# Exhibit 88


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 Community Catalyst in response to the request for public comment on the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26.[1]

Community Catalyst is a national non-profit advocacy organization dedicated to quality affordable health care for all. Since 1997, Community Catalyst has been working to build the consumer and community leadership required to transform the American health system. With the belief that this transformation will happen when consumers are fully engaged and have an organized voice, Community Catalyst works in partnership with national, state and local consumer organizations, policymakers and foundations, providing leadership and support to change the health care system so it serves everyone - especially vulnerable members of society.

This proposed regulation would exacerbate the challenges that many patients -- especially women, LGBTQ people, people of color, immigrants and low-income people -- already face in getting the health care they need in a timely manner and at an affordable cost. The rule would expose vulnerable patients to increased discrimination and denials of medically-indicated care by broadening religious health care provider exemptions beyond the existing limited circumstances allowed by law. Moreover, while protecting health providers who deny care, the rule would provide *no protections for patients who are being denied care – even in emergencies*. As drafted, the rule would not even require that patients be informed of all their potential treatment options and referred to alternative providers of needed care.

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

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

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

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

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

We are also concerned about potential enabling of care denials by providers based on their non-scientific personal beliefs about other types of health services. For example, certain religiously-affiliated hospitals and individual clinicians have refused to provide rape victims with emergency contraception to prevent pregnancy[5] based on the belief that it can cause an abortion, even though there is no scientific evidence that this is the case. Providers could conceivably be motivated by the proposed rule to object to administering vaccinations or refuse to prescribe or dispense Pre-exposure Profylaxis (PrEP) medication to help gay men reduce the risk of HIV transmission through unprotected sex.

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

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

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

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

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

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

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

On an institutional level, the right to refuse to "assist in the performance of" a service could mean a religiously-affiliated hospital or clinic could deny care, and *then also refuse to provide a patient with a referral or transfer to a willing provider* of the needed service. Indeed, the proposed rule's definition of "referral" goes beyond any common understanding of the term, allowing refusals to provide *any information,* including location of an alternative provider, that could help people get care they need.[6]

The proposed rule thus could be read as allowing health providers to refuse to inform patients of all potential treatment options. A 2010 publication of the National Health Law Program, "Health Care Refusals: Undermining Quality of Care for Women," noted that "refusal clauses and institutional restrictions can operate to deprive patients of the complete and accurate information necessary to give informed consent."[7]

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

There have been reported instances in which pregnant women suffering medical emergencies – including premature rupture of membranes (PPROM) and ectopic pregnancies[8] -- have gone to hospital emergency departments and been denied prompt, medically-indicated care because of institutional religious restrictions.[9] This lack of protections for patients is especially problematic in regions of the country, such as rural areas, where there may be no other nearby hospital to which a patient could easily go without assistance and careful medical monitoring enroute.[10]

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

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[6] *See* Rule *supra* note 1, at 183.

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

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

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

[10] For example, a 2016 study found there were 46 Catholic-affiliated hospitals that were the federally-designated "sole community providers" of hospital care for their geographic regions. Women needing reproductive health services that are prohibited by Catholic health restrictions would have no other easily accessible choice of hospital care. Uttley, L., and Khaikin, C., *Growth of Catholic Hospitals and Health Systems,* MergerWatch, 2016, accessed at www.MergerWatch.org

to another facility.[11] Under EMTALA every hospital is required to comply – even those that are religiously affiliated.[12] Because the proposed rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

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

The rule sets forth extensive requirements for health care institutions, such as hospitals, to notify employees about their refusal rights, including how to file a discrimination complaint with OCR. The rule requires posting of such notices on the employer's website and in prescribed physical locations within the employer's building. The rule also sets forth the expectation that OCR would investigate or do compliance reviews of whether health care institutions are following the posting rule.[13]

By contrast, the rule contains no requirement that patients be notified of institutional restrictions on provision of certain types of care. Such notification is essential because research has found that patients often are unaware of service restrictions at religiously-sponsored health care institutions. [14]

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

The Proposed Rule generates chaos through its failure to account for existing laws that conflict with the refusals of care it would create. For example, the proposed rule makes no mention of Title VII,[15] the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[16] 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.[17] For decades, Title VII has

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[11] 42 U.S.C. § 1295dd(a)-(c) (2003).

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

[13] The notice requirement is spelled out in section 88.5 of the proposed rule.

[14] *See*, for example, Freedman, Lori R., Luciana E. Hebert, Molly F. Battistelli, and Debra B. Stulberg, *Religious hospital policies on reproductive care: what do patients want to know?* American Journal of Obstetrics & Gynecology 218, no. 2 (2018): 251-e1, accessed here: http://www.ajog.org/article/S0002-9378(17)32444-4/fulltext; also Guiahi, Maryam, Jeanelle Sheeder, and Stephanie Teal, *Are women aware of religious restrictions on reproductive health at Catholic hospitals? A survey of women's expectations and preferences for family planning care*, Contraception and Stulberg, D., et all, accessed here: http://www.contraceptionjournal.org/article/S0010-7824(14)00358-8/fulltext; *Do women know when their hospital is Catholic and how this affects their care? Restrictions in Catholic Hospitals (PARRCH) national survey*, Contraception, Volume 96, Issue 4, 268-269,accessed here: http://www.contraceptionjournal.org/article/S0010-7824(17)30235-4/fulltext; a

[15] 42 U.S.C. § 2000e-2 (1964).

[16] *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.

[17] *See id.*

established the legal framework for religious accommodations in the workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on patients, coworkers, public safety, and other legal obligations. The proposed rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both. Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.[18]

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.[19] 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.

**6. There is no provision protecting the rights of health care providers with religious or moral convictions to *provide* (not deny) services their patients need.**

The proposed rule ignores those providers with deeply held moral convictions that motivate them to provide patients with health care, including abortion, transition-related care and end-of-life care. The rule fails to acknowledge the Church Amendment's protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce.[20]

Doctors are, in effect, forced to abandon their patients when they are prevented by health care institutions from providing a service they believe is medically-indicated. This was the case for a doctor in Sierra Vista, Arizona, who was prevented from helping end a patient's wanted, but doomed, pregnancy after she suffered premature rupture of membranes. The patient had to be sent to the nearest non-objecting hospital, which was 80 miles away, far from her family and friends. The physician described the experience as "a very gut wrenching thing to put the staff through and the patient, obviously."[21]

**7. The proposed rule carries severe consequences for patients and would exacerbate existing inequities.**

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

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[18] 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.
[19] *See* Rule *supra* note 1, at 180-181.
[20] *See* The Church Amendments, 42 U.S.C. § 300a-7(c) (2018).
[21] Uttley, L, et all, *Miscarriage of Medicine,* MergerWatch and the ACLU (2013), p. 16, https://www.aclu.org/report/miscarriage-medicine.

Across the country, refusals of care based on personal beliefs have been invoked in countless ways to deny patients the care they need.[22] 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.[23] Another woman experiencing pregnancy loss was denied care for 10 days at a religiously affiliated hospital outside Chicago, Illinois.[24] In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy.[25] A 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.[26] Another woman was sent home by a religiously affiliated hospital with two Tylenol after her water broke at 18 weeks of pregnancy. Although she returned to the hospital twice in the following days, the hospital did not give her full information about her condition and treatment options.[27]

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 obtain health care and have real consequences for those denied the care they need because of a clinician's 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.[28] 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.[29] In rural areas there may be no other sources of health and life preserving medical care.[30] When these individuals encounter refusals of care, they may have nowhere else to go.

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[22] *See, e.g., supra* note 2.

[23] *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.

[24] *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.

[25] *See* Kira Shepherd, et al., *supra* note 23, at 29..

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

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

[28] 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.

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

[30] 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/.

This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals. For example, new research shows that In 19 states, women of color are more likely than white women to give birth in Catholic hospitals.[31] Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provide guidance on a wide range of hospital matters, including reproductive health care, and can keep providers from offering the standard of care.[32] 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.[33] 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.[34]

We concur with the comments submitted by the National Health Law Program (NHeLP) that the regulations fail to consider the impact of refusals on persons suffering from substance use disorders. Rather than promoting the evidence-based standard of care, the rule could allow practitioners to refuse to provide, or even recommend, Medication Assisted Treatment (MAT) and other evidence-based interventions due simply to a personal objection.

Stigma associated with drug use stands in the way of saving lives.[35] America's prevailing cultural consciousness -- after decades of treating the disease of addiction as largely a criminal justice and not the public health issue it is -- generally perceives drug use as a moral failing and drug users as less deserving of care. For example, a needle exchange program designed to protect injection drug users from contracting blood borne illnesses such as HIV, Hepatitis C, and bacterial endocarditis was shut down in October 2017 by the Lawrence County, Indiana County Commission due to their moral objection to drug use, despite overwhelming evidence that these programs are effective at reducing harm and do not increase drug use.[36] One commissioner even quoted the Bible as he voted to shut it down. Use of MAT to reverse overdose has been decried as "enabling these people" to go on to overdose again.[37]

In this frame of mind, only total abstinence is seen as successful treatment for substance use disorders, usually as a result of a 12-step or faith-based program, even though evidence for 12-step

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[31] *See* Kira Shepherd, et al., *supra* note 23, at 12.
[32] *See id.* at 10-13.
[33] 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/.
[34] *See, e.g., Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care*, AM. CIVIL LIBERTIES UNION & MERGER WATCH (2013), https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf.
[35] Ellen M. Weber, *Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance*, 13 J. HEALTH CARE L. & POL'Y 49, 56 (2010); German Lopez, *There's a highly successful treatment for opioid addiction. But stigma is holding it back.*, https://www.vox.com/science-and-health/2017/7/20/15937896/medication-assisted-treatment-methadone-buprenorphine-naltrexone.
[36] German Lopez, *An Indiana county just halted a lifesaving needle exchange program, citing the Bible,* VOX, Oct. 20, 2017, https://www.vox.com/policy-and-politics/2017/10/20/16507902/indiana-lawrence-county-needle-exchange.
[37] Tim Craig & Nicole Lewis, *As opioid overdoses exact a higher price, communities ponder who should be saved*, WASH. POST, Jul. 15, 2017, https://www.washingtonpost.com/world/as-opioid-overdoses-exact-a-higher-price-communities-ponder-who-should-be-saved/2017/07/15/1ea91890-67f3-11e7-8eb5-cbccc2e7bfbf_story.html?utm_term=.4184c42f806c.

programs is weak. The White House's own opioid commission found that "negative attitudes regarding MAT appeared to be related to negative judgments about drug users in general and heroin users in particular."[38]

People with substance use disorders already suffer due to stigma and have a difficult time finding appropriate care. This rule, which allows misinformation and personal feelings to get in the way of science and lifesaving treatment, would not help achieve the goals of the administration; it could instead trigger countless numbers of deaths.

