic exemptions, would create confusion and undermine the federal government's ability to properly enforce federal laws.

Withdrawal is Warranted

The Jacobs Institute of Women's Health urges withdrawal of this proposed rule because it would result in fewer options, worse health outcomes, and wider health disparities, with particularly harmful impacts on women's access to contraception and abortion and on multiple forms of healthcare for LGBTQ individuals and rural residents.

Thank you for this opportunity to comment in response to the proposed rule, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority." If you have any questions or concerns about our recommendations, please contact Jacobs Institute managing director Liz Borkowski at 202-994-0034 or borkowsk@gwu.edu.

Exhibit 94



March 27, 2018

Submitted electronically via regulations.gov

U.S. Department of Health & Human Services Office for Civil Rights Hubert H. Humphrey Building 200 Independence Avenue SW Washington, DC 20201

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority Notice of Proposed Rule Making (RIN 0945-ZA03; Docket No. HHS-OCR-2018-0002)

Justice in Aging appreciates the opportunity to respond to the Department of Health and Human Services (HHS) Notice of Proposed Rule Making entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority." For the reasons below, we strongly urge HHS not to finalize the proposed rule. This submission supplements the comments of the Leadership Conference on Civil and Human Rights, which we also support.

Justice in Aging is an advocacy organization with the mission of improving the lives of low-income older adults. We use the power of law to fight senior poverty by securing access to affordable health care, economic security and the courts for older adults with limited resources. We have decades of experience with Medicare and Medicaid, with a focus on the needs of low-income beneficiaries and populations that have traditionally lacked legal protection such as women, people of color, LGBTQ individuals, and people with limited English proficiency.

Ensuring that all consumers are protected from discrimination in health care is integral to the mission of the HHS Office for Civil Rights (OCR). This mission cannot be carried out without also ensuring that providers, whatever their religious beliefs or moral convictions, adhere to nondiscrimination laws and the medical and health-related standard of care. The proposed rule would greatly expand current "conscience" protections and religious refusals, and we are deeply concerned that it would allow employees in health care settings to discriminate against and deny care to older adults and people with disabilities. Existing law already provides ample protection for health care providers to refuse to participate in a health care service to which they have religious or moral objections. As proposed, the rule will harm consumers by increasing barriers to care, allowing health care professionals to ignore established medical guidelines, and undermining open communication between providers and patients.

WASHINGTON

1444 Eye Street, NW, Suite 1100 Washington, DC 20005 202-289-6976

LOS ANGELES

3660 Wilshire Boulevard, Suite 718 Los Angeles, CA 90010 213-639-0930

OAKLAND

1330 Broadway, Suite 525 Oakland, CA 94612 510-663-1055 The proposed rule's expansion of conscience protections and religious refusals could seriously compromise the health, autonomy, and well-being of older adults and people with disabilities.

The extremely broad language proposed in the rule would allow any individual or entity with an "articulable connection" to a service, referral, or counseling described in the relevant statutory language to deny assistance due to a moral or religious objection. The rule's definitions could both undermine nondiscrimination laws that are meant to protect consumers and even foster health care settings and interactions between patients and providers that are informed by bias instead of medically accurate, evidence-based, person-centered care. This would seriously jeopardize the health, autonomy, and well-being of older adults and people with disabilities.

We are concerned that the rule's proposed definitions and applicability, which HHS repeatedly states are meant to be "broadly defined" and "illustrative, not exhaustive," could allow any member of the health care workforce to refuse to serve a patient in any way. Under the proposed rule's definitions, any individual who is a member of an entity's workforce could refuse to assist in the performance of any services or activities that have any "articulable connection" to a procedure they object to. This includes "volunteers, trainees or other members or agents of a covered entity, broadly defined when the conduct of the person is under the control of such entity." Also, the definition of "referral" would allow an entity to refuse to provide any information distributed by any method, including online or print, regarding any service, procedure, or activity if that information would lead to a service, activity, or procedure that the entity objects to.

The proposed rule does not articulate a definition of moral beliefs. This opens the door to a provider's own prejudices serving as the basis of denying services or care based on an individual's characteristics. For example, could a nurse assistant refuse to serve lunch to a transgender patient? Could office staff refuse to schedule an appointment for a person whom they believe to be from another country or who does not speak English well?

II. The expansion of religious refusals under the proposed rule is contrary to the mission of HHS and OCR and would disproportionately harm communities that already lack access to care

HHS OCR has worked for decades to ensure that the health programs and activities it regulated comply with vital nondiscrimination laws, including Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, Section 504 of the Rehabilitation Act of 1973, and Section 1557 of the Affordable Care Act (ACA). HHS has enforced these laws by ending overtly discriminatory practices such as race segregation and segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for gender transition related services, and insurance benefit designs that

JUSTICE IN AGING

¹⁸³ Fed. Reg. 3880, 3892 (Jan 26, 2018).

² Id. at 3894 (Jan 26, 2018).

³ Id.

discriminate against people who are HIV positive. OCR has also sought to ensure compliance with civil rights statutes by requiring covered entities to provide auxiliary aids and services to ensure effective communication for individuals with disabilities and taking steps to ensure that individuals with limited English proficiency have meaningful access to health facilities, such as providing interpreters free of charge. These actions have gone a long way towards combating discrimination and disparities in health care.

Nevertheless, further work is needed to address discrimination and reduce these disparities. Older adults are no exception to the stark health disparities that persist across race, national origin, gender, sexual orientation, and poverty lines. For example, a larger share of Black and Hispanic Medicare beneficiaries report fair or poor health status than white beneficiaries. Similarly, Black and Hispanic adults age 65 and older are almost twice as likely as white older adults to develop diabetes. Older adults who are limited English proficient (LEP), including over four million Medicare beneficiaries, face difficulties finding providers, especially for in-home supports and services, who speak their preferred language and often are forced to rely on family members to interpret for them. Lesbian, gay and bisexual older adults face higher rates of disability and mental health challenges; older bisexual and gay men face higher rates of physical health challenges; bisexual and lesbian older women have higher obesity rates and higher rates of cardiovascular disease; and transgender older adults face greater risk of suicidal ideation, disability, and depression compared to their peers. HIV disproportionately impacts the LGBTQ community, and it is affecting an increasing number of older adults.

However, the expansion of religious refusals under the proposed rule would only make these disparities worse by disproportionately harming communities that already face barriers to care: women, people of color, people living with disabilities, people with limited English proficiency, and Lesbian, Gay, Bisexual, Transgender, Queer (LGBTQ) individuals, as well as people living in rural communities. The harmful effects would be compounded for individuals who hold multiple disadvantaged identities. For example, an older adult who is gay might also have limited English proficiency, or a physical or mental disability, and may not have a choice of providers and therefore nowhere to go if they are refused care in the rural community where they live.

JUSTICE IN AGING

^{*} Kaiser Family Foundation, Profile of Medicare Beneficiaries by Race and Ethnicity, (March 9, 2016), available at http://kff.org/medicare/report/profile-of-medicare-beneficiaries-by-race-and-ethnicity-a-chartpack/.

⁵ Centers for Disease Control and Prevention, *The State of Aging and Health in America*, (2013) at Figure 2, available at www.cdc.gov/aging/pdf/state-aging-health-in-america-2013.pdf

⁶ CMS Office of Minority Health, Understanding Communications and Language Needs of Medicare Beneficiaries, at 8 (April 2017), available at www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Issue-Briefs-Understanding-Communication-and-Language-Needs-of-Medicare-Beneficiaries.pdf

⁷ Fredriksen-Goldsen et al., The Aging And Health Report: Disparities And Resilience Among Lesbian, Gay, Bisexual, And Transgender Older Adults (Nov. 2011), available at www.lgbtagingcenter.org/resources/resource.cfm?r=419
⁸ See Ctrs. for Disease Control & Prevention, HIV in the United States: At a Glance (June 2017), available at www.cdc.gov/hiv/statistics/overview/ataglance.html; Ctrs. for Disease Control & Prevention, HIV and Transgender Communities (2016), www.cdc.gov/hiv/pdf/policies/cdc-hiv-transgender-brief.pdf.

A. The proposed rule would harm LGBTQ older adults who continue to face widespread discrimination and health disparities.

We are particularly concerned that the proposed rule would exacerbate the barriers to care that LGBTQ older adults face and the effects of ongoing and pervasive discrimination by potentially allowing providers to refuse to provide services and information vital to LGBTQ health. In addition to experiencing the health disparities described above, LGBT elders are more likely to be single, childless, estranged from their biological family, and reliant on families of choice, such as friends and other loved ones. Because they do not have traditional support systems in place, many LGBT elders rely on nursing homes or other long-term care facilities to receive needed services. Results of a recent survey by AARP show that at least a third of LGBT adults are worried about having to hide their LGBT identity in order to have access to housing options that are suitable for older adults. Over half of LGBT adults fear discrimination in health care as they age and are especially concerned about neglect, abuse, and verbal or physical harassment in long-term care facilities. These concerns are even greater among Black and Latino LGBT adults and individuals who identify as non-binary.

Unfortunately, these fears are a reality for many LGBT older adults. In a survey of LGBT seniors reported in our publication, *Stories from the Field*, we found numerous cases where LGBT older adults experienced discrimination in long-term care facilities ranging from verbal and physical harassment, to visiting restrictions and isolation, to being denied basic care such as a shower or being discharged or refused admission.¹³ In addition to being denied care or provided inadequate care, LGBT older adults and their loved ones may be afraid to seek care because they are not treated with dignity and respect. Several LGBT older adults reported being "prayed over" without their consent or being told they would go to hell—violating their right to practice their own beliefs.¹⁴ These discriminatory actions by facility staff could be protected under this ill-advised rule.

As proposed, the rule could allow individuals and facilities to not only refuse to provide treatment for LGBTQ individuals, but to also deny doctors and other professionals the ability to provide that treatment in their facilities. Such refusals implicate standards of care that are vital to LGBTQ health. Medical professionals are expected to provide LGBTQ individuals with the same quality of care as they would anyone else. The American Medical Association recommends that providers use culturally appropriate language and have basic familiarity and

⁹ SAGE (Services and Advocacy for Gay, Lesbian, Bisexual & Transgender Elders) and Movement Advancement Project, Improving the Lives of LGBT Older Adults, (March 2010), available at www.sageusa.org, www.lgbtmap.org.
¹⁰ Houghton, Angela, AARP, Maintaining Dignity: Understanding and Responding to the Challenges Facing Older LGBT Americans. (Mar. 2018), available at https://doi.org/10.26419/res.00217.001.

¹¹ ld.

¹² ld.

¹³ Justice in Aging et al., LGBT Older Adults in Long-Term Care Facilities: Stories from the Field (updated June 2015), available at www.justiceinaging.org.customers.tigertech.net/wp-content/uploads/2015/06/Stories-from-the-Field.pdf

¹⁴ Id. at 11.

competency with LGBTQ issues as they pertain to any health services provided. The World Professional Association for Transgender Health guidelines provide that gender-affirming interventions, when sought by transgender individuals, are medically necessary and part of the standard of care. The American College of Obstetricians and Gynecologists warns that failure to provide gender-affirming treatment can lead to serious health consequences for transgender individuals. The proposed rule would interfere with the ability of providers to meet these standards since they would not be able to rely on the consistent support of the facilities and care teams where they practice.

B. The proposed rule will harm older adults and people living with disabilities who rely on long-term services and supports.