By expanding refusals of care, the proposed rule will exacerbate the barriers to health care services patients need. It is evident that the harm caused by this proposed rule will fall hardest on those most in need of care. 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."[39] 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.[40] 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.[41] Because the proposed rule would cause substantial harm, including to patients, it would violate the Establishment Clause.[42]

**8. 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.[43] Instead, the proposed rule appropriates language from civil

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

[39] *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.

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

[41] 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).

[42] 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.

[43] *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

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.[44]

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.[45] 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.[46]

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.[47] Black women are three to four times more likely than white women to die during or after childbirth.[48] According to a recent report, doctors often fail to inform Black women of the full range of reproductive health options regarding labor or delivery, possibly due to stereotypes about Black women's sexuality and reproduction.[49] Young Black women said they felt they were shamed by

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programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").

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

[45] 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.

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

[47] *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.

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

[49] CTR. FOR REPROD. RIGHTS, NAT'L LATINA INST. FOR REPROD. HEALTH & SISTERSONG WOMEN OF COLOR REPROD. JUSTICE COLLECTIVE, *Reproductive Injustice: Racial and Gender Discrimination in U.S. Health Care* 20-22 (2014), *available at*

providers when seeking sexual health information and contraceptive care, due to their age and in some instances, sexual orientation.[50]

Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.[51] Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a health care provider had refused to see them because of their actual or perceived sexual orientation or gender identity in the year before the survey.[52]

As NHelP's comments note, many people with disabilities receive home and community-based services (HCBS), including residential and day services, from religiously-affiliated providers. Historically, people with disabilities who rely on these services have sometimes faced discrimination, exclusion and a loss of autonomy due to provider objections. Group homes have, for example, refused to allow residents with intellectual disabilities who were married to live together in the group home.[53] Individuals with HIV – a recognized disability under the Americans with Disabilities Act (ADA) – have repeatedly encountered providers who deny services, necessary medications and other treatments citing religious and moral objections. One man with HIV was refused care by six nursing homes before his family was finally forced to relocate him to a nursing home 80 miles away.[54] Given these and other experiences, the extremely broad proposed language at 45 C.F.R. § 88.3(a)(2)(vi) that would allow any individual or entity with an "articulable connection" to a service, referral, or counseling described in the relevant statutory language to deny assistance due to a moral or religious objection is extremely alarming and could seriously compromise the health, autonomy and well-being of people with disabilities.

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.[55]

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https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/CERD_Shadow_US_6.30.14_Web.pdf [hereinafter *Reproductive Injustice*]; IN OUR OWN VOICE: NAT'L BLACK WOMEN'S REPROD. JUSTICE AGENDA, *The State of Black Women & Reproductive Justice* 32-33 (2017), *available at* http://blackrj.org/wp-content/uploads/2017/06/FINAL-InOurVoices_Report_final.pdf.

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

[51] *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.

[52] *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.

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

[54] 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.

[55] *See supra* note 42.

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

The proposed rule will have a chilling effect on the enforcement 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.[56] 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.[57]

**10. 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.[58] For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling[59] and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.[60] 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.[61] The Proposed Rule creates uncertainty about whether Title X grantees may ensure that the sub-recipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. Such actions are particularly concerning in the context of federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for low-income populations.[62] 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.[63]

**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, ignores

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[56] *See, e.g.*, Rule, *Supra* note 1, at 3888-89.
[57] *See id.*
[58] *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.
[59] *See, e.g.*, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).
[60] *See* What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).
[61] *See, e.g.*, Rule *supra* note 1, at 180-185.
[62] *See* NFPRHA *supra* note 34.
[63] *See id.*

congressional intent, fosters confusion and harms patients, all of which are contrary to the Department's stated mission. For all of these reasons, Community Catalyst calls on the Department to withdraw the proposed rule in its entirety.

Respectfully submitted,

Robert Restuccia
Executive Director
Community Catalyst

# Exhibit 89

National
**Family Planning**
& Reproductive Health Association

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

**Attn: Protecting Statutory Conscience Rights in Health Care NPRM, RIN 0945-ZA03**

The National Family Planning & Reproductive Health Association (NFPRHA) is pleased to provide comments on the US Department of Health and Human Services' (HHS) notice of proposed rulemaking (NPRM), "Protecting Statutory Conscience Rights in Health Care," RIN 0945-ZA03.

NFPRHA is a national membership organization representing the nation's publicly funded family planning providers, including nurse practitioners, nurses, administrators, and other key health care professionals. NFPRHA's members operate or fund a network of more than 3,500 health centers and service sites that provide high-quality family planning and other preventive health services to millions of low-income, uninsured, or underinsured individuals in 50 states and the District of Columbia. Services are provided through state, county, and local health departments as well as hospitals, family planning councils, Planned Parenthoods, federally qualified health centers and other private nonprofit organizations.

NFPRHA is deeply concerned that this NPRM ignores the needs of the patients and individuals served by HHS' programs and creates confusion about the rights and responsibilities of health care providers and entities. Because they receive Title X, Medicaid, and other HHS funds, NFPRHA members would have no choice but to comply with this rule: failure to do so could lead to termination of current or pending HHS funds, as well as return of money previously paid to NFPRHA members for services they have provided. This means hundreds of millions of dollars in federal funding are at stake for NFPRHA members if they run afoul of the rule. Without federal support, many of our members would be forced to drastically scale back the services they provide to their patients or to close completely. Because NFPRHA members represent the vast majority of Title X clinical locations that serve people who cannot afford to pay for health care on their own, this would leave many low-income and uninsured or under-insured patients without access to family planning and other critical health care services.

Although this NPRM claims the authority to interpret numerous statutes of concern and interest, NFPRHA will limit its comments primarily to the unjustified and unauthorized expansion of the Church amendments (42 USC 300a-7), Coats-Snowe amendment (42 USC 238n), and Weldon amendment (e.g. Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, Tit. V, sec. 507(d)) (together, "Federal health care refusal statutes"). Because this NPRM encourages unprecedented discrimination against patients and opens the door to undermining the intent and integrity of key HHS programs, including the Title X family planning program, it should be withdrawn.

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**Background on the 2008 Health Care Refusal Regulations**

In the decades-long history of the federal health care refusal statutes, none of which delegate rulemaking authority to HHS, regulations purporting to clarify and interpret these laws have been promulgated only once, in late 2008.

In 2008, HHS promulgated an NPRM purporting to interpret and enforce the federal health care refusal statutes claiming "concern…that there is a lack of knowledge on the part of States, local governments, and the health care industry" of the refusal rights contained within these statutes. (73 Fed. Reg. at 50, 278). Despite allowing only a 30-day comment period, HHS received more than 200,000 comments in response to the proposed rule—the vast majority of which opposed the rule as unnecessary, unauthorized, and overbroad.[1] Notably, HHS conceded, it received "no Comments indicating that there were any [federal] funding recipients not currently compliant with [the underlying statutes]" (73 Fed. Reg. at 78,095). HHS published a final rule on December 19, 2008, which did not materially differ from the NPRM and was immediately subject to legal challenge by multiple parties, including NFPRHA and seven state attorneys general.[2]

In 2011, HHS rescinded those aspects of the 2008 rule that were "unclear and potentially overbroad in scope," but maintained those parts of the rule establishing an enforcement process for the Federal health care refusal statutes and began an "initiative designed to increase the awareness of health care providers about the protections provided by the health care provider conscience statutes, and the resources available to providers who believe their rights have been violated." (76 Fed. Reg. at 9969). This rule remains in effect.

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[1] Comments to Provider Conscience Regulations, 73 Fed. Reg. 50274 (August 26, 2008) (to be codified at 45 CFR 88).

[2] *National Family Planning and Reproductive Health Association et al v. Leavitt*, No. 09-cv-00055 (Dist. Conn. Jan. 15, 2009) *State of Conn. et al. v. United States of America*, No. 09-cv-00054 (Dist. Conn. Jan. 15, 2009); *Planned Parenthood Federation of America v. Leavitt*, No. 09-cv-00057 (Dist. Conn. Jan. 15, 2009); *State of Conn. et al. v. United States of America*, No. 09-cv-00054 (Dist. Conn. Jan. 15, 2009).

According to the current NPRM, since 2008, "OCR [Office for Civil Rights] has received a total of forty-four complaints [related to Federal health care refusal laws], the large majority of which (thirty-four) were filed since the November 2016 election." (83 Fed. Reg. at 3886). To place that figure into context, OCR in total received approximately 30,166 complaints in fiscal year (FY) 2017.

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**The NPRM overstates statutory authority and seeks to dramatically expand the reach of the underlying statutes.**

For decades, federal health care refusal statutes have given specified individuals and institutions certain rights to refuse to perform, assist in the performance, and/or refer for abortion and/or sterilization services. Despite the lack of a congressional mandate to do so, the NPRM seeks to dramatically expand the scope and reach of these laws, as well as grant overall responsibility for ensuring and enforcing compliance with those statutes to OCR, using identical language to many aspects of the now-rescinded 2008 regulation that faced widespread opposition at that time.[3]

The Church amendments were enacted by Congress in the 1970s in response to debates about whether the receipt of federal funds required recipients to provide abortion or sterilization services. These provisions make clear, among other things, that:

- The receipt of federal funding under the Public Health Service Act (PHSA) (42 U.S.C. § 201 et seq.) does not itself obligate any individual to perform or assist in the performance of sterilization or abortion procedures if those procedures are contrary to the individual's religious or moral beliefs (Church (b)(1)); and,
- Health care personnel employed by certain federally funded programs and facilities cannot be discriminated against in terms of employment, promotion, or the extension of staff or other privileges for performing or assisting in the performance of sterilization or abortion services, or refusing to perform or assist in the performance of such services based on their religious or moral beliefs (Church (c)(1)).

In 1996, Congress adopted the Coats amendment in response to a decision by the accrediting body for graduate medical education to require OB/GYN residency programs to provide or permit abortion training. The Coats amendment prohibits federal, state, and local governments from discriminating against health care entities, such as "individual physicians, postgraduate physician training programs, or . . . participant[s] in a program of training in the health profession," that refuse to provide or require training in abortions or individuals who refuse to be trained to provide abortions.

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[3] Comment of the National Family Planning & Reproductive Health Association to Provider Conscience Regulations, Tracking Number 8072403d to 73 Fed. Reg. 50274 (proposed August 26, 2008) (comment dated September 25, 2008) (to be codified at 45 CFR 88).

Since 2004, Congress has attached the Weldon amendment to the annual appropriations measure that funds the Departments of Labor, Health and Human Services, and Education (Labor-HHS). That amendment prohibits federal agencies and programs and state and local governments that receive money under the Labor-HHS Appropriations Act from discriminating against individuals, health care facilities, insurance plans, and other entities because they refuse to provide, pay for, provide coverage of, or refer for abortion.

The Church, Coats-Snowe, and Weldon amendments were never intended to provide individual health care providers and/or entities with the myriad and expansive rights of refusal this NPRM seeks to achieve. Without statutory authorization, the NPRM expands the reach of the Church, Coats-Snowe, and Weldon Amendment beyond what was contemplated by Congress and is permitted by existing federal law, by expanding the categories of individuals and entities whose refusals to provide information and services are protected; expanding the types of services that individuals and entities are allowed to refuse to provide; and expanding the types of entities that are required to accept such refusals. For example:

- Despite the plain language of the Weldon amendment, the NPRM attempts to extend it to apply to funding beyond that appropriated by Labor-HHS appropriations and to non-governmental entities, as well. The statute of the Weldon amendment states:

  > "(1) None of the funds ***made available in this Act*** may be made available to ***a Federal agency or program, or to a State or local government***, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.

  Yet § 88.3(c) of the NPRM adds new language that applies the Weldon amendment's prohibitions not only to federal agencies and programs and state and local governments that receive Labor-HHS funds, but also to "***[a]ny entity that receives funds through a program administered by the Secretary or under an appropriations act for the Department that contains the Weldon amendment***" [emphasis added].

  This language broadens Weldon's reach in two impermissible ways: 1) it extends the restrictions to entities that do not even receive funding via Labor-HHS appropriations, to apply to funding through any program administered by HHS; and, 2) it applies the restrictions of the Weldon amendment beyond the statutory reach of federal agencies or programs, or state or local governments, to any entity receiving certain federal funds. These extensions of Weldon's reach are clearly contrary to both the plain language of the Weldon amendment and to congressional intent.

- While the Church amendment prevents PHSA funds from being used to require individuals and institutions to, among other things, "assist in the performance" of abortions and sterilizations, and prevents employment discrimination against those who refuse to do so, § 88.3 of the NPRM

transforms this statutory shield into a sword, creating out of whole cloth a categorical right of refusal for any recipient of PHSA funds. Moreover, § 88.2 of the NPRM provides an unprecedentedly and unjustifiably broad definition of the term "assist in the performance" that runs counter to congressional intent and common sense. The NPRM would define "assist in the performance" as participating "in ***any activity*** with an ***articulable connection*** to a procedure, health service or health service program, or research activity" [emphasis added]. In other words, HHS proposes to create refusal rights for anyone who can ***simply express a connection*** between something they do not want to do and an abortion or sterilization procedure (e.g., scheduling appointments, processing payments, or treating complications). Even the sole instance of previous rulemaking under the Church amendments in 2008, which was rescinded before it ever took effect, was not so broad.

- Likewise, the NPRM's definition of referral/refer seeks to dramatically expand the scope and reach of the Coats-Snowe and Weldon amendments and runs counter to congressional intent and common sense. Section 88.2 of the NPRM defines "referral/refer for" abortion to include:

  > "the provision of any information (including but not limited to name, address, phone number, email, website, instructions, or description) by any method (including but not limited to notices, books, disclaimers, or pamphlets, online or in print), pertaining to a health care service, activity, or procedure, including related to availability, location, training, information resources, private or public funding or financing, or directions that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity, or procedure, where the entity or health care entity making the referral sincerely understands that particular health care service, activity, or procedure to be a purpose or possible outcome of the referral."

  This definition would impair the ability of health care professionals to fulfill their legal and ethical duties of providing complete, accurate, and unbiased information to their patients. For example, as discussed further below, the NPRM could be read to permit employees of Title X-funded health centers and other federally funded entities to refuse to provide information and referrals to patients, without ever addressing patient needs and in clear violation of the fundamental tenets of informed consent.

As interpreted by the NPRM, the Church, Coats-Snowe, and Weldon amendments would be radically expanded to create far-reaching protections for individuals and entities that would refuse to provide patients not only with health care services, but also the most basic information about their medical options and that seek to obstruct the ability of certain patients to access any care at all. This is impermissible and, as discussed below, would cause unprecedented harm to patients and undermine the integrity of key HHS programs.

This NPRM goes beyond HHS' statutory authority and should be withdrawn. If HHS promulgates a final rule, however, it must identify the source of its legal authority, if any at all, to promulgate these regulations and to alter and expand the meaning of the statutory language.

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**The NPRM attempts to grant OCR oversight authority and enforcement discretion that is overly broad and vague; unduly punitive; and ripe for abuse.**

While some of the investigative authority and enforcement powers of the current NPRM appear to comport with similar provisions in other areas subject to OCR oversight and enforcement authority, the NPRM 1) includes new, troubling provisions that are vague, overly broad, and overly punitive; and 2) as a whole, appear to impart in OCR authority and enforcement discretion that is ripe for abuse.

Indeed, while the NPRM claims to "borrow...from enforcement mechanisms already available to OCR to enforce similar civil rights laws," the NPRM contains troubling differences. For example, the NPRM states that investigations may be based on anything from 3rd party-complaints to news reports, and yet at the same time appears to give OCR the authority to withhold federal financial assistance and suspend award activities, based on "threatened violations" alone, without first allowing for the completion of an informal resolution process. (See 83 Fed. Reg. at 3891, 3930-31). By contrast, the Department of Justice (DOJ) regulations implementing Title VI of the Civil Rights Act of 1964 (prohibiting discrimination on the basis of race in federally funded programs) state that DOJ will not take such drastic steps to respond to actual or threatened violations unless noncompliance cannot first be corrected by informal means. (See 28 C.F.R. § 42.108(a)). When combined with other aspects of the NPRM, concern over the breadth and potential harm of such provisions is obvious and legitimate. For instance:

- Under § 88.6, the NPRM includes a 5-year reporting requirement that requires any recipient or sub-recipient subject to an OCR compliance review, investigation, or complaint related to the health care refusal rules to inform any current HHS "funding component" of the review/investigation/complaint, as well as to disclose that information in any application for new or renewed "Federal financial assistance or Departmental funding." Once again, this is distinct from the DOJ regulations enforcing Title VI, which only require disclosure of compliance reviews (not every investigation or complaint, regardless of whether it is unfounded) over the past two years. (28 C.F.R. § 42.406(3)). Yet the NPRM fails to explain the purpose of the vastly expanded reporting requirement and period. In light of the broad investigative authority and harsh penalties described above, this leaves affected entities with significant concern about how such information is intended to be used and whether it will unfairly prejudice consideration of applicants for federal funds or penalize currently funded entities in ways that could be extremely harmful.

The NPRM also includes very troubling language that appears to be little more than a pretext for defunding entire classes of providers, which it cannot do. The preamble text accompanying § 88.7

states, "The Director may, in coordination with a relevant Department component, restrict funds for noncompliant entities in whole or in part, including by ***limiting funds to certain programs and particular covered entities, or by restricting a broader range of funds or broader categories of covered entities***" [emphasis added]. This delegation of authority is not only far beyond the scope of the underlying laws but seems designed to grant arbitrary authority that is ripe for abuse, with no mechanism of due process or oversight to prevent entire categories of providers or programs from being penalized without cause. To the extent § 88.7 seeks to create a back door to excluding certain family planning providers from the Title X and Medicaid programs—efforts that have been repeatedly rejected by the courts—it, again, exceeds the scope of the agency's authority and will do nothing more than harm the health and well-being of patients.

Given the lack of evidence that the system currently in place cannot adequately handle complaints, as well as any sufficient justification for departing from the processes used to ensure compliance with other federal statutes, HHS must, at a minimum, adequately explain the reason for these changes, what safeguards exist to prevent abuse, and demonstrate that this language is not simply a pretext for unlawfully excluding certain categories of providers from participating in federally funded programs.

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**The NPRM opens the door to undermining the intent and integrity of key HHS programs, including the Title X family planning program.**

The NPRM ignores the reality that some individuals and entities are opposed to the essential health services that are the foundation of longstanding, critical HHS programs like Title X. In the arena of health care, and particularly family planning and sexual health, HHS-funded programs cannot achieve their fundamental, statutory objectives if grantees, providers, and contractors have a categorical right to refuse to provide essential services, such as non-directive pregnancy options counseling.

The Title X family planning program was created by Congress in 1970 "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services" (42 USC 300). Title X projects are designed to "consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children" (42 CFR 59).

In 2014, more than 20.2 million women in the United States were in need of publicly funded contraceptive services. Women in need of publicly funded family planning services is defined as follows: "1) they were sexually active (estimated as those who have ever had voluntary vaginal intercourse, 2) they were able to conceive (neither they nor their partner had been contraceptively sterilized, and they did not believe they were infecund for any other reason); 3) they were neither intentionally pregnant nor trying to become pregnant; and, 4) they have a family income below 250% of the federal poverty level. In addition, all women younger than 20 who need contraceptive services, regardless of their family income are assumed to need publicly funded care because of their heightened need—for reasons of

confidentiality—to obtain care without depending on their family's resources or private insurance."[4] In the face of this widespread need, publicly funded family planning and sexual health care provides a crucial safety net for women and families. The impact of these services cannot be underestimated. Without publicly funded family planning services, there would be 67% more unintended pregnancies (1.9 million more) annually than currently occur.[5]

Congress has specifically required that "all pregnancy counseling shall be non-directive" (Public Law 110-161, p. 327), and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination (42 CFR 59.5(a)(5)). Despite the incredible success of the Title X program and the critical services it provides, Title X has been chronically underfunded, with no new service dollars allocated in nearly a decade. It is a testament to the dedication of the existing Title X network to meeting the goals of the program that, despite limited resources, these providers still serve more than four million patients per year.[6]

However, in addition to the overly broad definitions of "referral" and "assist in the performance" discussed above, by proposing a definition of "discrimination" that appears to jettison the longstanding framework that balances individual conscience rights with the ability of health care entities to continue to provide essential services to their patients, the NPRM seems designed to allow entities that refuse to provide women with the basic information, options counseling, and referrals required by law to compete on the same footing for federal money with family planning providers who adhere to the law and provide full and accurate information and services to patients. The NPRM thus threatens to divert scarce family planning resources away from entities that provide comprehensive family planning services to organizations that refuse to provide basic family planning and sexual health care services. Diverting funds away from providers offering the full range of family planning and sexual health services would not only seriously undermine public health, especially for the low-income, uninsured, and under-insured, but would also be contrary to congressional intent and explicit statutory requirements of the Title X family planning program.