Many older adults and people with disabilities receive long-term services and supports, including home and community-based services (HCBS), from religiously-affiliated providers. However, some people who rely on these services have faced discrimination, exclusion, and a loss of autonomy due to provider objections to providing specified care. For example, individuals with HIV—a recognized disability under the ADA—have repeatedly encountered providers who deny services, necessary medications, and other treatments citing religious and moral objections. One man with HIV was refused care by six nursing facilities before his family was finally forced to relocate him to a facility 80 miles away.¹⁸

Older adults and people with disabilities often live or spend much of their day in provider-controlled settings where they receive supports and services. They may rely on a case manager to coordinate necessary services, a transportation provider to get them to community appointments, or a personal care attendant to help them take medications and manage their daily activities. Under this broad new proposed language, any of these providers could believe they are entitled to object to providing a service covered under the regulation and not even tell the individual where they could obtain that service, how to find an alternative provider, or even that the service is available to them. In these cases, a denial based on a provider's personal moral objection can potentially impact every facet of life for an older adult or person with disabilities — including visitation rights, autonomy, and access to the community. For example,

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¹⁵ Gay Lesbian Bisexual & Transgender Health Access Project, Community Standards of Practice for the Provision of Quality Health Care Services to Lesbian, Gay, Bisexual, and Transgender Clients, available at www.glbthealth.org/documents/SOP.pdf; A.M.A., Creating an LGBTQ-friendly Practice, available at www.ama-assn.org/delivering-care/creating-lgbta-friendly-practice.

¹⁶ World Prof. Ass'n for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (2011), available at

https://s3.amazonaws.com/amo_hub_content/Association140/files/Standards%20of%20Care%20V7%20-%202011%20WPATH%20(2)(1).pdf.

¹⁷ Am. Coll. Obstetricians & Gynecologists, Committee Opinion 512: Health Care for Transgender Individuals, (Dec. 2011), available at https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-for-Transgender-Individuals.

¹⁸ Nat'l Women's Law Ctr., Fact Sheet: Health Care Refusals Harm Patients: The Threat to LGBT People and Individuals Living with HIV/AIDS, (May 2014), available at https://nwlc.org/wp-content/uploads/2015/08/lgbt-refusals-factsheet-05-09-14.pdf.

could a case manager ignore an individual's request to see an HIV specialist? Could a group home refuse to allow a same-sex couple who are residents to live together in the group home?

Finally, due to limited provider networks, older adults and people with disabilities living in rural areas may have particular difficulty finding an alternate provider. For example, home care agencies and home-based hospice agencies in rural areas are facing significant financial difficulties staying open. Seven percent of all zip codes in the United States do not have any hospice services available to them. ¹⁹ Finding providers competent to treat people with certain disabilities increases the challenge, and adding in the possibility of a case manager or personal care attendant who objects to serving the individual under this proposed rule could make the barrier to accessing these services insurmountable. Moreover, older adults and people with disabilities who identify as LGBTQ or who belong to a historically disadvantaged racial or ethnic group may be both more likely to encounter service refusals and also face greater challenges to receive (or even know about) accommodations.

III. The proposed rule undermines longstanding ethical and legal principles of informed consent and would undermine effective provider-patient communication

The proposed rule undermines informed consent, a necessary principle of person-centered decision making and a critical component of quality of care. Informed consent relies on providers disclosing medically accurate information so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.²⁰

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

Additionally, while virtually every state already provides for a conscience objection and a provider's right to refuse to comply with a patient's directive, state laws also impose an obligation on providers to inform patients of their objection and to make some level of effort to transfer the patient to another provider or facility that will comply with the patient's wishes. This proposed rule appears to require neither and may even preempt these state laws which protect patients' rights. If this rule is finalized, which we oppose, HHS should clarify that state conscience rule procedural requirements are not preempted.

In particular, the principles of informed consent, respect for autonomy, and self-determination are important when individuals are seeking end-of-life care or have diminishing capacity. These

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¹⁹ Julie A. Nelson & Barbara Stover Gingerich, Rural Health: Access to Care and Services, 22 HOME HEALTH CARE MGMT. PRAC. (2010), available at http://globalag.igc.org/ruralaging/us/2010/access.pdf.

²⁰ Tom Beauchamp & James Childress, PRINCIPLES OF BIOMEDICAL ETHICS (4th ed. 1994); Charles Lidz et al., INFORMED CONSENT: A STUDY OF DECISION MAKING IN PSYCHIATRY (1984).

patients should be the center of health care decision-making and they or their representatives should be fully informed about their treatment options. Under the proposed rule, however, providers who object to various procedures could withhold vital information about treatment options—including options such as palliative sedation or declining artificial nutrition and hydration—and refuse to provide a referral to a provider who would honor the patient's wishes. For patients who cannot currently make health care decisions, their advance directives should be honored, regardless of the physician's personal objections, either through immediate assistance or through transfer to another facility. The blanket refusals permissible under this proposed rule would violate informed consent principles by ignoring patients' needs, desires, and autonomy and self-determination at critical times in their lives.

IV. Conclusion

Justice in Aging is deeply concerned that the proposed rule's expansion of conscience protections and religious refusals would be detrimental to older adults' health and well-being and greatly harm communities who already lack access to care and endure discrimination. HHS must ensure that all consumers are protected from discrimination and that all providers treat every patient whom they serve with dignity and respect. The proposed rule would give carte blanche to any provider to withhold care on the basis of prejudice cloaked as "moral conviction." Therefore, we strongly urge HHS not to finalize the proposed rule.

Thank you for considering our comments. If any questions arise concerning this submission, please contact me at igoldberg@justiceinaging.org.

Sincerely,

Jennifer Goldberg Directing Attorney

Exhibit 95



March 27, 2018

VIA ELECTRONIC SUBMISSION

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

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

To Whom It May Concern:

Lambda Legal Defense and Education Fund, Inc. ("Lambda Legal") appreciates the opportunity provided by the Department of Health and Human Services ("HHS" or the "Department") to offer comments in response to the Proposed Rule, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03 ("Proposed Rule" or "Rule"), published in the Federal Register on January 26, 2018. As described herein, the Proposed Rule both exceeds its statutory authority and contravenes this Department's mission, the legal rights of patients, the ethical obligations of health professionals, and the legal rights and responsibilities of institutional health care providers. It should be withdrawn.

Lambda Legal is the oldest and largest national legal organization dedicated to achieving full recognition of the civil rights of lesbian, gay, bisexual, and transgender ("LGBT") people and everyone living with HIV through impact litigation, policy advocacy, and public education. For decades, Lambda Legal has been a leader in the fight to ensure access to quality health care for our vulnerable communities. In recent years, Lambda Legal has submitted a series of comments to HHS regarding the importance of reducing discrimination against LGBT people in health care services, the fact that current law already protects health worker conscience rights appropriately, and the ways that conscience-based exemptions to health standards endanger LGBT people and others.² Recently, Lambda Legal also has opposed an HHS proposal to expand

^{1 83} Fed. Reg. 3880 et seq. (proposed Jan. 26, 2018) (to be codified at 45 C.F.R. pt. 88).

² Lambda Legal Comments on Proposed Rule 1557 Re: Nondiscrimination in Health Programs and Activities, 1557 NPRM (RIN 0945-AA02) (submitted Nov. 9, 2015) ("Lambda Legal 1557 Comments"), https://www.lambdalegal.org/in-court/legal-docs/hhs_dc_20151117_letter-re-1557; Lambda Legal Comments on Request for Information Regarding Nondiscrimination in Certain Health Programs or Activities (RIN 0945-AA02 & 0945-ZA01) (submitted Sept. 30, 2013) ("Lambda Legal Nondiscrimination Comments"), https://www.lambdalegal.org/in-court/legal-docs/ltr_hhs_20130930_discrimination-in-health-services. See also Brief of Amici Curiae Lambda Legal et al., Zubik v. Burwell, 136 S. Ct. 1557



the ability of religiously-affiliated health care institutions and individuals to impose their religious beliefs on workers and on patients, cautioning in detail about the likely harmful consequences of any such expansions for LGBT people and people living with HIV.³

As to the Proposed Rule now under consideration, Lambda Legal emphatically recommends its withdrawal because:

- (1) It improperly expands statutory religious exemptions in multiple ways, including by:
 - (a) permitting workers to refuse job duties that cannot reasonably be understood as "assisting" with an objected-to procedure, ⁴ and instead have merely an "articulable" connection to the procedure⁵;
 - (b) expanding who may assert religious objections from employees performing or assisting in specified procedures to any member of the workforce⁶;
 - (c) using an improperly expanded definition of "referral" that includes providing any information or directions that could assist a patient in pursuing care; and
 - (d) defining "discrimination" to focus on protecting the interests of health care providers in continuing to receive favorable financial, licensing or other treatment, rather than on patients' interest in receiving medically appropriate care⁸; and
 - (e) defining health care entity to include health insurance plans, plan sponsors, and third-party administrators.⁹

^{(2016) (}Nos. 14-1418, 14-1453, 14-1505, 15-35, 15-105, 15-119, 15-191), http://www.lambdalegal.org/in-court/legal-docs/zubik us 20160217 amicus.

³ See, e.g., Lambda Legal Comments on Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (RIN 0938-AT46) (submitted Dec. 5, 2017), https://www.lambdalegal.org/in-court/legal-docs/dc_20171205_aca-moral-exemptions-and-accommodations; Lambda Legal Comments on Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (RIN 0938-AT20) (submitted Dec. 5, 2017), https://www.lambdalegal.org/in-court/legal-docs/dc_20171205_aca-religious-exemptions-and-accommodations.

⁴⁴² U.S.C.A. § 300a-7(b) and (d).

⁵ Section 88.2, 83 Fed. Reg. at 3923.

⁶ Section 88.2, 83 Fed. Reg. at 3924.

⁷ Id.

⁸ Id.

⁹ Id.



- (2) It encourages workers and institutions to refuse care and does not acknowledge the rights of patients, such as the right against sex discrimination provided by Section 1557 of the Affordable Care Act. 10
- (3) It encourages workers and institutions to refuse care and does not acknowledge the legal rights and duties of health care providers, such as those under Title VII of the Civil Rights Act of 1964, 11 or health professionals' ethical obligations to patients.
- (4) Using broad, vague language, it addresses a purported "problem" of health workers being pressed to violate their conscience, suggesting that workers should have broad religious rights to decline care and refuse other work of any sort in any context, going far beyond the narrow contexts specified in the authorizing statutes.
- (5) Its proposed enforcement mechanisms are draconian, threatening the loss of federal funding and even the potential of funding "claw backs," with limited if any due process protections, all of which would skew health systems improperly in favor of religious refusals and against patient care.
- (6) The heavy-handed enforcement mechanisms inevitably would invite discrimination and aggravate existing health disparities and barriers to health care faced by LGBT people and others, contrary to the mission of HHS and, in particular, its Office for Civil Rights.
- (7) It is the result of a rushed, truncated process inconsistent with procedural requirements including the Administrative Procedure Act. 12

In sum, the role of the HHS Office for Civil Rights ("OCR") described in the Proposed Rule is not to promote access to health care and to safeguard patients against discrimination, but instead to impose vague, overbroad restraints on health care provision, as a practical matter elevating "conscience" objections of workers over the needs of patients. In so doing, the Proposed Rule turns the mission of HHS/OCR on its head. Freedom of religion is a core American value, which is why it is already protected by the First Amendment of the Constitution. But, that freedom does not and must not allow anyone to impose their beliefs on others or to discriminate. This basic principle is nowhere more important than in medical contexts where religion-based refusals can cost patients their health and even worse.

^{10 42} U.S.C.A. § 18116.

¹¹ Civil Rights Act of 1964 § 7, 42 U.S.C.A. § 2000e et seq. (1964).

^{12 5} U.S.C.A. § 500 et seq.



I. The Proposed Rule Improperly Expands Statutory Religious Exemptions.

The Proposed Rule improperly expands statutory religious exemptions beyond their narrow, specific parameters in numerous ways. It includes definitions that would broaden the exemptions in the Church Amendments, which currently allow health workers to decline to assist in an abortion or sterilization procedure if doing so "would be contrary to [their] religious beliefs or moral convictions." The Proposed Rule reinterprets what it means to "assist in the performance" of a procedure from participating in "any activity with a reasonable connection" to a procedure ¹⁴ to "any ... activity with an articulable connection" to an objected-to procedure. In other words, any connection that can be described, no matter how tenuous, potentially could suffice. Confirming the potentially indefinite expansion of what can be deemed "assistance" is a broad definition of who may object. From the prior common language understanding of who might be involved in a medical procedure, the new definition appears to authorize any member of the workforce to object to performing their job duties. In the prior common language understanding of the workforce to object to performing their job duties.

The Proposed Rule also includes an aggressive expansion of the concept of "referral" from the common understanding of actively connecting a patient with an alternate source of a particular service to the provision of any information or directions that could possibly assist a patient who might be pursuing a form of care to which the employee objects. ¹⁷ This goes far beyond a reasonable understanding of what the underlying statute justifies.

Similarly, where the statute authorizes "health care entities" to assert religious objections, the Proposed Rule grossly expands the entities covered by that term to include health insurance plans, plan sponsors, and third-party administrators. ¹⁸ It also adds a definition of "discrimination" that focuses not on patients' interest in receiving equal, medically appropriate services, but rather on protecting health care providers' interests in continuing to receive favorable financial, licensing or other treatment while refusing on religious or moral objections to provide care despite medical standards, nondiscrimination rules, or other requirements. ¹⁹

^{13 42} U.S.C.A. § 300a-7.

^{14 45} C.F.R. § 88.2 (2008) (emphasis added).

¹⁵ Proposed Rule, 83 Fed. Reg. at 3923 (emphasis added).

¹⁶ Section 88.2, 83 Fed. Reg. at 3924.

¹⁷ Section 88.2, 83 Fed. Reg. at 3924.

¹⁸ Section 88.2, 83 Fed. Reg. at 3924.

¹⁹ Section 88.2, 83 Fed. Reg. at 3924.



In numerous places, the Proposed Rule seems to indicate that HHS is adopting interpretations that would extend the Amendments' reach beyond current understanding that the exemptions only concern abortion and sterilization and follow the common medical understanding of those terms. ²⁰ As one example, it seems likely that the "sterilization" references within the Proposed Rule could be applied to deny health care to transgender patients because the Rule itself, at footnote 36, cites *Minton v. Dignity Health* approvingly. ²¹ *Minton* addresses whether a Catholic hospital was legally justified when it blocked a surgeon from performing a hysterectomy for a transgender man as part of the prescribed treatment for gender dysphoria. The hospital defended on religious freedom grounds, arguing that it was bound "to follow well-known rules laid down by the United States Conference of Catholic Bishops," including rules prohibiting "direct sterilization." ²²

But, to equate hysterectomy to treat gender dysphoria with direct sterilization is medically inaccurate. Sterilization procedures undertaken for the *purpose* of sterilization are fundamentally different from procedures undertaken for other medical purposes that incidentally affect reproductive functions. Regardless of whether the United States Conference of Catholic Bishops considers gender transition-related care to be sterilization as a religious matter, were the federal government to approve a religious rationale as grounds for stretching a federal statute and permitting denial of medically necessary care would be problematic for both statutory interpretation and Establishment Clause reasons.

The Proposed Rule's apparent embrace of the Bishops' view poses an overtly discriminatory and unacceptable threat to transgender patients. This concern is not speculative. The Proposed Rule's footnote referencing *Minton* supports the following statement: "Many religious health care personnel and faith-based medical entities have further alleged that health care personnel are being targeted for their religious beliefs." For the Proposed Rule to equate a transgender patient expecting to receive medically necessary care from health care personnel with those personnel "being targeted for their religious beliefs" is a chilling indicator of the direction the Proposed Rule would take health care in this country. Not only would health providers be invited to turn away transgender patients, but those that abide by their obligation to

²⁰ Compare cases describing statute's applicability to provision or refusal provide abortions or sterilization, e.g., Cenzon-DeCarlo v. Mount Sinai Hosp., 626 F.3d 695 (2d Cir. 2010), and Chrisman v. Sisters of St. Joseph of Peace, 506 F.2d 308 (9th Cir. 1974), with Geneva Coll. v. Sebelius, 929 F. Supp. 2d 402 (W.D. Pa. 2013), on reconsideration in part (May 8, 2013) (statute does not apply to provision of emergency contraception, which is not abortion or sterilization).

²¹ No. 17-558259 (Calif. Super. Ct. Apr. 19, 2017).

²² Defendant Dignity Health's Reply Brief in Support of Demurrer to Verified Complaint, Minton v. Dignity Health, No. 17-558259, at 2 (Calif. Super. Ct. Apr. 19, 2017) (filed Aug. 8, 2017), https://www.aclusocal.org/sites/default/files/brf.sup_.080817_defendant_dignity_healths_reply_in_support of demurrer to verified complaint.pdf.

²³ Proposed Rule, 83 Fed. Reg. at 3888 n. 36.



provide nondiscriminatory care and require their employees to act accordingly could be stripped of federal funding if equal treatment of those patients offended any workers' personal beliefs.

The overbroad definitions and suggestive language all contribute to the alarming overall theme of the Proposed Rule—that it addresses a purported problem of health workers ostensibly being pressed wrongfully to act against their rights of conscience. The Proposed Rule's suggested cure appears to be that workers should have broad religious rights to decline care of any sort in any context. This theme starts with the broad language stating the Proposed Rule's purpose and runs throughout the rule. ²⁴ It creates at least a serious concern that, for example, language long understood to be bounded by its statutory context only to concern abortion and sterilization could be misconstrued as authorizing health care providers to refuse to participate in any part of any health service program or research activity "contrary to [their] religious beliefs or moral convictions." While such an interpretation obviously could be challenged legally, many patients have neither the knowledge nor the means to resist such improper care refusals and would simply suffer the delay or complete denial of medically needed treatments.

II. The Proposed Rule Invites Workers And Institutions To Refuse Care And Does Not Acknowledge The Rights Of Patients.

By issuing the Proposed Rule, HHS invites health workers and institutions to refuse to provide medical care for religious reasons, without acknowledging that patients often have countervailing rights. Yet, all federal agencies, including HHS, must comply with the federal statutes that protect LGBT people and others from discrimination, such as Section 1557 of the Affordable Care Act, which bars discrimination based on sex in federally funded health services and programs. Properly understood, Section 1557 protects transgender patients from discriminatory denials of care based on their gender identity or transgender status. It also protects lesbian, gay, and bisexual patients. Even if it were not contrary to the mission of OCR

²⁴ See, e.g., Section 88.1 (Purpose); Appendix A (required notice to employees) to 45 C.F.R., 83 Fed. Reg. at 3931 (declaring broad right to accommodation for any religious or moral belief); 83 Fed. Reg. at 3881, 3887-89, 3903 (addressing "problem" of workers being required to meet patient needs despite their personal beliefs).

^{25 42} U.S.C.A. § 300a-7(d). See cases cited supra note 20.

^{26 42} U.S.C.A. § 18116.

²⁷ Rumble v. Fairview Health Services, 2015 WL 1197415 (D. Minn. March 16, 2015) (Affordable Care Act, Section 1557). See also Whitaker v. Kenosha Unified School District No. 1 Board of Education, 858 F.3d 1034 (7th Cir. 2017) (analogous protection against sex discrimination in Title IX protects transgender students); EEOC v. R.G. v. G.R. Harris Funeral Homes, Inc., ___ F.3d ___, 2018 WL 1177669 (6th Cir. March 7, 2018) (analogous protection against sex discrimination in Title VII protects transgender workers).

²⁸ Cf. Zarda v. Altitude Express, Inc., 883 F.3d 100 (2d Cir. 2018) (sexual orientation discrimination is sex discrimination under Title VII); Hively v. Ivy Tech Comm'ty College, 853 F.3d 339 (7th Cir. 2017) (same).



to undermine patient protections against discrimination, the agency lacks the authority to reduce the protections provided to patients by separate statutes.

The ACA also includes patient protections to ensure access to essential health services, including reproductive health services. Yet, the Proposed Rule's aggressive approach to advancing conscience rights offers nothing to explain how those refusal rights are to coexist with patients' rights under the ACA. As to these conflicts, Lambda Legal joins the comments submitted by the National Health Law Program.

Moreover, the Proposed Rule also is inconsistent with several core constitutional guarantees: (1) each of us is entitled to equal protection under law; (2) the Establishment Clause forbids our government from elevating the religious wishes of some above the needs of others to be protected from harm, including the harms of discrimination; and (3) congressional spending powers have limits. On the latter point, the Proposed Rule references the spending powers of Congress as grounds for the new enforcement powers created for HHS to condition federal funding upon health care providers' acquiescence in religious refusal demands of their workers.²⁹ However, as well-established by *South Dakota v. Dole*³⁰ and its progeny, Congress's spending powers are limited. Any exertion of power must be in pursuit of the general welfare; must not infringe upon states' abilities "to exercise their choice knowingly, cognizant of the consequences of their participation"; must be related "to the federal interest in particular national projects or programs;" and must be otherwise constitutionally permissible.³¹

Multiple Equal Protection and Establishment Clause concerns implicate the final prong of the *South Dakota v. Dole* test for unconstitutional conditions on federal funds. But the first prong deserves immediate focus because it obviously does not serve the general welfare to use severe de-funding threats to intimidate medical facilities into deviating from medical practice standards in favor of religious interests in secular settings, to the detriment of individual and public health.

In addition, with its explicit intention to enforce federal "conscience" rights despite contrary state and local protections for patients, the Proposed Rule further implicates federalism concerns. It states: "Congress has exercised the broad authority afforded to it under the Spending Clause to attach conditions on Federal funds for respect of conscience, and such conscience conditions supersede conflicting provisions of State law[.]" It then asserts that it "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. "Yet, by inviting health professionals and

²⁹ Proposed Rule, 83 Fed. Reg. at 3889.

^{30 483} U.S. 203 (1987).

³¹ Id. at 207-08.

³² Proposed Rule, 83 Fed. Reg. at 3889.

³³ Id. at 3918-19.



other workers to turn away patients and refuse job duties in such a sweeping way, the Proposed Rule directly conflicts with state and local nondiscrimination laws and other patient protections. Its assertions to the contrary are patently inaccurate.

III. The Proposed Rule Invites Workers To Refuse Care And Does Not Acknowledge The Legal Rights And Duties, And Ethical Obligations, Of Health Care Providers.

The Proposed Rule aims improperly to empower workers to object to job duties without addressing the impacts on employers and coworkers left somehow to try to ensure that patient needs are met by others, with whatever increased costs, workload, and other burdens it may entail. The proposed approach fails to acknowledge that the federal employment nondiscrimination law, Title VII of the Civil Rights Act of 1964, limits the extent to which employers are to be burdened by employee demands for religious accommodation. Undue burdens on employers could include objections by coworkers to unfair additional job duties or to coworker proselytizing. Likewise, it certainly would impose unjustifiable burdens to require employers to hire duplicate staff simply to ensure patient needs are met by employees willing to perform basic job functions. Indeed, courts have confirmed that when denial of a requested accommodation is "reasonably necessary to the normal operation of the particular business or enterprise," employers, including health care employers, need only show that they "offered a reasonable accommodation or that a reasonable accommodation would be an undue burden."

Such limitations on employee religious rights are essential to ensure that health care employers can hire those who will perform the essential functions of their jobs, and will comply with all statutory obligations including prohibitions against discrimination. If instead, employees who claim "conscience" objections to providing the health care services to LGBT people or people living with HIV are empowered by the Proposed Rule to threaten their employees with loss of federal funding if they do not allow such discrimination, employers will face logistical

³⁴ 42 U.S.C.A. § 2000e et seq. See, e.g., See, e.g., Bruff v. North Miss. Health Servs., Inc., 244 F.3d 495, 497-98 (5th Cir. 2001) (Title VII duty to accommodate employees' religious concerns did not require employer to accommodate employee's requests to be excused from counseling patients about non-marital relationships, which meant "she would not perform some aspects of the position itself"); Berry v. Dep't of Social Servs., 447 F.3d 642 (9th Cir. 2006) (employer entitled to prohibit employee from discussing religion with clients).

^{35 42} U.S.C.A. § 2000e-2(e).