The NPRM likewise creates confusion 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. To the extent that the rule seeks to immunize subrecipients who refuse to provide essential services and complete information about all of a woman's pregnancy options, it undermines the very foundation of the Title X program and the health of the patients who rely on it.

In addition to potential issues with the selection of grantees and subrecipients, the proposed definition of "discrimination" also poses significant employment issues for all Title X-funded health centers. As

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[4] Jennifer Frost et al, *Contraceptive Needs and Services, 2014 Update* (New York: Guttmacher Institute, 2016).
[5] Jennifer Frost et al, *Publicly Funded Contraceptive Services at U.S. Clinics, 2015* (New York: Guttmacher Institute, April 2017).
[6] Christina Fowler, *Family Planning Annual Report: 2016 national summary* (Research Triangle Park, NC: RTI International, 2017).

discussed further below, the language in the NPRM could put Title X-funded health centers in the position of being forced to hire people who intend to refuse to perform essential elements of a position. For example, the rule provides 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 individual refuses to provide non-directive options counseling. Furthermore, the NPRM does not provide guidance on whether it is impermissible "discrimination" for a Title X-funded state or local health department to transfer such a counselor or clinician out of the health department's family planning project to a unit where pregnancy counseling is not done.

Because the NPRM threatens to undermine the integrity of key HHS programs, including the Title X family planning program, HHS must, at a minimum, clarify that any final rule does not conflict with preexisting legal requirements for and obligations of participants in the Title X program, or of employers, as set forth under Title VII of the Civil Rights Act of 1964, discussed below.

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**The NPRM fails to sufficiently address patient needs or achieve the careful balance struck by existing civil rights laws and encourages unprecedented discrimination against patients that will likely impede their access to care and harm their health.**

The stated mission of HHS is "to enhance and protect the health and well-being of all Americans." Yet, the NPRM elevates the religious and moral objections of health care providers over the health care needs of the patients who HHS is obligated to protect. The NPRM appears to allow individuals to refuse to provide health care services or information about available health care services to which they object on religious or moral grounds, with virtually no mention of the needs of the patient who is turned away. Patients should not be forced to bear the brunt of the objector's religious or moral beliefs, particularly to the detriment of their own health. In fact, legal and ethical principles of informed consent require health care providers to tell their patients about all of their treatment options, including those the provider does not offer or favor, so long as they are supported by respected medical opinion. As such, health care professionals must endeavor to give their patients complete and accurate information about the services available to them.

Furthermore, the NPRM fails to address serious questions as to whether its purpose is to upset the careful balance struck in current federal law between respecting employee's religious and moral beliefs and employers' ability to provide their patients with health care services. Title VII provides a balance between health care employers' obligations to accommodate their employees' religious beliefs and practices (including their refusal to participate in specific health care services to which they have religious objection) with the needs of the patients they serve. Under Title VII, employers have a duty to reasonably accommodate an employee or applicant's religious beliefs, unless doing so places an "undue hardship" on the employer. This law provides protection for individual belief while still ensuring patient access to health care services. The NPRM provides no guidance about how, if at all, health care

employers are permitted to consider patients' needs when faced with an employee's refusal to provide services.

The NPRM ignores the needs of patients and fails to consider whether an employer can accommodate such a refusal without undue hardship. In so doing, the NPRM invites health care professionals to violate their legal and ethical duties of providing complete, accurate, and unbiased information necessary to obtain informed consent. The failure of health care professionals to provide such information threatens patients' autonomy and their ability to make informed health care decisions.

Title VII is an appropriate standard that protects the needs of patients and strikes an appropriate balance. At a minimum, HHS should clarify that any final rule does not conflict with Title VII.

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**The NPRM vastly underestimates the financial burden it would impose on federally funded health care providers who already operate with limited resources.**

NFPRHA is particularly well positioned to comment upon the extremely burdensome effect the NPRM will have on the variety of public and private entities awarded federal dollars to provide health services to underserved communities.

As an initial matter, for a non-lawyer to simply read and understand the regulatory language and the lengthy preamble of the NPRM requires numerous hours – much longer than the roughly "10 minutes per law" estimated by HHS. (See 83 Fed. Reg. at 3913). A Final Rule, which would respond to prior comments and provide explanation and commentary elaborating on the Regulation, would require the same at minimum. Moreover, given the magnitude of funds at stake, the complexity and ambiguity of the NPRM's employment provisions, and the diverse staffing arrangements among recipients of federal funds, many NFPRHA members will need to pay for the time of legal counsel to review and consult with them on how to adjust their policies and practices prior to certifying compliance. This will also require time and cost for legal counsel to research and advise how, or if, it is possible for an entity to achieve compliance with the rule as well as with potentially conflicting obligations under State or other Federal laws. A reasonable estimate of these tasks alone would include at least several hours of attorney as well as multiple hours of executive and management staff time – not just the average of 4 hours (total) per year of lawyer and staff time estimated by HHS. (See 83 Fed. Reg. at 3913).

In particular, it appears that policies and practices to comply with the Department's articulated standard will be different than those necessary to comply with existing federal laws such as Title VII. Thus, in estimating an average of 4 hours (total) per year to update policies and procedures *and* retrain staff (see 83 Fed. Reg. at 3913), the NPRM utterly fails to account for:

- Time and cost for legal and human resources or executive staff to review and revise job postings, job descriptions, job application materials, interview and hiring policies and practices, and other employment recruitment and hiring materials.

- Time and cost for legal and human resources or executive staff to review and revise employee manuals and handbooks, and other employment related policies and documents.

- Time and cost to devise and provide trainings for managers and other supervisory staff on interviewing, hiring, and responding to accommodation requests from employees and volunteers who object to participating in the provision of certain health care services.

- Time and cost of hiring and training additional employees and/or paying and retraining existing employees for additional hours to accommodate other employees who refuse to provide services.

While these comments do not attempt to identify and detail each of the likely costs that NFPRHA members and other regulated entities would face if the NPRM was finalized, they demonstrate the qualitatively and quantitatively substantial costs overlooked by HHS in its NPRM. In light of these burdens and the HHS's inability to demonstrate a countervailing need for the rule, NFPRHA strongly urges HHS to withdraw the NPRM. Failure to do so will result in substantial resources being diverted away from providing critical health care to patients in an already underfunded family planning safety net.

***

NFPRHA appreciates the opportunity to comment on the NPRM, "Protecting Statutory Conscience Rights in Health Care." If you require additional information about the issues raised in these comments, please contact Robin Summers at rsummers@nfprha.org or 202-552-0150.

Sincerely,

Clare M. Coleman

Clare Coleman
President & CEO

# Exhibit 90


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:

I am writing on behalf of Boston Medical Center (BMC), a private, not-for-profit, 487-bed, academic medical center located in Boston, Massachusetts, in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26, 2018. BMC is the primary teaching affiliate for Boston University's School of Medicine. It is the busiest trauma and emergency services center and the largest safety net hospital in New England. BMC is dedicated to providing accessible health care to everyone. 57% of its patients are from under-served populations and 32% of patients do not speak English as a primary language. Seeing more than one million patient visits a year in over 70 medical specialties and subspecialties, BMC physicians are leaders in their fields with the most advanced medical technology at their fingertips and working alongside a highly-skilled nursing and professional staff. BMC's mission is to provide exceptional care, without exception to all patients. BMC's staff is committed to providing quality care to every patient and family member with respect, warmth and compassion.

Providing quality, consistent patient care is a priority at our hospital. Through its commitment to serve everyone, BMC offers numerous outreach programs and services. BMC offers Interpreter Services in over 250 Languages, 24 hours a day. We are proud of the diversity of our patients and employees and hold strong in our belief that many faces create our greatness. BMC has a long history of caring for lesbian, gay, bi-sexual, transgender and gender queer (gender non-conforming) (LGBTQ) patients. In 2016 BMC proudly established its Center for Transgender Medicine and Surgery (CTMS), which is the first medical center in New England to provide a comprehensive transgender health care program and is a leader nationally in the delivery of transgender medical care. BMC recognizes that the transgender patient population has been severely marginalized because of discrimination and bias, which

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has resulted in significant health disparities for this group. The 2015 U.S. Transgender Survey Report, prepared by the National Center for Transgender Equality, found that one-third of the survey respondents reported having at least one negative health care related experience because of being transgender and nearly one-fourth, of the almost 28,000 respondents, did not seek health care due to a fear of mistreatment by health care providers because of being transgender. As a result of the historical harm and mistreatment faced by transgender people, many health care institutions throughout the United States are providing more targeted health care services for transgender and LGBQ patients and thereby working towards decreasing the health care disparities for LGBTQ patients that are still pervasive throughout the United States.

The Department of Health and Human Services' Proposed Rule "Protecting Statutory Conscience Rights in Health Care", as currently drafted, has the potential to significantly detract from the progress made and increase the health disparities faced by the LGBTQ patient population. First, the proposed rule, under the notion of religious protection, overreaches with an embedded catch-all provision that essentially states that no entity shall discriminate against a physician or other health care personnel for refusing to perform "**any lawful health service"** on grounds that "it is contrary to [the health care provider's] religious beliefs or moral convictions." (Proposed Rule §88.3(a)(2)(v)). **This provision is too broad.** Second, both federal and state laws already protect individual health care employees from discrimination on the basis of their religious beliefs. For example, to be in compliance with the existing federal and Massachusetts laws, BMC has a policy, as do many other hospitals, that establishes a procedure to excuse an employee from participating in a patient's care or treatment when the prescribed care or treatment conflicts with the employee's values, ethics, or religious beliefs. The existing protections are meaningful and familiar to health care providers who have navigated these personal obligations alongside their commitment to providing seamless, respectful health care to patients. There is no need to augment the existing protections. Third, HHS' proposed regulation creates a complex, burdensome notice and reporting process for organizations and hospitals that is not only unnecessary and threatens to undermine the continuity of patient care, but also results in significant additional costs at a time when we as a society are trying to bring down the cost of health care in the United States. Finally, the proposed rule does not address what should happen in emergency departments or emergent care situations in which a patient's life is in danger. There are specific requirements under the federal Emergency Medical and Labor Treatment Act (EMTALA) that prohibit hospitals with emergency departments from refusing to treat people based on their insurance status or ability to pay. EMTALA requires hospitals to provide "an appropriate medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available in emergency departments, to determine whether or not an emergency medical condition exists." (42 C.F.R. 489.24(a)(1)(i)). The proposed rule is silent on how EMTALA's requirements can be reconciled with its catch-all provision. **For these reasons and as further explained below, we urge the Department to withdraw the proposed rule.**

1. **The proposed rule attempts to inappropriately broaden religious exemptions in a way that would deny patients medically necessary care and could lead to discrimination against entire patient groups.**

Hospitals and health care organizations are in the business of providing health care services and information to patients and communities. The broad and undefined nature of the proposed rule gives individual providers' beliefs priority over life-saving patient care and threatens to prevent the provision of services to patients in need. The lack of definition, structure, and guidelines will leave health care providers without standards and structures to guide the provision of necessary care to the most vulnerable populations, including LGBTQ people.