³⁶ See, e.g., Grant v. Fairview Hosp. & Healthcare Servs., No. Civ. 02-4232JNEJGL, 2004 WL 326694 (D. Minn. Feb. 18, 2004) (hospital wasn't required to accommodate employee's request to be able to proselytize or provide pastoral counseling to patients to try to persuade them not to have abortions); Robinson v. Children's Hosp. Boston, Civil Action No. 14-10263-DJC, 2016 WL 1337255 (D. Mass. Apr. 5, 2016) (granting hospital employee's request to forgo flu shot would have been an undue hardship for hospital).

³⁷ See, e.g., Sánchez-Rodríguez v. AT & T Mobility P. R., Inc., 673 F.3d 1, 8 (1st Cir. 2012).



nightmares and the employees without such beliefs will be unfairly subjected to increased workloads.

This seems like an inevitable repercussion particularly in light of the Proposed Rule's explanation in its definition of prohibited "discrimination" that "religious individuals or institutions [must] be allowed a level playing field, and that their beliefs not be held to disqualify them from participation in a program or benefit." This definition lacks any qualifying language confirming that employers may condition employment on willingness to perform essential parts of a job. The likely effects would include increased burnout among those staff who have additional work delegated to them when religious exemptions are claimed. The Proposed Rule also would drain institutional resources as employers must respond (with management time and legal fees) to complaints filed by overburdened workers and by those who file implausible "conscience" objections upon receiving negative work evaluations. The waste of essential health care resources in service of improper denials of medical care cannot be justified.

Moreover, the Proposed Rule similarly ignores that health professionals are bound by ethical standards to do no harm and to put patient needs first. Concerning the application of this point to ensuring patients' reproductive health needs are not improperly subordinated to others' religious concerns, Lambda Legal endorses the comments submitted by the National Health Law Program. Concerning patients' needs to be treated equally regardless of gender identity, sexual orientation, and other irrelevant personal characteristics, the Joint Commission's accreditation standards and the ethical rules of the American Medical Association and other leading medical associations all impose a duty of nondiscrimination. For example, AMA Ethical Rule E-9.12 prohibits discrimination against patients and Ethical Rule E-10.05 provides that health professionals' rights of conscience must not be exercised in a discriminatory manner. But that is precisely what results when, for example, a medically necessarily hysterectomy is denied to a patient because it is needed as treatment for gender dysphoria, and is provided to other patients as treatment for fibroids, endometriosis, or cancer. And the professionals are bounded to a property of the patients as treatment for fibroids, endometriosis, or cancer.

The Tennessee Counseling Association has expressed the bottom line cogently. Like many medical associations across the country, the TCA has codified the "do no harm" mandate and issued a formal statement opposing legislation proposing to allow denials of medical care through religious exemptions in that state: "When we choose health care as a profession, we

³⁸ Proposed Rule, 83 Fed. Reg. at 3892.

³⁹ AMA ethical rule E-9.12, "Patient-Physician Relationship: Respect for Law and Human Rights," E-10.05, "Potential Patients."

⁴⁰ See discussion of Proposed Rule reference to Minton v. Dignity Health, No. 17-558259 (Calif. Super. Ct. Apr. 19, 2017), at page 5, footnote 22. See also Conforti v. St. Joseph's Healthcare Sys. (D. N.J. filed Jan. 5, 2017), case documents at https://www.lambdalegal.org/in-court/cases/nj-conforti-v-st-josephs; Amy Littlefield, Catholic Hospital Denies Transgender Man a Hysterectomy on Religious Grounds, Rewire.News, Aug. 31, 2016, https://rewire.news/article/2016/08/31/catholic-hospital-denies-transgenderman-hysterectomy-on-religious-grounds/.



choose to treat all people who need help, not just the ones who have goals and values that mirror our own."41

IV. The Proposed Rule's Enforcement Mechanisms Are Draconian And Would Skew Health Systems In Favor Of Religious Refusals And Against Patient Care.

The Proposed Rule's enforcement mechanisms include aggressive investigation, require medical facilities to subject themselves to an extensive scheme of regulatory surveillance by HHS, and allocate authority to OCR "to handle complaints, perform compliance reviews, investigate, and seek appropriate action." The Proposed Rule even "make[s] explicit the Department's authority to investigate and handle violations and conduct compliance reviews whether or not a formal complaint has been filed." In addition to conditioning federal funding on prospective pledges to comply with broad, vague requirements, penalties can include not just the loss of future federal funding but even the potential of funding "claw backs," all with limited if any due process protections.

For many major medical providers, the threat of loss of federal funding is a threat to the facilities' very existence. It is nearly unfathomable that the government intends to force medical facilities either to forego their ethical obligations not to harm their patients or to close their doors. But, that easily could be the effect of the Proposed Rule in many instances. More often, the likely result would be simply to skew health systems dangerously in favor of religious refusals and against patient care. Doing so would both invite discrimination and aggravate existing health disparities and barriers to health care faced by LGBT people and others, contrary to the mission of HHS and, in particular, its Office for Civil Rights.

V. The Proposed Rule Inevitably Would Invite Discrimination And Worsen Health Disparities Affecting LGBT People And Others.

Discrimination and related health disparities already are widespread problems for LGBT people and people living with HIV. 45 In 2010, Lambda Legal conducted the first-ever national

⁴¹ See Emma Green, When Doctors Refuse to Treat LGBT Patients, The Atlantic, April 19, 2016, https://www.theatlantic.com/health/archive/2016/04/medical-religious-exemptions-doctors-therapists-mississippi-tennessee/478797/, citing Tenn. Counseling Assoc., TCA Opposes HB 1840 (2016), http://www.tncounselors.org/wp-content/uploads/2016/03/TCA-Opposes-HB-1840-3.9.16.pdf.

⁴² Proposed Rule, 83 Fed. Reg. at 3898.

⁴³ Id. (emphasis added).

⁴⁴ Id

⁴⁵ See, e.g., Inst. of Med., The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding (2011) ("IOM Report") (undertaken at the request of the National Institutes of Health, and providing an overview of the public health research concerning health disparities for LGBT people and the adverse health consequences of anti-LGBT attitudes),



survey to examine the refusals of care and other barriers to health care confronting LGBT people and people living with HIV, When Health Care Isn't Caring: Survey on Discrimination Against LGBT People and People Living with HIV. 46 Of the nearly 5,000 respondents, more than half reported that they had experienced at least one of the following types of discrimination in care:

- Health care providers refusing to touch them or using excessive precautions;
- Health care providers using harsh or abusive language;
- · Health care providers being physically rough or abusive;
- Health care providers blaming them for their health status.⁴⁷

Almost 56 percent of lesbian, gay, or bisexual (LGB) respondents had at least one of these experiences; 70 percent of transgender and gender-nonconforming respondents had one or more of these experiences; and almost 63 percent of respondents living with HIV experienced one or more of these types of discrimination in health care. Almost 8 percent of LGB respondents reported having been denied needed care because of their sexual orientation, and 19 percent of respondents living with HIV reported being denied care because of their HIV status. The picture was even more disturbing for transgender and gender-nonconforming respondents, who reported the highest rates of being refused care (nearly 27 percent), being subjected to harsh language (nearly 21 percent), and even being abused physically (nearly 8 percent).

Respondents of color and low-income respondents reported much higher rates of hostile treatment and denials of care. Nearly half of low-income respondents living with HIV reported that medical personnel refused to touch them, while the overall rate among those with HIV was

https://www.ncbi.nlm.nih.gov/books/NBK64806; Sandy E. James et al., Nat'l Ctr. For Transgender Equality, The Report of the 2015 U.S. Transgender Survey 93-129 (2016), https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf; Lambda Legal, Health Care; Shabab Ahmed Mirza & Caitlin Rooney, Ctr. For Am. Progress, Discrimination Prevents LGBTQ People from Accessing Health Care (Jan. 18, 2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

⁴⁶ Lambda Legal, When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV (2010) ("Lambda Legal, Health Care"), http://www.lambdalegal.org/publications/when-health-care-isnt-caring.

⁴⁷ Id. at 5, 9-10.

⁴⁸ Id.

⁴⁹ Id. at 5, 10.

⁵⁰ Id.

⁵¹ Id. at 10-11.



nearly 36 percent. ⁵² And while transgender respondents as a whole reported a care-refusal rate of almost 27 percent, low-income transgender respondents reported a rate of nearly 33 percent. ⁵³ People of color living with HIV and LGB people of color were at least twice as likely as whites to report experiencing physically rough or abusive treatment by medical professionals. ⁵⁴

Also detailed in the report are particular types of discrimination in health care based on gender identity, sex discrimination against LGB people, and discrimination against people living with HIV. Such discrimination can take many forms, from verbal abuse and humiliation to refusals of care; ⁵⁵ to refusal to recognize same-sex family relationships in health care settings to the point of keeping LGBT people from going to the bedsides of their dying partners; ⁵⁶ to lack of understanding and respect for LGBT people. ⁵⁷ The resulting harms are manifold, from transgender patients denied care postponing, delaying, or being afraid to seek medical treatment, sometimes with severe health consequences, or resorting out of desperation to harmful self-treatment; ⁵⁸ to the mental and physical harms of stigma; ⁵⁹ to other immediate physical harms from being denied medical care.

As described, the discriminatory treatment of LGBT people too often occurs in the name of religion. When it does, that religious reinforcement of anti-LGBT bias often increases the mental health impacts of discrimination.⁶⁰

Since the 2010 Lambda Legal survey, other studies have similarly documented the disparities faced by LGBT people seeking health care. For example, *The Report of the 2015 U.S. Transgender Survey*, a survey of nearly 28,000 transgender adults nationwide, found that 33 percent "of respondents who had seen a health care provider in the past year reported having at least one negative experience related to being transgender, such as verbal harassment, refusal of treatment, or having to teach the health care provider about transgender people to receive

⁵² Id. at 11.

⁵³ Id.

⁵⁴ Id. at 12.

⁵⁵ Id. at 5-6.

⁵⁶ Id. at 15-16.

⁵⁷ Id. at 12-13.

⁵⁸ Id. at 6, 8, 12-13.

⁵⁹ Id. at 2.

⁶⁰ Ilan H. Meyer et al., The Role of Help-Seeking in Preventing Suicide Attempts among Lesbians, Gay Men, and Bisexuals, Suicide & Life Threatening Behavior, 8 (2014), http://www.columbia.edu/~im15/papers/meyer-2014-suicide-and-life.pdf ("[A]lthough religion and spirituality can be helpful to LGB people, negative attitudes toward homosexuality in religious settings can lead to adverse health effects") (internal citations omitted).



appropriate care" and that "23% of respondents did not see a doctor when they needed to because of fear of being mistreated as a transgender person[.]"61

The Center for American Progress in 2017 conducted another nationally representative survey with similar results about LGBT health disparities, including findings that:

Among lesbian, gay, bisexual, and queer (LGBQ) respondents who had visited a doctor or health care provider in the year before the survey:

8 percent said that a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation.

6 percent said that a doctor or other health care provider refused to give them health care related to their actual or perceived sexual orientation.

7 percent said that a doctor or other health care provider refused to recognize their family, including a child or a same-sex spouse or partner.

9 percent said that a doctor or other health care provider used harsh or abusive language when treating them.

7 percent said that they experienced unwanted physical contact from a doctor or other health care provider (such as fondling, sexual assault, or rape).⁶²

Among transgender people who had visited a doctor or health care providers' office in the past year:

29 percent said a doctor or other health care provider refused to see them because of their actual or perceived gender identity.

12 percent said a doctor or other health care provider refused to give them health care related to gender transition.

23 percent said a doctor or other health care provider intentionally misgendered them or used the wrong name.

⁶¹ James et al., supra n. 45, at 93.

⁶² Mirza & Rooney, supra n. 45.



21 percent said a doctor or other health care provider used harsh or abusive language when treating them.

29 percent said that they experienced unwanted physical contact from a doctor or other health care provider (such as fondling, sexual assault, or rape).⁶³

Independently of our own and others' research studies, Lambda Legal has become distressingly aware of the nature and scope of the discrimination problem from our legal work and requests for assistance received by our Legal Help Desks. We have repeatedly submitted information about the pattern of religion-based refusals of medical care to LGBT people in response to HHS requests. For example, in our 2013 response to the Request For Information for Section 1557 of the ACA, we documented numerous cases in which health professionals had denied medical care or otherwise discriminated against LGBT people and/or people living with HIV, based on the professionals' personal religious views, including:

- Guadalupe "Lupita" Benitez was referred for infertility care to North Coast Women's Care Medical Group, a for-profit clinic that had an exclusive contract with Benitez's insurance plan. After eleven months of preparatory treatments, including medication and unwarranted surgery, Lupita's doctors finally admitted they would not perform donor insemination for her because she is a lesbian. The doctors claimed a right not to comply with California's public accommodations law due to their fundamentalist Christian views against treating lesbian patients as they treat others. In a unanimous decision, the California Supreme Court held that religious liberty protections do not authorize doctors to violate the civil rights of lesbian patients. North Coast Women's Care Med. Grp., Inc. v. San Diego Cnty. Superior Court (Benitez), 189 P.3d 959 (Cal. 2008)
- Counseling student's objections to providing relationship counseling to samesex couples. Keeton v. Anderson-Wiley, 664 F.3d 865 (11th Cir. 2011) (finding student unlikely to prevail on free speech and religious liberty claims challenging her expulsion from counseling program due to her religiously based refusal to counsel same-sex couples, contrary to professional standards requiring nonjudgmental, nondiscriminatory treatment of all patients).
- Physician's objection to working with an LGB person. Hyman v. City of Louisville, 132 F. Supp. 2d 528, 539-540 (W.D. Ky. 2001) (physician's religious beliefs did not exempt him from law prohibiting employment discrimination based on sexual orientation or gender identity), vacated on other grounds by 53 Fed. Appx. 740 (6th Cir. 2002).

⁶³ Id.



- Proselytizing to patients concerning religious condemnation of homosexuality.
 Knight v. Connecticut Dep't of Pub. Health, 275 F.3d 156 (2d Cir. 2001) (rejecting free exercise wrongful termination claim of visiting nurse fired for antigay proselytizing to home-bound AIDS patient).
- Refusal to process lab specimens from persons with HIV. Stepp v. Review Bd. of Indiana Emp. Sec. Div., 521 N.E.2d 350, 352 (Ind. 1988) (rejecting religious discrimination claim of lab technician fired for refusing to do tests on specimens labeled with HIV warning because he believed "AIDS is God's plague on man and performing the tests would go against God's will").⁶⁴

In addition, testimonies received in Lambda Legal's health survey describe similar encounters with health professionals who felt free to express their religiously grounded bias toward LGBT patients:

- Kara in Philadelphia, PA: "Since coming out, I have avoided seeing my primary physician because when she asked me my sexual history, I responded that I slept with women and that I was a lesbian. Her response was, 'Do you know that's against the Bible, against God?" 65
- Joe in Minneapolis, MN: "I was 36 years old at the time of this story, an out gay man, and was depressed after the breakup of an eight-year relationship. The doctor I went to see told me that it was not medicine I needed but to leave my 'dirty lifestyle.' He recalled having put other patients in touch with ministers who could help gay men repent and heal from sin, and he even suggested that I simply needed to 'date the right woman' to get over my depression. The doctor even went so far as to suggest that his daughter might be a good fit for me." 66

Lambda Legal documented additional recent examples of health care denials or discriminatory treatment in its amicus brief to the Supreme Court in *Masterpiece Cakeshop v. Colorado Civil Rights Commission*, ⁶⁷ including the following two Lambda Legal cases:

Lambda Legal client Naya Taylor, a transgender woman in Mattoon, Illinois, who
sought hormone replacement therapy (HRT), a treatment for gender dysphoria, from the
health clinic where she had received care for more than a decade. When her primary
care physician refused her this standard treatment, clinic staff told her that, because of

⁶⁴ Lambda Legal Nondiscrimination Comments (citations partially omitted).

⁶⁵ Id.

⁶⁶ Id.

⁶⁷ See Brief of Amici Curiae Lambda Legal et al., Masterpiece Cakeshop Ltd. v. Colorado Civil Rights Comm'n, No. 16-111, at 11-14, 17-18, 26, 30 (filed Oct. 30, 2017), https://www.lambdalegal.org/in-court/cases/masterpiece-cakes-v-co-civil-rights-commission.



the religious beliefs of the clinic's doctors, they do not have to treat "people like you."68

 Lambda Legal client Jionni Conforti, who was refused a medically necessary hysterectomy despite his treating physician's desire to perform the surgery. The hospital where the surgeon had admitting privileges was religiously affiliated and withholds permission for all gender transition-related care.⁶⁹

These examples are just a tip of the iceberg, a few of many incidents across the country in which religion has been used to justify denial of health care or other discrimination against LGBT people and people living with HIV. Although courts consistently have rejected such reliance on religion to excuse discrimination, examples of religion-based discrimination in health care continue to occur with regularity. This mistreatment contributes to persistent health disparities, including elevated rates of stress-related conditions.

Given this landscape, Lambda Legal is deeply concerned that this Proposed Rule, designed to protect and even encourage religious refusals of health care, inevitably will facilitate further discrimination by health professionals in contexts involving sexual orientation, gender identity, or HIV status. As a result, the health of patients across the country, as well as others, would be at risk, and "conscience" claims could too easily become a way for providers to turn away LGBT patients. The past examples of religiously-based discrimination indicate there is significant likelihood that too-many individual and institutional care providers will demand exemptions from rules and standards designed to ensure that patients receive proper treatment regarding the following needs:

- Treatment of patients who need counseling, hormone replacement therapy, gender confirmation surgeries, or other treatments for gender dysphoria.
- For patients with a same-sex spouse or who are in a same-sex relationship, bereavement
 counseling after the loss of a same-sex partner or other mental health care that requires

⁶⁸ In April 2014, Lambda Legal filed a claim of sex discrimination on Ms. Taylor's behalf under Section 1557 of the ACA; however, Ms. Taylor subsequently passed away and her case was voluntarily dismissed. See Complaint, Taylor v. Lystila, 2:14-cv-02072-CSB-DGB (C.D. III., Apr. 15, 2014), available at https://www.lambdalegal.org/in-court/legal-docs/taylor_il_20140416_complaint.

⁶⁹ See Conforti v. St. Joseph's Healthcare Sys. (D. N.J. filed Jan. 5, 2017) case documents at https://www.lambdalegal.org/in-court/cases/nj-conforti-v-st-josephs. See also Amy Littlefield, Catholic Hospital Denies Transgender Man a Hysterectomy on Religious Grounds, Rewire.News, Aug. 31, 2016, https://rewire.news/article/2016/08/31/catholic-hospital-denies-transgender-man-hysterectomy-on-religious-grounds/.

Nee Lambda Legal 1557 Comments; Brief of Amici Curiae Lambda Legal et al., Zubik v. Burwell, 136 S. Ct. 1557 (2016).

⁷¹ See Mark Hatzenbuehler, Structural Stigma: Research Evidence and Implications for Psychological Science, 71 AM. PSYCHOLOGIST, 742, 742–51 (2016), http://dx.doi.org/10.1037/amp0000068; IOM Report, supra n. 45.



respectful acknowledgment of a person's sexual orientation or gender identity.

- Care for patients living with HIV, including the option of pre-exposure prophylaxis (PrEP), a highly effective medication that dramatically reduces the risk of HIV infection among those who are otherwise at high risk, including people who are in a sexual relationship with a partner who is living with HIV.
- Treatment of patients who are unmarried or in a same-sex relationship and require infertility treatment or other medical services related to pregnancy, childbirth or pediatric needs.

In addition, the Proposed Rule threatens to undermine the community's trust in health care providers. Although there may be health care facilities that remain safer places for patients who face increased risk of discrimination in health care facilities, those facilities that are more welcoming of LGBT patients and patients seeking HIV care and willing to provide them with full health care access will become overburdened and increasingly unable to meet the needs of all who come through their doors.

If the number of health care facilities that LGBT people can feel comfortable going to, knowing they won't be turned away is reduced as the inevitable result of this Proposed Rule, access to health care will become harder, and nearly impossible for some, who, for example, are low income⁷² or who live in remote areas and cannot travel long distances for medical care. Patients seeking more specialized care such as infertility treatments or HIV treatment or prevention are already often hours away from the closest facility. The Proposed Rule threatens to build even greater barriers between those who are most vulnerable and the health care they need.

For the Proposed Rule to transform the role of HHS from an agency focused on ensuring nondiscriminatory provision of health care to one that facilitates refusals of care is a disturbing about-face contrary to the Department's mission and authorizing statutes. Its failure to explain how the enhanced powers of health care providers to refuse patient care in the name of "conscience" should be reconciled with the protections for patients under the ACA and other statutes, and for employers under Title VII, make clear that this proposal is legally untenable as well as unjustifiably dangerous as a matter of federal health policy.

VI. The Proposed Rule Is The Result Of A Rushed, Truncated Process Contrary To The Department's Mission And Inconsistent With Procedural Requirements.

Considering the well-recognized health disparities and difficulty obtaining nondiscriminatory care that already confront the LGBT community, the Proposed Rule's apparent goal of inviting more discrimination and care denials to LGBT people and is peculiar

⁷² Contrary to some misperceptions, LGBT people and people living with HIV are disproportionately economically disadvantaged. See, e.g., M.V. Lee Badgett et al., New Patterns of Poverty in the Lesbian, Gay, and Bisexual Community, WILLIAMS INST. (June 2013), https://williamsinstitute.law.ucla.edu/research/census-lgbt-demographics-studies/lgbt-poverty-update-june-2013.



and alarming. Indeed, the lack of concern for the Proposed Rule's inevitable impacts is especially shocking because this Department itself has conducted studies revealing disparities in LGBT health outcomes. As reported in the 2014 National Health Statistics Reports:

[R]ecent studies have examined the health and health care of lesbian, gay, and bisexual (LGB) populations and have found clear disparities among sexual minority groups (i.e., gay or lesbian and bisexual) and between sexual minorities and straight populations. These disparities appear to be broad-ranging, with differences identified for various health conditions (e.g., asthma, diabetes, cardiovascular disease, or disability) ... health behaviors such as smoking and heavy drinking ... and health care access and service utilization Across most of these outcomes, sexual minorities tend to fare worse than their nonminority counterparts. 73

Thus, in addition to the legal and ethical conflicts it would generate, the Proposed Rule also would undermine HHS's national and local efforts to reduce LGBT health disparities. For example, this Department's "Healthy People 2020 initiative" and the Institute of Medicine have called for steps to be taken to address LGBT health disparities" medical associations including the American Medical Association, the Association of American Medical Colleges, the American College of Physicians, the American Psychiatric Association, and others are committed to improving medical care for LGBT people through education and cultural competency training; and legislation is increasingly being considered and passed to improve LGBT health access and reduce health disparities. The Proposed Rule endangers the important progress made on this front.

With this Department's past focus on addressing LGBT health disparities, it would be a bizarre and disturbing reversal of course for HHS now to become an active participant in the very denials of health care and discriminatory treatment that cause these disparities. Years of careful study and deliberation went into framing the protections against discrimination implemented pursuant to Section 1557 of the ACA, including the explicit protections against gender identity discrimination and other forms of sex discrimination and the accompanying

Prian W. Ward et al., Sexual Orientation and Health Among U.S. Adults: National Health Interview Survey, 2013, Nat'l Health Statistics Report No. 77, 1, (July 15, 2014), https://www.cdc.gov/nchs/data/nhsr/nhsr077.pdf.

⁷⁴ Dep't of Health & Human Servs., Healthy People 2020: LGBT Health Topic Area (2015), http://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health; IOM Report.