The broad scope of the proposed rule's catch-all provision and the health care workers it applies to will make it possible for some providers to deny certain treatments or to decline to see certain patients. The proposed rule contemplates extending the interpretation of existing statutory exemptions, for procedures such as abortion and sterilization, far beyond the current standards. Forty-five states, including Massachusetts, have state laws that protect health care providers who object to participating in abortion procedures and several states also include protections for providers who do not want to participate in sterilization procedures.[1] Massachusetts General Law Ch. 112 §12I provides a protocol through which a health care provider shall not be discriminated against for not participating in a patient's care or treatment related to abortion and sterilization. These type of state laws and the existing federal laws (Church Amendment, Coats-Snowe Amendment and the Weldon Amendment) already provide health care provider protection. Hospital policies throughout the country should reflect compliance with their state and federal laws. For example, BMC has a policy that delineates a protocol so that an employee "shall not be required to participate in tubal ligations, vasectomies, abortions, or any other procedures that conflict with his/her ethical principles unless the patient's life is in immediate danger." The BMC policy is tailored to address specific procedures that may be contrary to a provider's religious beliefs or ethical principles, it also makes a reference to "any other procedure" that may conflict with a provider's ethical principle and outlines a specific method (in writing) by which a provider can request to be relieved from certain patient care duties, while taking patient safety into consideration. The existing protections are sound and protect the religious beliefs and moral convictions of BMC's health care providers, as well as ensure that necessary patient care is provided.

[1] "*Refusing to Provide Health Services*" Published on *Guttmacher Institute* (https://www.guttmacher.org.) March 1, 2018. See https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services

Roger Severino, Director of HHS' Office of Civil Rights stated in an interview that "The way these conscience claims work is that providers do not deny service to patients because of identities. What happens is providers choose not to provide or engage in certain procedures at all."[2] The problem with this approach is that the scope of what procedures are covered by the proposed rule are not clear. The proposed rule certainly emphasizes abortion, sterilization and assisted suicide, but Section 88.3 (a)(2)(v) is a catch-all provision that essentially empowers any physician or other health care personnel "to refuse to perform or assist in the performance of such service or activity on the grounds that doing so would be contrary to his or her religious beliefs or moral convictions, or because of his or her religious beliefs or moral convictions."

Under HHS' proposed rule a provider could be seen as empowered to refuse to provide **any** health care service or information for a religious or moral reason – extending beyond abortion and sterilization procedures, to other types of procedures in general and other areas of health care services, such as the provision of Pre-Exposure Prophylaxis (PrEP), infertility care, hormone therapy and other non-surgical gender transition-related services, and possibly even HIV treatment under the auspices of "any" service. The language of the proposed rule extends beyond specific procedures to health care services in general. This is problematic because, as drafted, the catch-all provision could also be viewed as protecting a health care provider who refuses to treat a transgender person for a condition that is completely unrelated to a gender transition procedure, such as providing treatment for a broken leg, cancer care, the flu or appendicitis, if the health care provider asserts that caring for a transgender person is contrary to his/her moral conviction. The language of this proposed rule potentially authorizes discrimination by health care providers towards an entire patient group regardless of the procedure, treatment or service that is needed.

**2. The proposed rule conflicts with Title VII and fails to inform hospitals of the boundaries of the rule when the exemption may cause an undue hardship on the hospital.**

Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e) already 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, which 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. BMC and other hospitals and health organizations are at a loss as to how to reconcile the proposed rule and Title VII given the dearth of litigation on the subject and the lack of explanation in the proposed rule.

[2] "*New Trump Initiatives: A win for anti-abortion activists, protections for "conscience" objections*" By Jessica Ravitz, CNN, January 19, 2018.

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The Equal Employment Opportunity Commission (EEOC) addressed this problematic intersection in its public comment in response to the 2008 Federal Health Care Conscience Rule 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." On this point, Boston Medical Center agrees with the EEOC.

**3. The proposed rule creates additional and unnecessary cost for hospitals.**

The proposed rule requires each hospital to make routine assurances, certifications and employee and public notifications related to compliance with its requirements. The Proposed Rule's Notice Requirement, § 88.5, requires that notices concerning the Federal Health Care Conscience and Associated Anti-Discrimination Protections be placed on hospital websites, posted in prominent and conspicuous physical locations in every department where notices to the public and notices to their workforce are customarily posted. This section also makes reference to including the notification in personnel manuals, employment applications and student handbooks. The costs associated with these requirements are unnecessary because most hospitals, including BMC, already have policies and references in employee manuals that respect religious freedoms and offer relief to employees from patient care duties that conflict with an individual's religious beliefs or ethical principles.

Furthermore, according to the proposed rule's preamble (Table 4: Summary of Costs) the estimated financial burden for the proposed rule will be $312.3 million in the first year and $125.5 million, annual recurring costs, during years two to five. The total estimated burden for compliance with this proposed rule, over its first five years, is $814.3 million dollars; over three-quarters of a billion dollars. This is an exorbitant amount of money for the facilities within the health care industry to spend at a time when there are calls to action and efforts being made to bring down the cost of health care throughout the United States. The return on investment will not justify the estimated burden, especially since there are already protections in place at the federal and state level related to conscience objections to participating in procedures such as abortion, sterilization and assisted suicide.

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**4. The proposed rule lacks safeguards to ensure patients would receive emergency care as required by federal law and ethical standards.**

The proposed rule is dangerously silent in regards to ensuring patient wellbeing. The lack of consideration of patients' rights is evidenced by the fact that the proposed rule contains no provision to ensure that patients receive legally available, 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 proposed rule also fails to address potential conflicts with emergency care requirements. Under the Emergency Medical Treatment and Active Labor Act (EMTALA) (42 U.S.C. § 1395dd), a hospital receiving government funds and providing emergency services is required to provide medical screening and stabilizing treatment to a patient who has an emergency medical condition (including severe pain or labor) (42 U.S.C. § 1395dd(a) and (b)). However, the proposed regulation contains a blanket right of refusal for physicians, with no discussion of their duties under EMTALA or how conflicts should be resolved. In fact, the proposed rule's preamble specifically identifies as problematic the 2016 American Congress of Obstetricians and Gynecologists reaffirmation of its ethics opinion that providers have an obligation to provide care regardless of the provider's personal moral objections if a referral is not possible or would negatively impact the patient's health. This reaffirmation is a tenet of providing necessary care for all who are in need. The requirements of EMTALA must be reconciled with the elements of the proposed rule, since EMTALA contains significant civil penalties (up to $50,000 for each violation) to prevent hospitals and physicians from disregarding their duties in treating all patients in similar manner (42 U.S.C. § 1395dd(d)(1)).

**Conclusion**

BMC is committed to providing exceptional care, without exception to everyone in our community. Hospitals and health systems exist to treat patients and provide them with access to the information they need for treatment. Entities that serve patients must be committed to respecting both the values of health care workers and the patients and the communities they serve in a way that allows for the delivery of care. BMC respects the dignity and rights of its diverse employees and patients. Our vision is to meet the health needs of the people of Boston and beyond by providing high quality comprehensive care to all, particularly mindful of the needs of vulnerable populations. HHS's proposed rule would stymie our ability to do this. The sweeping catch-all provision and the undefined boundaries of this proposed rule will have a chilling effect on the provision of life saving and medically necessary health care, result in significant unnecessary costs and contradict existing federal and state laws. BMC strongly urges the Department to withdraw the proposed rule. Alternatively, the rule should be re-proposed and (1) narrowed in scope to, at a minimum, remove the broad and vague catch-all language found in §88.3, (2) be drafted in a way that it does not contradict or is silent towards existing federal

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laws, such as Title VII and EMTALA and (3) should not include an expensive and burdensome notification and certification protocol.

If you would like additional information, please contact Melissa Shannon, Vice-President of Government Affairs at (617) 638-6732 or melissa.shannon@bmc.org or Wendoly Ortiz Langlois, Associate General Counsel at (617) 638-7901 or wendoly.langlois@bmc.org.

Sincerely,

Kate Walsh

Kate Walsh
President and Chief Executive Officer
Boston Medical Center

# Exhibit 91

AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

March 27, 2018

The Honorable Alex M. Azar, II
Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Secretary Azar:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to provide comments to the Department of Health and Human Services (HHS) in response to the Notice of Proposed Rulemaking (Proposed Rule or Proposal) on "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," issued by the Office of Civil Rights (OCR). In its Proposed Rule, OCR proposes to revise existing regulations and create new regulations to interpret and enforce more than 20 federal statutory provisions related to conscience and religious freedom. Under OCR's broad interpretation of these provisions, individuals, health care organizations, and other entities would be allowed to refuse to provide or participate in medical treatment, services, information, and referrals to which they have religious or moral objections. This would include services related to abortion, contraception (including sterilization), vaccination, end-of-life care, mental health, and global health support, and could include health care services provided to patients who are lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ).

For the reasons discussed below, the AMA believes the Proposed Rule would undermine patients' access to medical care and information, impose barriers to physicians' and health care institutions' ability to provide treatment, impede advances in biomedical research, and create confusion and uncertainty among physicians, other health care professionals, and health care institutions about their legal and ethical obligations to treat patients. We are very concerned that the Proposed Rule would legitimize discrimination against vulnerable patients and in fact create a right to refuse to provide certain treatments or services. Given our concerns, we urge HHS to withdraw this Proposal.