⁷⁵ See Timothy Wang et al., The Fenway Inst., The Current Wave of Anti-LGBT Legislation: Historic Context and Implications for LGBT Health at 6, 8-9 (June 2016), http://fenwayhealth.org/wp-content/uploads/The-Fenway-Institute-Religious-Exemption-Brief-June-2016.pdf.



value statement that "HHS supports prohibiting sexual orientation discrimination as a matter of policy[.]" 76

In addition, the Proposed Rule has been issued without adequate time spent considering the thousands of comments submitted on related proposals. It lacks acknowledgment of countervailing interests of patients and many health provider institutions, let alone any explanation of how those interests are to be reconciled with the proposed aggressive enforcement of inconsistent religious interests. All in all, the Department's process has been arbitrary, capricious, and dangerous. ⁷⁷ Consequently, along with its numerous other legal infirmities, it also violates the Administrative Procedure Act. ⁷⁸

VII. Conclusion

The Proposed Rule would have a chilling effect on the full and unbiased provision of health care, including to members of the LGBT community and everyone living with HIV, in a manner that conflicts with ethical, legal, and constitutional standards. While freedom of religion is a fundamental right protected by our Constitution and federal laws, it does not give anyone the right to use religious or moral beliefs as grounds for violating the rights of others. Instead, the Constitution commands that any religious or moral accommodation must be "measured so that it does not override other significant interests" or "impose unjustified burdens on other[s]." Indeed, when the Supreme Court addressed the related question in *Burwell v. Hobby Lobby Stores, Inc.*, it explained that a religious accommodation should be provided in that case because the impact on third parties would be "precisely zero." 80

Here, the Proposed Rule conflicts with statutory rights of health care providers to operate with reasonable efficiency and cost, and within their ethical obligations to care for patients according to professional standards. Most importantly, it also conflicts with legal and ethical protections for patients, potentially putting their health and even lives at risk. It is ill conceived and has no place in federal health policy.

⁷⁶ Press Release, U.S. Dep't of Health & Human Servs., HHS Finalizes Rule to Improve Health Equity Under the Affordable Care Act (May 13, 2016), https://wayback.archive-it.org/3926/20170127191750/https://www.hhs.gov/about/news/2016/05/13/hhs-finalizes-rule-to-improve-health-equity-under-affordable-care-act.html.

^{77 5} U.S.C.A. § 706(2)(a).

^{78 5} U.S.C.A. § 500 et seq.

⁷⁹ Cutter v. Wilkinson, 544 U.S. 709, 722, 726 (2005).

⁸⁰ 134 S. Ct. 2751, 2760 (2014). Indeed, every member of the Court, whether in the majority or in dissent, reaffirmed that the burdens on third parties must be considered. See id at 2781 n. 37; id. at 2786–87 (Kennedy, J., concurring); id. at 2790, 2790 n. 8 (Ginsburg, J., joined by Breyer, Kagan, and Sotomayor, JJ., dissenting).



For the foregoing reasons, we emphatically recommend that the Department set aside this Proposed Rule.

Most respectfully,

LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.

Jennifer C. Pizer, Senior Counsel and Director of Law and Policy jpizer@lambdalegal.org

Nancy C. Marcus, Senior Law and Policy Attorney nmarcus@lambdalegal.org 4221 Wilshire Blvd., Suite 280 Los Angeles, CA 90010 Sasha Buchert, Staff Attorney sbuchert@lambdalegal.org 1875 I Street, NW, 5th Floor Washington, DC 20006

Exhibit 99

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 Proposed Rule, "Protecting Statutory Conscience Rights in HealthCare, Department of Health and Human Services, Office for Civil Rights RIN 0945-ZA03

To whom it may concern:

This comment is in response to the Proposed Rule, "Protecting Statutory Conscience Rights in HealthCare; Delegations of Authority" for the Department of Health and Human Services, Office for Civil Rights RIN 0945-ZA03.

This comment is provided on behalf of the LGBT Community Advisory Board of Washington, DC. The LGBT Community Advisory Board is comprised of members of the Washington, DC metropolitan community who wish to support research and education toward the advancement of lesbian, gay, bisexual, transgender, queer and intersex health in our region.

This comment commends certain clauses in the "ESTIMATED BENEFITS" provision of the Proposed Rule, however, not as they are currently intended to be interpreted. Specifically, we agree that "in **supporting a more diverse medical field, the proposed rule would create ancillary benefits for patients...a society free from discrimination**..." Securing a diverse health care professional workforce is critical to ensure that children and adults from all racial, ethnic, sexual and gender minority, socioeconomic, religious and geographic backgrounds see role models in their health care providers that reflect their cultures, preferences and values and to ensure that the highest quality health care is provided to all. Health care professionals currently do not reflect the racial, ethnic, sexual, gender, and religious diversity of Americans in need of health care services.

The Proposed Rule as it is written is troublesome in several ways. **Most** concerning is a lack of balance between protections of health care professionals and the patients they serve. A patient enters into a relationship with a health care professional for certain services that affect the life and health of the patient. Historically, rules of conscience protecting health care providers have been limited to performing direct and highly controversial procedures such as

abortion and sterilization. This proposed rule goes much farther in allowing health care providers to refuse appointment scheduling, ancillary services, symptom relief or other services to a woman who has recently had an abortion: this is detrimental to the health and life of the patient. The proposed rule suggests that any action, even if tangential to a health care service, could be refused on the basis of moral conviction. Refusing to provide a referral to any individual in need of health care services on the basis of religion is in direct violation of the Hippocratic Oath.

Lesbian, gay, bisexual, transgender, queer and intersex individuals already face discrimination in the health care system and denial of care. This proposed rule exacerbates an already unequal system and widens health disparities to privilege those with the most power at the expense of those with the least. The broad scope of the Proposed Rule could lead health care providers to discriminate against patients for any health service, simply because the health care professional claims to have a moral reason to do so. This could prevent protected classes of people, based on race, ethnicity, nationality, sexual orientation, gender identity, religion or other reasons from receiving lifesaving services and/or services critical to quality of life simply because the health care provider objects to providing care to that patient.

Specifically, we are concerned that the proposed rule could prevent health care services that patients have a right to and deserve, including:

- Access to birth control and family planning
- In vitro fertilization for lesbian and gay couples and/or transgender persons
- Treatment for individuals with HIV/AIDS
- Hormone replacement therapy and indicated gender-affirming surgical interventions for transgender individuals
- End of life care
- Basic health care for any sexual or gender minority to whom a health care provider states a moral objection to treating for any reason.

These risks are not hypothetical. In the 2017 federal case Conforti v. St. Joseph's Healthcare System, a transgender man was denied a medically indicated hysterectomy; a Catholic hospital refused his surgery on the basis of his gender. In another documented case, a pediatrician refused care of an infant based on the sexual orientation of the child's parents. In another recent case, a patient with HIV was refused medication by a hospital. Another hospital discharged a transgender teen admitted for suicidal ideation who ended up completing suicide. Approximately, 29% of transgender people in a 2017 survey reported being refused basic health care simply because of their gender identity and a similar percentage were assaulted in medical settings.

Furthermore, health insurance coverage for any sexual or gender minority, racial/ethnic minority, religious minority or any other person could be compromised or completely lost in order to cater to a stated religious or moral belief of a health

¹ Baldas, T. (2015). Pediatrician wouldn't care for baby with 2 moms. Detroit Free Press. Available at https://www.freep.com/story/news/local/michigan/macomb/2015/02/18/discrimination-birth/23640315/

insurance executive or employee, clearly creating discrimination toward those with fewer financial resources in order to protect those with greater financial resources. Health insurance providers have, in fact, already refused coverage for infertility treatment to lesbian women while covering the same services for straight women.²

Protecting health professionals from referring patients to services in order to protect the "conscience" of the provider will result in the loss of life and health for patients. Patients attend clinics, hospitals and Emergency Rooms with the expectation of receiving needed health care services based on their individual symptoms. Not providing these citizens with health care aligned with their health needs because of a claim to right of conscience laws is akin to a police officer not protecting an individual about to be shot, a teacher refusing to teach a child or a lawyer refusing to defend an innocent citizen due to bias developed, taught or learned over time.

Refusing health care services is not a benign action. In a 2017 survey, 41% of lesbian, gay, bisexual, transgender and queer people who reside in non-urban settings indicated that it would be "very difficult" or impossible" to find health care elsewhere if not provided by their local hospital. Thus deciding not to provide a needed health care service may be the difference between care and no care, or even life and death for some patients.

Additionally, protecting parental religious beliefs is important. However, balance between parent beliefs and children's health is warranted. Vaccinations, provision of mental health services and **basic medical care should not be out of reach of children** due to parental beliefs.

Furthermore, the threat of withholding funding to organizations reliant on federal funds, such as grantees, due to potential conflicts of moral conscience impedes science, creates obstacles to limiting the spread of communicable diseases and stirs confusion among those working daily to advance the health of Americans.

Overall, the Proposed Rule invites conflicts between the rights of health care professionals and patients as well as between health care professionals and their employing organizations. Such broad-sweeping and vague language will create a litigious system where patients avoid and delay care due to perceived or actual discrimination and health care organizations err on the side of executives and employees over patient care.

The Proposed Rule clearly violates Title VII of the Civil Rights Act by inviting discrimination of individuals whom the Department of Health and Human Services has an obligation to protect. It should be substantially revised

Reuters. (2016), Lesbians sue New Jersey for discrimination over infertility law. NBC News. Available at https://www.nbcnews.com/feature/nbc-out/lesbians-sue-new-jersey-discrimination-over-infertility-law-n628216 ³ Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtg-peopleaccessing-health-care.

to narrow specifically what services a health care professional can legally refuse to a patient and in what context while ensuring alternative and expeditious health care services for those in need of health care and ancillary services--including those with gender dysphoria and any racial, ethnic, sexual, gender, religious or other minority in need of health care services for any reason.

Submitted by the following groups and individuals,

The LGBT Community Advisory Board, Washington, DC

Mandi Pratt-Chapman, citizen of Alexandria, VA

Rachelle Tepel, citizen of Arlington, VA

Joshua Riley, citizen of Cheverly, MD

Tony Burns, citizen of Washington, DC

Audra Campbell, citizen of the DC metropolitan area

Sean Randolph, citizen of the DC metropolitan area

Sherry Davis Molock, Ph.D., M.Div. Pastor, Beloved Community Church, Accokeek, MD

Robin Lewis, Outreach and Social Justice Ministry Director, Beloved Community Church, Accokeek, MD

Exhibit 101



March 27, 2018

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

Re: Docket No.: HHS- OCR - 2018—0002, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority; Proposed Rule issued January 26, 2018

Dear Mr. Severino:

The Massachusetts Health & Hospital Association (MHA), on behalf of its member hospitals, health systems, physician organizations, and allied healthcare providers appreciates this opportunity to offer comments related to the Department of Health and Human Services (HHS) Office for Civil Rights' (OCR) proposed rule regarding certain statutory conscience protections.

At the outset it is important to note that the Massachusetts provider community has consistently worked with our medical staff to ensure that personal views that are raised and discussed within various levels of care are respected as they relate to providing care and treatment of our patients and our communities that we serve. The adoption of the conscience protections for health care professionals within the federal affordable care act was similar to requirements that have been adopted within both Massachusetts statues as well as healthcare licensure requirements. In particular, healthcare providers have had the ability to raise religious concerns related to care and treatment, during which the facility or clinic will work with the provider to determine how to accommodate those concerns as well as ensure continued care and treatment for the patients.

However, the Massachusetts provider community also has a strong commitment to ensuring that all patients are able to access emergent, urgent, and medically necessary care. In Massachusetts, it is standard policy for all hospitals and health system to not discriminate in the delivery of emergent, urgent, and medical necessary care on the basis of the patient's race, color, national origin, citizenship, alienage, religion, creed, sex, sexual orientation, gender identity, age, or disability. As a result, we are concerned about possible conflicts that may result in the enforcement of the proposed regulations by OCR given conflicting state laws and regulations. To that end, we provide the following comments for consideration by OCR to reflect hospital and other healthcare provider's obligations under specific state requirements.

OCR Enforcement of Provider Conscience Rights:

While MHA and our members are considerate of a healthcare provider's ability to determine the medical necessity and treatment options for patients, hospitals and health system also recognize the individual clinician's religious rights (as their conscience rights) related to participating in various care and treatment.

MHA Comment Letter: Docket No.: HHS- OCR - 2018-0002

Page 1



In keeping with the principle that the conscience (or religious) protections should be treated akin to an individuals' civil rights, MHA urges OCR to ensure that the enforcement policies and practices applicable to the conscience protections are comparable to the long-standing policies and practices applicable when guaranteeing other civil rights protections for employees and staff. OCR should not invent new, distinct, or additional policies and practices that add unnecessary complexity and burden or prefer conscience protections over other civil rights.

Specifically, OCR should use existing civil rights frameworks as the model for the conscience protections at issue, such as evaluating facts and circumstances to determine whether a hospital has done all it reasonably can to accommodate religious conscience objections of individual medical staff. This not only would place the conscience protections on a level playing field with other civil rights, but would ensure that the conscience protections are guaranteed through an enforcement framework that already has proven effective in analogous civil rights contexts. We would urge not sanctioning a healthcare provider (the hospital or health care system) for failing to accommodate the moral or religious beliefs of an employee or medical staff where, despite being on notice of his or her right to do so, the individual did not give the hospital or health care system advance notice of his or her religious beliefs.

Again it is important to note that under existing federal and state laws/regulations, healthcare facilities already provide reasonable accommodation for employees who disclose their sincerely held religious beliefs. This type of framework has successfully protected employees, including those of hospitals and health systems, from religious discrimination. For this reason we would urge OCR to keep the framework for review based on the requirement of reasonably accommodating the sincerely held religious beliefs of employees and medical staff. The regulation should not be expanded to include moral objections without creating a framework for considering such concern that is not based on existing state laws or regulations.

Conflict with Existing Provider Licensure and Standards of Care:

We would also strongly urge OCR to consider the current requirements that healthcare providers have under existing Centers for Medicare and Medicaid Services (CMS) conditions of participation as well as other federal and state requirements. There are specific requirements related to the delivery of care and treatment for all patients by a provider who is receiving federal and state funding through Medicare, state Medicaid programs (like the Massachusetts MassHealth program), and the Social Security Act. More specifically, Massachusetts providers are required under state law and regulations to meet specific access requirements for low income patients under the Health Safety Net program. In addition state licensure requirements for a facility and individual professional licensure requirements also stipulate the care and treatment of a patient regardless of their race, color, national origin, citizenship, alienage, religion, creed, sex, sexual orientation, gender identity, age, or disability.

We strongly urge OCR to recognize the potential conflicting requirements under existing federal and state laws and regulations that would prevent the enforcement of a provider conscience regulation as outlined in the draft regulations. If strictly enforced as drafted, we are also concerned that many providers would be out of compliance with the requirements outlined above

MHA Comment Letter: Docket No.: HHS- OCR - 2018-0002



impacting provider eligibility for reimbursement under the federal and state public programs. For these reasons we urge OCR to consider the government's interests in not only ensuring fundamental fairness but also avoiding inappropriate disruption of health services that are funded by federal and state resources.

Increase of Unnecessary Regulatory Burdens:

In the proposed rule, MHA would also request OCR to consider the increased regulatory burdens of both the certification of compliance as well as the proposed notice requirements.

Healthcare providers, such as hospitals and health systems, already have to sign cost reports and other documents with CMS that indicate that the facility is in compliance with all applicable federal rules and regulations. These include applicable civil rights laws, access to care standards, and operational requirements issued by a multitude of federal Health and Human Services (HHS) agencies. The provider community strongly feels that in addition to the four stated exceptions for providing compliance with the regulations, providers should also be able to utilize existing certification requirements that express the facilities adherence to federal regulatory requirements under HHS. Requiring a detailed analysis and certification for this specific rule may result in the slippery slope of requiring similar certifications for all other rules and requirements issued by HHS. This would add to the overall paperwork burden and unnecessary use of resources by providers that should be focused on patient care.

MHA is also opposed to the requirement of having a separate HHS notice requirement. Hospitals in particular are already required to provide a multitude of forms and notices to patients when they arrive for services (inpatient or outpatient) that create substantial confusion for patients and caregivers. We would strongly urge that COR instead allow providers to use those notices that are developed in various states that take into consideration the key messages of the provider conscience religious considerations, but tailored to each state specific standards. Adding in additional notice requirements that are contradictory to the state requirements is confusing to patients which lead to delays in care. In addition, duplicative notifications increase costs in signage, postage, and other materials. So we urge OCR to reconsider their approach and allow notices to be based on state specific requirements.

Thank you for considering our comments. Should you have any questions about the points raised in this letter, please do not hesitate to contact me at (781) 262-6034 or agoel@mhalink.org.

Sincerely,

Anuj K. Goel, Esq.

Contin

Vice President, Legal and Regulatory Affairs

MHA Comment Letter: Docket No.: HHS- OCR - 2018-0002

Exhibit 103



March 23, 2018

HENRY L. DORKIN, MD, FAAP President

ALAIN A. CHAOUI, MD, FAAFP President-Elect

MARYANNE C. BOMBAUGH, MD, MSc, MBA, FACOG Vice President

COREY E. COLLINS, DO, FAAP Secretary-Treasurer

JOSEPH C. BERGERON, JR., MD, FCAP Assistant Secretary-Treasurer

DAVID A. ROSMAN, MD, MBA Speaker

FRANCIS P. MACMILLAN, JR., MD, FACG Vice Speaker

LOIS DEHLS CORNELL Executive Vice President The Honorable Alex Azar Secretary U.S. Department of Health and Human Services Hubert H. Humphrey Building 200 Independence Avenue SW Washington, D.C., 20201

Re: 45 CFR Part 88; HHS-OCR-2018-0002; RIN 0945-ZA03

Dear Secretary Azar:

I am submitting the following comments on behalf of the 25,000 physicians, residents and medical students of the Massachusetts Medical Society (MMS) in response to the notice of proposed rulemaking "Protecting Statutory Conscience Rights in Health care, Delegations of Authority." 45 CFR, Part 88, HHS-OCR-2018-0002; RIN 0945-ZA03. As the following comments detail, the MMS is strongly opposed to these proposed rules, which would undermine the basic tenets of a physician's oath to provide care to all patients.

The proposed rule would expand the ability of individuals and entities in health care settings to elect not to participate in activities that they deem contrary to their religious and/or moral beliefs. It would also make the Office of Civil Rights (OCR) responsible for the oversight and enforcement of complaints made on those grounds.

The MMS recognizes the importance and value of allowing physicians and other clinicians not to participate in interventions that they personally feel to be immoral; however, existing "conscience clauses" encoded in state law, federal statutes, institutional policies, and professional societies policies—including the policies of the MMS—already provide such protections.

If passed, this proposed rule would therefore create a problem where none exists, and would exacerbate an existing one. In explaining the grounds for this proposed rule, the OCR has cited a recent increase in complaints from clinicians who claim to have been compelled to participate in interventions to which they were morally opposed. However, the number of such claims—36 complaints in a three-month period—is so modest as to suggest that existing mechanisms to protect physicians are operating as well as could reasonably be expected. iii

The proposed rule would expand the already sufficient provisions far beyond the scope needed to protect the religious freedom of clinicians, and in so doing, would further jeopardize vulnerable patients' access to health care. Discrimination towards patients is a significant issue under the current system: in 2017, the OCR received over 30,000 complaints on behalf of patients on the basis of discrimination and/or privacy violations. If the proposed rules are adopted, even more patients will face discrimination in healthcare.

860 WINTER STREET

WALTHAM, MA 02451-1411

TEL (781) 893-4610

TOLL-FREE (800) 322-2303

FAX (781) 893-9136

WWW.MASSMED.ORG

The Honorable Alex Azar March 23, 2018 Page Two

The MMS has long held anti-discriminatory policies affirming the rights of all patients to evidence-based health care. Specifically, our policy states that the MMS "strongly supports the rights of individuals to health, happiness, and liberty regardless of sexual orientation, gender identity, or nationality, and urges all governments to recognize these rights." Physicians have a fundamental duty to care for all patients.

If this rule were enacted as written, it would erode the essential right to care for already disadvantaged patient populations, including but not limited to patients on the LGBTQ spectrum—particularly transgender patients—and patients seeking abortion services. The rule could also have negative public health consequences on a population level. We are concerned that a misreading of this policy could lead to consequences such as clinicians being punished for refusing to treat patients who are not vaccinated due to religious beliefs; decreases in school immunization rates; undermining of public health efforts to protect children against vaccine preventable diseases; and interference with hospital programs which require healthcare workers to be immunized against influenza.

Furthermore, the proposed rule contravenes the intent upon which protections to religious freedom are based. The fundamental right underlying religious tolerance is the right to freedom from discrimination on the basis of religion. Encouraging discrimination against vulnerable patient populations by warping religious freedom protections for clinicians is an affront to the principles on which religious freedom is fundamentally based.

As physicians, we have an obligation to ensure patients are treated with dignity while accessing and receiving the best possible care to meet their clinical needs. We will not and cannot, in good conscience, compromise our responsibility to heal the sick based upon a patient's racial identification, national or ethnic origin, sexual orientation, gender identity, religious affiliation, disability, immigration status, or economic status. In view of this, the Massachusetts Medical Society opposes this current rulemaking. We look forward to working with you on other issues to help improve the health and welfare of our patients and physicians who serve them.

Sincerely,

Henry L. Dorkin, MD, FAAP

https://www.thehastingscenter.org/briefingbook/conscience-clauses-health-care-providers-and-parents/#

http://www.massmed.org/Governance-and-Leadership/Policies,-Procedures-and-Bylaws/MMS-Policy-Compendium-(pdf)/

See policies on "Medical Education/Performing Procedures" and "Abortion"

https://khn.org/news/at-new-health-office-civil-rights-means-doctors-right-to-say-no-to-patients/

https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf

Exhibit 104



March 27, 2018

VIA ELECTRONIC SUBMISSION

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

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

The Medicare Rights Center (Medicare Rights) appreciates the opportunity to comment on the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority." We are concerned that this rule would put people with Medicare at risk of lacking access to medically necessary treatment and information they need to make educated, personcentered choices. Medicare beneficiaries, their families, and caregivers need to know their medical needs and choices will be honored within the Medicare program and the health care system as a whole.

Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Each year, Medicare Rights provides services and resources to over three million people with Medicare, family caregivers, and professionals.

The Department of Health and Human Services ("HHS" or "the Department") has introduced this NPRM in an effort to ensure that the religious and conscience rights of medical providers and practitioners are not infringed. While Medicare Rights respects the exercise of such conscience rights, we have serious concerns with the proposed rule, including how the rule fails to balance the potential conflict between providers' conscience rights and the rights of citizens to access needed heath care without discrimination or undue barriers, the potential implications for emergency care, and the need for informed choice and transparency.

Below, please find our comments on (1) Balancing Rights, (2) Emergency Care, and (3) Informed Choice and Transparency.

Balancing Rights

We are very concerned that the proposal fails to address two vital things: (1) How this rule will interact with existing federal and state laws that already protect sincerely held religious beliefs; and (2) How this rule will interact with the rights of patients. These omissions make uncertainty, confusion, and disorder surrounding the rights and obligations of patients, physicians, other health care providers, and health care institutions more likely, not less.

In the preamble, the Department states that the proposed rule is an attempt 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." While protecting those who provide health care from discriminatory policies that may force them to choose between their beliefs and their continued or future employment is an important goal, the right of a provider to conscientiously object is not absolute.