The AMA supports conscience protections for physicians and other health professional personnel. We believe that no physician or other professional personnel should be required to perform an act that violates good medical judgment, and no physician, hospital, or hospital personnel should be required to perform any act that violates personally held moral principles. As moral agents in their own right, physicians are informed by and committed to diverse cultural, religious, and philosophical traditions and beliefs. According to the *AMA Code of Medical Ethics*, "physicians should have considerable latitude to practice in accord with well-considered, deeply held beliefs that are central to their self-identities."

Conscience protections for medical students and residents are also warranted. The AMA supports educating medical students, residents, and young physicians about the need for physicians who provide termination of pregnancy services, the medical and public health importance of access to safe termination of pregnancy, and the medical, ethical, legal, and psychological principles associated with termination of pregnancy, while maintaining that the observation of, attendance at, or any direct or indirect participation in abortion should not be required.

Nonetheless, while we support the legitimate conscience rights of individual health care professionals, the exercise of these rights must be balanced against the fundamental obligations of the medical profession and physicians' paramount responsibility and commitment to serving the needs of their patients. As advocates for our patients, we strongly support patients' access to comprehensive reproductive health care and freedom of communication between physicians and their patients, and oppose government interference in the practice of medicine or the use of health care funding mechanisms to deny established and accepted medical care to any segment of the population.

According to the AMA *Code of Medical Ethics*, physicians' freedom to act according to conscience is not unlimited. Physicians are expected to provide care in emergencies, honor patients' informed decisions to refuse life-sustaining treatment, and respect basic civil liberties and not discriminate against individuals in deciding whether to enter into a professional relationship with a new patient. Physicians have stronger obligations to patients with whom they have a patient-physician relationship, especially one of long standing; when there is imminent risk of foreseeable harm to the patient or delay in access to treatment would significantly adversely affect the patient's physical or emotional well-being; and when the patient is not reasonably able to access needed treatment from another qualified physician. The Code provides guidance to physicians in assessing how and when to act according to the dictates of their conscience. Of key relevance to the Proposed Rule, the *Code* directs physicians to:

- Take care that their actions do not discriminate against or unduly burden individual patients or populations of patients and do not adversely affect patient or public trust.
- Be mindful of the burden their actions may place on fellow professionals.
- Uphold standards of informed consent and inform the patient about all relevant options for treatment, including options to which the physician morally objects.
- In general, physicians should refer a patient to another physician or institution to provide treatment the physician declines to offer. When a deeply held, well-considered personal belief leads a physician also to decline to refer, the physician should offer impartial guidance to patients about how to inform themselves regarding access to desired services.
- Continue to provide other ongoing care for the patient or formally terminate the patient-physician relationship in keeping with ethics guidance.

The ethical responsibilities of physicians are also reflected in the AMA's long-standing policy protecting access to care, especially for vulnerable and underserved populations, and our anti-discrimination policy, which opposes any discrimination based on an individual's sex, sexual orientation, gender identity, race, religion, disability, ethnic origin, national origin or age. We are concerned that the Proposed Rule, 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 based on religious beliefs or moral convictions, will allow discrimination against patients, exacerbate health inequities, and undermine patients' access to care.

We would like to note that no statutory provision requires the promulgation of rules to implement various conscience laws that have been in existence for years. We believe physicians are aware of their legal obligations under these requirements and do not think that the promulgation of this rule is necessary to enforce the conscience provisions under existing law. OCR has failed to provide adequate reasons or a satisfactory explanation for the Proposed Rule as required under the Administrative Procedure Act (APA). As OCR itself acknowledges, between 2008 and November 2016, OCR received 10 complaints alleging violations of federal conscience laws; OCR received an additional 34 similar complaints between November 2016 and January 2018. In comparison, during a similar time period, from fall 2016 to fall 2017, OCR received over 30,000 complaints alleging violations of either HIPAA or civil rights. These numbers demonstrate that the Proposed Rule to enhance enforcement authority over conscience laws is not necessary.

OCR's stated purpose in revising existing regulations is to ensure that persons or entities are not subjected to certain practices or policies that violate conscience, coerce, or discriminate, in violation of federal laws. We believe that several provisions and definitions in the Proposed Rule go beyond this stated purpose and are ambiguous, overly broad, and could lead to differing interpretations, causing unnecessary confusion among health care institutions and professionals, thereby potentially impeding patients' access to needed health care services and information. The Proposed Rule attempts to expand existing refusal of care/right of conscience laws—which already are used to deny patients the care they need—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. But the Proposed Rule attempts to broaden this provision to allow individuals to refuse to perform aspects of their jobs based on a mere reference to a religious or moral belief regardless of whether it relates to the specific biomedical or behavioral service or research activity they are working on. Such an attempted expansion goes beyond what the statute enacted by Congress allows.

We are concerned that the scope of the services and programs that would be covered under the Proposed Rule is broader than allowed by existing law. While OCR claims that it is trying to clarify key terms in existing statutes, it appears that they are actually redefining many terms to expand the meaning and reach of these laws. For example, "health program or activity" is defined in the proposed regulatory text to include "the provision or administration of any health-related services, health service programs and research activities, health-related insurance coverage, health studies, or any other service related to health or wellness whether directly, through payments, grants, contracts, or other instruments, through insurance, or otherwise." Likewise, "health service program" is defined in the proposed regulatory text to include "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded, in whole or in part, by [HHS]." These definitions make clear that OCR intends to interpret these terms to include an activity related in any way to providing medicine, health care, or any other service related to health or wellness, including programs where HHS provides care directly, grant programs such as Title X, programs such as Medicare where HHS provides reimbursement, and health insurance programs where federal funds are used to provide access to health coverage, such as Medicaid and CHIP. The definitions inappropriately expand the scope of the conscience provisions to include virtually any medical treatment or service, biomedical and behavioral research, and health insurance.

Furthermore, the Proposed Rule's new and expanded definitions often exceed, or are not in accordance with, existing definitions contained within the existing laws OCR seeks to enforce. For example, "health care entity" is defined under the Coats and Weldon Amendments to include a limited and specific range of individuals and entities involved in the delivery of health care. However, 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 by including a wide range of individuals, e.g., not just health care professionals, but any personnel, and institutions, including not only health care facilities and insurance plans, but also plan sponsors and state and local governments. This impermissibly expands statutory definitions and will create confusion.

We are also concerned that the proposed rule expands the range of health care institutions and individuals who may refuse to provide services, and broadens the scope of what qualifies as a refusal under the applicable law beyond the actual provision of health care services to information and counseling about health services, as well as referrals. For example, "assist in the performance" is defined as "participating in any program or activity with an articulable connection to a given procedure or service." The definition also states that it includes "counseling, referral, training, and other arrangements for the procedure, health service, or research activity." While "articulable connection" is not further explained, OCR states in the preamble that it seeks to provide broad protection for individuals and that a narrower definition, such as a definition restricted to those activities that constitute direct involvement with a procedure, health service, or research activity, would not provide sufficient protection as intended by Congress.

However, this definition goes well beyond what was intended by Congress. Specifically, the Church Amendments prohibit federal funding recipients from discriminating against those who refuse to perform, or "assist in the performance" of, sterilizations or abortions on the basis of religious or moral objections, as well as those who choose to provide abortion or sterilization. The statute does not contain a definition for the phrase "assist in the performance." Senator Church, during debate on the legislation, stated that, "the amendment is meant to give protection to the physicians, to the nurses, to the hospitals themselves, if they are religious affiliated institutions. 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." Read in conjunction with the rest of the proposed rule, it is clear this definition is intended to broaden the amendment's scope far beyond what was envisioned when the amendment was enacted. It allows 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.

In a similar fashion, the proposed definition of "workforce" extends the right to refuse not only to an entity's employees but also to volunteers and trainees. When both of these definitions are viewed together, this language seems to go well beyond those who perform or participate in a particular service to permit, for example, receptionists or schedulers to refuse to schedule or refer patients for medically necessary services or to provide patients with factual information, financing information, and options for medical treatment. It could also mean that individuals who clean or maintain equipment or rooms used in procedures to which they object would have a new right of refusal and would have to be accommodated. We believe this could significantly impact the smooth flow of health care operations for physicians, hospitals, and other health care institutions and could be unworkable in many circumstances.

The AMA is concerned that the Proposed Rule fails to address the interaction with existing federal and state laws that apply to similar issues, and thus is likely to create uncertainty and confusion about the rights and obligations of physicians, other health care providers, and health care institutions. Most notably, the Proposal is silent on the interplay with Title VII of the Civil Rights Act of 1964 and guidance by the Equal Employment Opportunity Commission, which along with state laws govern religious discrimination in the workplace. Title VII provides an important balance between employers' need to accommodate their employees' religious beliefs and practices—including their refusal to participate in specific health care activities to which they have religious objections—with the needs of the people the employer must serve. Under Title VII, employers have a duty to reasonably accommodate an employee or applicant's religious beliefs or practices, unless doing so places an "undue hardship" on the employer's business. It is unclear under the Proposed Rule if, for example, hospitals would be able to argue that an accommodation to an employee is an undue hardship in providing care. The Proposed Rule also could put hospitals, physician practices, and other health care entities in the impossible position of being forced to hire individuals who intend to refuse to perform essential elements of a job. Under Title VII, such an accommodation most likely would not be required.

Additional concerns exist for physicians with respect to their workforce under this Proposal. The Proposed Rule is unclear about what a physician employer's rights are in the event that an employee alleges discrimination based on moral or religious views when in fact there may be just cause for adverse employment decisions. For example, if a physician declines to hire an individual based on a lack of necessary skill, compensation and/or benefit requests out of the physician's budget, or simply because the individual is not a good fit in the office, but the individual also happens to be opposed to providing care to LGBTQ patients, does the physician open him/herself up to risk of a complaint to OCR? If so, physicians will be forced to substantially increase their documentation related to hiring and other decision-making related to human resources, adding administrative burden to already overworked practices. These considerations must not be overlooked by regulators, as OCR's enforcement mechanisms include the power to terminate federal funding for the practice or health care program implicated.

Adding to a practice's administrative burden is the Proposal's requirement that physicians submit both an assurance and certification of compliance requirements to OCR. Despite its reasoning in the preamble that HHS is "concerned that there is a lack of knowledge" about federal health care conscience and associated anti-discrimination laws, it remains unclear why OCR would require physicians to make two separate attestations of compliance to the same requirements, particularly given the administration's emphasis on reducing administrative burden in virtually every other space in health care. At the very least, OCR should (1) streamline the certification and assurance requirements with those already required on the HHS portal; and (2) expand the current exemptions from such requirements to include physicians participating not only in Medicare Part B, but also in Medicare Part C and Medicaid, as was the case in the 2008 regulation implementing various conscience laws. We reiterate, however, that we believe the overall compliance attestation requirements are unnecessary. If HHS' concern is about lack of awareness of the conscience laws, the AMA stands ready to assist with the agency's educational efforts in place of increased administrative requirements.

The Proposed Rule also seems to set up a conflict between conscience rights and federal, state, and local anti-discrimination laws, as well as policies adopted by employers and other entities and ethical codes of conduct for physicians and other health professionals. These laws, policies, and ethical codes are designed to protect individuals and patients against discrimination on the basis of race, gender, gender

identity, sexual orientation, disability, immigration status, religion, and national origin. It is unclear under the Proposed Rule how these important anti-discrimination laws, policies, and ethical codes will apply in the context of the expanded conscience rights proposed by OCR. The Proposed Rule also fails to account for those providers that have strongly held moral beliefs that motivate them to treat and provide health care to patients, especially abortion, end-of-life care, and transition-related care. For example, the Church Amendment affirmatively protects health care professionals who support or participate in abortion or sterilization services yet there is no acknowledgement of it in the Proposal.

Moreover, the Proposed Rule appears to conflict with, and in fact contradict, OCR's own mission, which states that "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" (emphasis added). In the past, HHS and OCR have played an important role in protecting patient access to care, reducing and eliminating health disparities, and fighting discrimination. There is still much more work to be done in these areas given disparities in racial and gender health outcomes and high rates of discrimination in health care experienced by LGBTQ patients. The Proposed Rule is a step in the wrong direction and will harm patients.

Likewise, the Proposed Rule does not address how conscience rights of individuals and institutions apply when emergency health situations arise. For example, the federal Emergency Medical Treatment and Labor Act (EMTALA) requires hospitals that have a Medicare provider agreement and an emergency room or department to provide an appropriate medical screening to any patient requesting treatment to determine whether an emergency medical condition exists, and to either stabilize the condition or transfer the patient if medically indicated to another facility. Every hospital, including those that are religiously affiliated, is required to comply with EMTALA. By failing to address EMTALA, the Proposed Rule might be interpreted to mean that federal refusal laws are not limited by state or federal legal requirements related to emergency care. This could result in danger to patients' health, particularly in emergencies involving miscarriage management or abortion, or for transgender patients recovering from transition surgery who might have complications, such as infections.

We are also concerned that the Proposed Rule could interfere with numerous existing state laws that protect women's access to comprehensive reproductive health care and other services. For example, the Proposed Rule specifically targets state laws that require many health insurance plans to cover abortion care (e.g., California, New York, and Oregon). OCR overturns previous guidance that was issued by the Obama administration providing that employers sponsoring health insurance plans for their employees were not health care entities with conscience rights; OCR argues that the previous guidance misinterpreted federal law, and, as discussed previously, proposes to add plan sponsors to the definition of health care entities. Likewise, the Proposed Rule could conflict with, and undermine, state laws related to contraceptive coverage. In addition, the Proposed Rule requires entities to certify in writing that they will comply with applicable Federal health care conscience and associated anti-discrimination laws. Under the broad language of the rule, hospitals, insurers, and pharmacies could claim they are being discriminated against if states attempt to enforce laws that require insurance plans that cover other prescription drugs to cover birth control, ensure rape victims get timely access to and information about emergency contraception, ensure that pharmacies provide timely access to birth control, and ensure that

hospital mergers and sales do not deprive patients of needed reproductive health services and other health care services.

In conclusion, the AMA believes that, as currently drafted, the Proposed Rule could seriously undermine patients' access to necessary health services and information, negatively impact federally-funded biomedical research activities, and create confusion and uncertainty among physicians, other health care professionals, and health care institutions about their legal and ethical obligations to treat patients. Given our concerns, we urge HHS to withdraw this proposed rule. If HHS does decide to move forward with a final rule, it should, at the very least, reconcile the rule with existing laws and modify the provisions we have identified to ensure that physicians and other health providers understand their legal rights and obligations.

Sincerely,

James L. Madara, MD

# Exhibit 92

KAISER PERMANENTE®

Kaiser Foundation Health Plan
Program Offices

Submitted electronically to: *www.regulations.gov*

March 27, 2018

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

RE: *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, Docket No. HHS–OCR–2018–0002*

Dear Sir or Madam:

Kaiser Permanente offers the following comments in response to the proposed rule, *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority* (the Proposed Rule) issued in the Federal Register (83 FR 3880) on January 26, 2018, which intends to promulgate regulations to ensure that the Department of Health and Human Services (the Department) funds do not support discriminatory practices or policies.

Kaiser Permanente is the largest private integrated health care delivery system in the United States, delivering health care to nearly 12 million members in eight states and the District of Columbia. Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii (Health Plan); the not-for-profit Kaiser Foundation Hospitals (Hospitals), which operates 39 hospitals and 680 other clinical facilities; and the Permanente Medical Groups (Medical Groups), independent physician group practices that contract with Kaiser Foundation Health Plan to meet the health needs of Kaiser Permanente's members.

This Proposed Rule will broadly impact Kaiser Permanente – as a provider of health care, through its Medical Groups, Hospitals and pharmacy system; as a health plan; and as a large employer of approximately 290,000 persons, including 22,100 physicians and 58,000 nurses.

Kaiser Permanente recognizes the importance of protecting the religious or moral beliefs of our workforce. We adhere to strict policies and practices that protect our workforce from religious and moral compromise and related discrimination. However, Kaiser Permanente also recognizes the importance of ensuring our members equitable access to high quality, affordable care. The Proposed Rule fails to acknowledge that conscience objections may conflict with patient rights

One Kaiser Plaza, 27L
Oakland, CA 94612

and professional obligations and fails to suggest or even allow for acceptable practices that balance the rights of the workforce with the needs of patients. A Final Rule should interpret the statutory language to balance the conscience protections of the health care workforce with the needs and rights of patients.

The Proposed Rule is at odds with numerous Department policies that place the patient at the center of health care delivery and focus on measurable quality of care, patient satisfaction, and access. Examples of this can be seen in the Department's strategic goals and movement towards value-based payment that rewards providers for improved patient outcomes and satisfaction. Similarly, the Rule is at odds with numerous state efforts to protect patients and improve their care experience. Additional guidance is needed to understand the intersection of the Proposed Rule with existing federal and state policies.

Kaiser Permanente's greatest concerns with the Proposed Rule are:

- The Department's proposed definitions for "assist in the performance" and "referral or refer" permit providers to withhold not just needed services, but information or referral to another provider or source of information, eliminating options for ensuring patients' access to needed care.
- The Proposed Rule's broad interpretation of the federal statutes appears to create conflicts with other federal and state laws and the Rule provides limited guidance on how to resolve such conflicts.
- The Proposed Rule's broad interpretation of the authorizing statutes creates confusion in several key areas that impact the business operations of physicians, hospitals, pharmacists, laboratories, health plans and others in the health care sector, including the rules governing relationships with employees, contracts with other entities, and systems of compliance. This will lead to significant administrative and financial burdens for health care businesses that will further strain health care resources.

Our detailed recommendations for clarifying or modifying the Proposed Rule follow.

**Section 88.2. Definitions**

Issue:
The Proposed Rule creates sweeping definitions for statutory terms that broaden the reach of those statutes and diminish health care entities' ability to ensure that the needs and rights of patients are met without compromising the moral or religious beliefs of the workforce. Additionally, several vague definitions create operational difficulties for health care entities required to comply with the regulations.

Recommendations:
Assist in the Performance. The Department would define "assist in the performance" to include participation "in any program or activity with an articulable connection to a procedure, health service, health program, or research activity." This includes but is not limited to "counseling, referral, training, and other arrangements for the procedure, health service, health program, or research activity." The definition encompasses an inappropriately broad scope of activities in

using the open-ended "articulable connection." The Proposed Rule provides examples of an "articulable connection" – counseling, referral, training, and other arrangements – but these examples only broaden the scope of the definition and create additional ambiguity.

Defining "assist in the performance" to include counseling and referral could conflict with physicians,' hospitals' and health plans' obligations and regulatory requirements to provide patients access to health care services and could potentially endanger patient health and safety in certain circumstances. For example, this definition would allow a provider with religious or moral objections to blood transfusions to refuse to offer that treatment to a patient with a life-threatening condition and fail to refer the patient to a provider who does not have an objection. As another example, the Proposed Rule would allow a provider with religious or moral objections to refuse to vaccinate a newborn or provide parents with information about recommended childhood vaccinations. Both situations could lead to immediate and irreparable harm to patients.

The Department should replace the open-ended "articulable connection" with language that directly connects the assistance to the objectionable procedure or service and limit it to the clinical setting. This definition should include a complete, not illustrative, description of the activities subject to the rule (i.e., providing, training, or ordering a procedure) and should not include counseling or referral.

Referral or Refer for. The Proposed Rule defines "referral or refer for" to include "the provision of any information… by any method…pertaining to a health care service, activity, or procedure..."[1] This definition would create an overly broad scope by allowing a single individual interacting with a patient to block access to information about medically necessary care. This definition would conflict with health care providers' legal and professional ethical obligations to refer patients who need medically necessary services.

This definition also eliminates an effective process for health care entities, particularly entities like Kaiser Permanente that use an integrated model of care, to protect the religious rights of our workforce. Referral allows providers to refrain from performing or assisting in the performance of an activity, while allowing organizations like ours to meet our legal obligations to provide access to services and treatment guaranteed under contract and frequently mandated under state law. The proposed language creates a dichotomy in which a health plan may be obligated to provide or arrange for a covered service but be unable to do so if a provider has a religious or moral objection to performing or referring for that service. The Department should permit and encourage providers to refer or otherwise arrange for patient care if they cannot provide it themselves due to religious or moral objections. In a Final Rule that includes "referral," we suggest narrowing the definition of "referral" to active facilitation of access.

Discriminate or Discrimination. The Proposed Rule's definition of "Discriminate or Discrimination" is also overly broad and creates operational challenges for employers. The definition appears to preclude an employer from denying employment to an applicant who objects on moral or religious grounds to performing the primary job responsibilities, even where no reasonable accommodation exists and the applicant's inability to perform the responsibilities

[1] 83 FR 3924

would disrupt business operations. Similarly, if a current employee expresses an objection to performing primary job responsibilities on religious grounds, removing the employee from the position and reassigning them to a comparable position could run afoul of the Rule.