Rather, the rights of providers to conscientiously object must be balanced against the rights of patients to access the care and information they need, consistent with their own sincerely held conscience and religious beliefs. Here, the rule falls far short. It appears instead to prioritize the conscience rights of organizations and personnel at the expense of the needs and rights of patients to receive care and information that is appropriate, medically necessary, freely chosen, transparent, and person centered, and to which they are entitled under federal law.²

Patients are the reason health care exists. Ensuring that patients have the care they need, to the extent they want such care, must be the primary goal of any health care system. The proposed rule is silent on the needs of patients, including what disclosures must be made to them, how care can be ensured, or what remedies they will have if their rights are infringed. Given the rule's silence, it is hard to know if the proposal intends religious objections to take precedence over patient needs and rights.

Additionally, the proposal does not address the limitations necessarily placed on the implementation of this rule by Title VII of the Civil Rights Act of 1964, or the careful balance that Act creates between religious rights, beliefs, and practices, and the need for employers and institutions to serve people. This failure will cause confusion for providers as practitioners, and expose them to liability and uncertainty as employers.

Title VII already requires that employers accommodate employees' religious beliefs to the extent there is no undue hardship on the employer.³ Yet, the proposed regulations make no reference to Title VII, current Equal Employment Opportunity Commission (EEOC) guidance, or the extensive, controlling case-law interpreting these provisions and carefully balancing the rights of employers and employees under which an employer many not discriminate against an employee based on that employee's race, color, religion, sex, and national origin, but an employee must be able to perform

¹ NPRM at 3880, available at: https://www.gpo.gov/fdsys/pkg/FR-2018-01-26/pdf/2018-01226.pdf

² 42 U.S.C. § 1395w-22

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

the essential functions of the job.⁴ The proposed rule must ensure that the long-standing balance set in Title VII between the right of individuals to enjoy reasonable accommodation of their religious beliefs and the right of employers to conduct their businesses without undue interference is maintained.

While the proposal does identify "avoidance of undue burden on the health care industry" as a policy objective, that is limited to the newly proposed section 88.4 regarding assurance and certifications of compliance.⁵ Nowhere does it discuss, even in passing, the complex issues that will arise if employees or institutions cannot meet their obligations under existing employment, anti-discrimination, or provision-of-service law because of their conscientious objections.

As Title VII provides protection for individual beliefs while still ensuring employers can operate their businesses as they see fit, so too do other existing federal and state civil rights laws balance the religious and other rights of providers with the very real need to protect patients against discrimination—including the adverse consequences of health care refusals—based on a variety of characteristics, such as race, gender, sexual orientation, immigration status, disability, and HIV status.⁶

For example, the Medicare program places conditions of participation on providers and institutions, including requiring Medicare Advantage organizations to provide access to all of the benefits of the Medicare fee-for-service program⁷ and holding hospitals to "Conditions of Participation" to ensure that patients' rights are respected and that they received medically appropriate care.⁸ Troublingly, the proposed rule does not explore the interaction between its mandate and these kinds of existing protections.

Additionally, the proposed rule does not define "discrimination." This lack of clarity regarding what constitutes discrimination may undermine non-discrimination laws. Because of the potential harm to individuals if religious refusals were allowed, courts have long rejected arguments that religiously affiliated organizations can opt out of anti-discrimination requirements. Instead, courts have held that the government has a compelling interest in ending discrimination and that anti-

⁴NPRM at 3880.

⁵ NPRM at 3897.

⁶ See, e.g. Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172, 54,194 (Sept. 8, 2015) (codified at 45 C.F.R. pt. 2).

⁷ 42 U.S.C. § 1395w–22

⁸ 42 CFR 482.13 (b) (2) (The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. . . .

⁽³⁾ The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives)

⁹ See e.g., *Bob Jones Univ. v. United States*, 461 U.S. 574 (1983) (holding that the government's interest in eliminating racial discrimination in education outweighed any burdens on religious beliefs imposed by Treasury Department regulations); *Newman v. Piggie Park Enters., Inc.*, 390 U.S. 400 (1968) (holding that a restaurant owner could not refuse to comply with the Civil Rights Act of 1964 and not serve African-American customers based on his religious beliefs); *Dole v. Shenandoah Baptist Church*, 899 F.2d 1389, 1392 (4th Cir. 1990) (holding a religious school could not compensate women less than men based on the belief that "the Bible clearly teaches that the husband is the head of the house, head of the wife, head of the family"); *Hamilton v. Southland Christian Sch., Inc.*, 680 F.3d 1316 (11th Cir. 2012) (reversing summary judgment for religious school that claimed a religious right to fire teacher for becoming pregnant outside of marriage).

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

Illustrating how organizations or personnel will be able to abide by each of these laws and regulations as well as this proposal is an absolutely vital step in rulemaking—but this proposed rule fails to make these interactions clear. As a result, its expansive definitions and seemingly broad application leaves open the question of whether health care personnel or institutions could potentially refuse to provide some or all services to entire categories of patients.

Emergency Care

In addition to the need for more specificity regarding the general balance between individual conscience rights and patient needs, there is the issue of emergency care, which is expressly addressed in the Social Security Act.¹¹ Federal and state laws reflect the long-standing obligation of health care institutions to provide assessment and care in an emergency. The Emergency Medical Treatment and Labor Act (EMTALA), for example, requires hospitals to stabilize patients who come to the emergency room in medical emergencies.¹² Any final rule should clarify the interplay of conscience rights with physicians' and hospitals' legal obligations under EMTALA.

It is concerning, then, that the proposed rule does not just avoid discussion of these legal obligations; it appears to suggest there should be no obligation to provide care in an emergency situation. In the preamble, the Department gives several reasons for this proposed rule, the first being that "allegations and evidence of discrimination and coercion have existed since 2008 and increased over time." ¹³

To support this claim, the Department states that the previous rule was promulgated to address "an environment of discrimination toward, and attempted coercion of, those who object to certain health care procedures based on religious or moral convictions" and that rescinding the guidance has allowed this discriminatory environment to prosper. ¹⁴ As evidence of this growing trend, the Department cites regulatory comments, lawsuits, news reports, and polling data.

In this discussion, the Department also points to the American Congress of Obstetricians and Gynecologists (ACOG) 2016 reaffirmation of an ethics document as confirmation of the aforementioned "environment of discrimination" toward health care providers. ¹⁵ The referenced

¹⁰ Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751, slip op. at 46 (2014).

¹¹ Centers for Medicare & Medicaid Services, *Emergency Medical Treatment & Labor Act*, available at: https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA/

^{12 42} U.S. Code § 1395dd

¹³ NPRM at 3887.

¹⁴ Ibid.

¹⁵ Ibid.

ACOG guidance—"The Limits of Conscientious Refusal in Reproductive Medicine"¹⁶—was originally issued in 2007 and, according to the Department "at least, in part, prompted the 2008 rule."¹⁷

While reproductive medicine is fertile ground for those seeking conscience exceptions and therefore may have a reasonable place in this policy making discussion, the Department does not to cite a reproductive health-related section of ACOG's ethics document as an example of provider coercion. Rather, HHS focuses on the following provision, in which ACOG addresses a provider's obligation to treat a patient in an emergency situation:

"[i]n an emergency in which referral is not possible or might negatively affect a patient's physical or mental health, providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections." 18

By citing this ACOG recommendation as a reason for the proposed rule, the Department is suggesting that it disagrees with this specific provision, and that providing medically indicated and requested care in an emergency runs counter to the purpose of the rule. We are extremely concerned about the impact such an approach to care provision would have on patients in emergent situations. For example, could the proposed rule allow institutional health care providers, such as hospital emergency rooms, to refuse to provide emergency care? If so, this puts patients who need emergency medical care at grave risk and would run afoul of EMTALA's requirements to, at a minimum, stabilize patients who come to the emergency room in medical emergencies. ¹⁹

The lack of clarity in the proposed rule will cause confusion and put the health and lives of patients at risk. A provider's right to refuse access to health care must not come at the expense of a patient's right to needed care.

Informed Choice and Transparency

We are also concerned that the under the rule, covered entities would be free not only to refuse to perform any given health care service, but also to deny patients access to information about or referrals for such services, by defining "referral" in a staggeringly broad way. ²⁰ Specifically, under the proposed rule, an objecting provider could refuse to provide a patient with any information distributed by any method, regarding any service, procedure, or activity when the provider "sincerely understands the particular health care service, activity, or procedure [to which he or she objects] to be a purpose or possible outcome of the referral." This would seemingly allow providers to refuse to give patients any information that they could then use to access care. In addition, the Department states that the underlying statute of the proposed rule permits entities to deny help to anyone who is likely to make a referral for an abortion or "for other kinds of

¹⁶ ACOG Committee Opinion, The Limits of Conscientious Refusal in Reproductive Medicine, available at: https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Ethics/The-Limits-of-Conscientious-Refusal-in-Reproductive-Medicine

¹⁷ NPRM at 3388, Footnote 37.

¹⁸ NPRM at 3388.

^{19 42} U.S. Code § 1395dd

²⁰ NPRM at 3894.

²¹ NPRM at 3895.

services."²² The breadth and vagueness of this definition could lead providers to refrain from providing information vital to patients out of anxiety and confusion of what the proposed rule permits, or requires, them to do.

The proposed regulation would allow a provider to refuse to counsel patients for services or provide medical information and options for any medical treatment without a mechanism to ensure patients get the information they need to make informed health care decisions. Cutting patients off from critical information without a disclosure that the information, services, or referral may be incomplete may not be the intent of the rule, but there is no requirement in the text that objectors be transparent about their refusals.

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

The NPRM establishes that transparency and openness are valuable, and we agree that "poor communication negatively affects continuity of care and undermines the patient's health goals." In addition to such practical concerns, ethical and legal standards also require that professionals ensure patients have the information they need to provide informed consent to care. However, the rule does not appear to require any disclosure on the part of objecting providers or institutions. Indeed, one case highlighted in the NPRM revolved around a hospital's lack of transparency about provider unwillingness to assist a patient through California's Aid-in-Dying rule. As it stands, the proposed regulation threatens to fundamentally undermine the relationship between providers and patients, who will have no way of knowing which services, information, or referrals they may have been denied.

By contrast, Medicare rules require that Medicare Advantage organizations that object to paying for particular referrals or counseling must notify both the Centers for Medicare & Medicaid Services and any current or prospective enrollees of their refusal, with advance notice for current enrollees. Such notice allows patients and their families to determine for themselves if the provider or institution offer sufficient services to meet the patient's wants and needs. Any finalized rule should use such notice requirements as a model and must be explicit in requiring that such notice be given, in writing, and in advance whenever possible, to ensure patients and families have the information they need to make informed, person-centered choices.

²² Ibid.

²³ NPRM at 3917.

²⁴ NPRM at 3889.

²⁵ The Centers for Medicare & Medicaid Services, *Managed Care Manual*, Chapter 6, available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c06.pdf.

Conclusion

The center of all health care decision making must be the person receiving care. The patient, in the medical context, is supposed to be the focus, in close partnership with their families if they choose and always with practitioners in order to "ensure that decisions respect patients' wants, needs and preferences and solicit patients' input on the education and support they need to make decisions and participate in their own care."²⁶

No system that ignores or overrides the person's wants, needs, or preferences, or that fails to provide necessary information, can ever be person centered. While person centeredness is an aspirational goal for the health care system, it must be at the forefront in our thinking, not shunted aside when there are other considerations on the table.

The proposed rule does not appear to take the person at the heart of health care—the patient—into account at all when discussing the rights of providers and other entities. No regulatory action in health care can succeed unless it accounts for the fundamental purpose of health care—patient well-being.

Coupled with this rule's silence about its interaction with various statutes, this omission would create chaos and confusion if this rule were finalized as-is. We urge that HHS abandon this approach and instead explore ways to bring this rule into harmony with existing law, to find a balance in the rights of patients and practitioners, to protect the health, well-being, and access to care of all patients, and to promote person-centered practices that must be at the heart of our health care system.

Thank you for the opportunity to provide comment.

For additional information, please contact Lindsey Copeland, Federal Policy Director at LCopeland@medicarerights.org or 202-637-0961 and Julie Carter, Federal Policy Associate at JCarter@medicarerights.org or 202-637-0962.

²⁶ Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: National Academy Press; 2001.