Federal Financial Assistance. The Proposed Rule defines "Federal Financial Assistance" to include "[a]ny Federal agreement, arrangement, or other contract that has as one of its purposes the provision of assistance."[2] The inclusion of any "arrangement" and the "provision of assistance" make this particularly challenging for business entities that provide health care and coverage to interpret. The Final Rule's definition of "Federal Financial Assistance" should not include the ill-defined category "arrangement" and should clarify whether this definition includes any claim for payment, payments in exchange for health care services, or applications to participate in a federal program through which payment would be made.

Health Care Entity. The Proposed Rule states that the definition of "health care entity" includes health care professionals and health care personnel, among other categories. The Department should specifically define "health care professional" or "health care personnel" in the definition of "health care entity." Health care businesses should know specifically which employees are included under this definition.

Sub-Recipient. The definition for "Sub-Recipient" is overly broad and has the potential to bring into scope individuals and entities that indirectly receive any amount of federal financial assistance. Administrative and operational costs to health care businesses to identify subrecipients and to track their compliance with the Proposed Rule would be significant. The Final Rule should specifically limit sub-recipients to those for whom there is a direct pass-through of federal financial assistance and who are identified as sub-recipients of such dollars in contracts with the direct recipient. This definition should not subsume every contracting party of a recipient of federal financial assistance.

Workforce. The Proposed Rule includes "volunteers" and "contractors" in the definition of "workforce." The Department should modify this definition to include only volunteers or contractors performing or assisting the performance of health care activities. If the Rule maintains a broader definition of "volunteers" and "contractors," it should clarify the statutory basis to support the decision to use such a broad definition.

Religious or Moral Objections. The Final Rule should define "Religious or Moral Objections" and thereby clarify the group of individuals who can object to performing or assisting in the performance of services. The Final Rule should adopt similar definitions of these terms as provided in the employment and First Amendment context when religious accommodations and protections are sought.

[2] 83 FR 3924

**Requirements for Conscience Objections**

Issue:
The Proposed Rule does not provide guidance about the processes that should be in place to enable a health care provider to raise a conscience objection, making it more challenging for health care businesses to ensure quality and patient satisfaction.

Recommendations:
The Proposed Rule fails to create an obligation for the objecting provider or employee to notify, in advance or otherwise, the employer of what services they object to providing. Without a duty to inform employers, an individual could be hired into and remain in a job he or she cannot fully perform. There are no guardrails that enable employers to take advance steps to ensure patients get the care they need. Likewise, there are no guardrails to ensure that employers are informed at the time when patients do not receive medically necessary services or information about those services. Particularly in an emergency, notice is critically important to patient safety.

Without appropriate notification requirements, the Rule will introduce inconsistencies in the quality of care patients receive, as it would depend on their providers' religious and moral beliefs. This limits health care entities' ability to ensure high-value coordinated care, patient safety and patient satisfaction and is inconsistent with numerous other Department policies.

The Final Rule should establish processes that an individual should follow when raising a conscience objection. Health care workers with a religious or moral objection to performing a service should have a duty to notify their employer or putative employer so that reasonable accommodations can be considered to respect the workers' beliefs, as well as the needs and rights of the patient. Under current law, employees are required to provide notice and request accommodation of disabilities and religious beliefs. The Final Rule should specify how a provider should exercise a conscience objection if an individual is in an emergency and in need of health care services.

**Section 88.4 Assurance and Certification**

Issue:
The Proposed Rule conditions the continued receipt of Federal financial assistance or Federal funds on an assurance and certification. Payment conditioned on assurance and certification goes beyond the intent of the underlying statutes. The broad enforcement remedies allow the Office for Civil Rights to choose an appropriate and effective means of enforcement, which is sufficient to increase awareness of and compliance with the requirements of the regulation. As drafted, the proposed Rule could result in health care entities being subject to both civil litigation and regulatory action.

Recommendations:
Section 88.4 of the Proposed Rule describes, as a condition of receipt of Federal financial assistance or Federal funds, the requirement that applicants or recipients provide written assurance and certification of compliance with federal conscience laws. The Department has stated that certifications "provide a demonstrable way of ensuring that applicants for such funding

know of, and attest that they will comply with, applicable Federal health care conscience and associated anti-discrimination laws" and that assurances and certifications "would provide an important vehicle for increasing awareness of [those] laws and thereby increas[e] compliance."[3]

Tying certification to payment is not necessary to accomplish the Department's stated goals, which can be met through the submission process for the proposed attestations and certifications themselves. Payment conditioned on certification is additionally unnecessary given the broad remedies proposed in Section 88.7 (Enforcement). Section 88.7 delegates to the Office for Civil Rights the authority to enforce the federal conscience laws, including handling complaints, conducting investigations, referring to the Department of Justice, and "tak[ing] other appropriate remedial action as the Director of OCR deems necessary and as allowed by law…."[4] The Proposed Rule also grants the Office for Civil Rights the authority to temporarily withhold cash payments, deny and/or terminate use of federal monies, refer matters to the Attorney General, and "tak[e] any other remedies that may be legally available."[5] The proposed remedies allow the Office for Civil Rights to choose an appropriate means of enforcement, bounded by law and the intent of the underlying statutes.

In contrast, requiring that certification be tied to payment does not effectuate the intent of the underlying statutes, and potentially provides an avenue for third party litigation outside of the Office for Civil Rights' purview. Under the Proposed Rule, a health care entity could be found to have violated the assurance and certification requirement, potentially subjecting it to two separate processes: one pursued by the Office for Civil Rights and civil litigation filed and pursued by a *qui tam* plaintiff. A health care entity would be required to defend against the litigation regardless of whether the Office for Civil Rights found an assurance and certification violation or otherwise pursued a remedy against the entity.

The Final Rule should not include an assurance or certification requirement tied to payment.

**Section 88.5 Notice**

Issue:
The notice requirements of the Proposed Rule will be administratively and financially burdensome to health care entities. The notice text in Appendix A may be misleading.

Recommendations:
The Proposed Rule requires the Department and all recipients to post the notice text in Appendix A within 90 days of the publication of the Final Rule on websites and in conspicuous physical locations.

Kaiser Permanente's experience with ACA Section 1557 Nondiscrimination and Language Assistance Notices (1557 Notices) leads us to believe that the notice requirements will create significant administrative and financial burdens on health care entities and that the Proposed Rule underestimates that burden. Various regulators required the publication of multiple versions

[3] 83 FR 3896
[4] Section 88.7(a)
[5] Section 88.7(j)

of the 1557 Notices with variations in content. The Department's recommended 1557 content for commercial plans differed from that required by the Centers for Medicare and Medicaid Services' for Medicare and/or Medicaid plans, and that required by state regulators based on state code requirements for nondiscrimination disclosures. For an integrated health system operating in eight states and the District of Columbia, this resulted in approximately 20 different versions of the 1557 Notices and an unexpected and ongoing operational impact to manage numerous versions of notices used with different types of documents based on line of business, region of operation, and medium. The varying requirements of both federal and state agencies created confusion and uncertainty. Without clarifying the notice requirements, we anticipate health care businesses and government agencies spending considerable time and resources responding to employees' inquiries.

We do not believe the notice requirements in the Proposed Rule will be any less burdensome. As written, the rule requires use of the exact text in Appendix A and claims that this approach maximizes efficiency and economies of scale, but the Department also authored ACA Section 1557 notices and the benefits were not realized due to the variations in regulatory guidance.

The Final Rule should reduce the burden on health care businesses by seeking ways to streamline notice requirements. The Department should coordinate with other federal and state agencies to align on the content of the Notice in the Final Rule's Appendix A. Additionally, the notice language in Appendix A may be overbroad in stating that "you" may decline to "refer for" or "pay for" "certain health care-related treatments, research, or services." Not all individuals have the right, in all circumstances, to refuse to refer for or pay for treatments. The text of the Notice in the Final Rule's Appendix A should be adjusted to more accurately reflect the scope and coverage of individual rights.

**Section 88.6 Compliance**

Issue:
If the Proposed Rule is adopted, health care entities will require additional guidance for implementing or modifying organizational compliance policies.

Recommendations:
The Proposed Rule states that recipients and sub-recipients must maintain records evidencing compliance. The Department should delineate what records must be retained and how an entity affirmatively demonstrates compliance or this provision should be deleted.

The Proposed Rule requires recipients and sub-recipients to inform Departmental funding components if they are subject to an Office for Civil Rights compliance review, investigation, or complaint related to a religious or moral objection. The Proposed Rule does not describe the process through which covered entities would inform Departmental Components. Health care businesses would benefit from more detail on these requirements and some limitations. Since large organizations may receive federal financial assistance from many different sources and for many different purposes, it is far too sweeping to require that recipients notify funding sources of any investigation into compliance.

Reporting should only be required when an investigation relates to alleged non-compliance during activities conducted with the federal funding provided by the funding component. The Final Rule should require federal agencies to communicate and not to place the burden on investigated entities to inform all agencies from which they obtain funding.

The Proposed Rule requires recipients and sub-recipients to disclose, with any application for new or renewed Federal financial assistance or Departmental funding, the existence of compliance reviews, investigation, and complaints filed with the Office for Civil Rights for five years from such complaints' filing. Given that recipients are subject to enforcement actions due to violations of sub-recipients, clarification is needed on whether recipients must disclose the compliance reviews, investigations, and complaints filed on sub-recipients. The Final Rule should exempt unsubstantiated complaints from the five-year retrospective reporting obligation on applications, since they are not relevant to a consideration of an entity's eligibility for funding.

Under the Proposed Rule, funding restrictions may be imposed on recipients if their sub-recipients are non-compliant. It is excessive for recipients to lose funds because one of their sub-recipients engaged in prohibited actions. At a minimum, this should be discretionary based upon the degree of fault or non-compliance by the recipient. Additionally, the only funding that should be at risk is the funding that the primary recipient received for the project or business relationship undertaken with the sub-recipient.

The Proposed Rule creates risks for recipients related to the behavior of sub-recipients, but does not account for the limited influence a recipient may have over sub-recipients regarding compliance. To the extent the Proposed Rule encourages recipients to control the compliance activities of its sub-recipients, the Propose Rule may potentially expose recipients to joint employer liability under other federal or state labor and employment laws. The guidelines should instead address how recipients may establish processes, including contractual representations and warranties, that can be used to support sub-recipient compliance and provide information to recipients to ensure sub-recipient compliance, including disclosure of any Office for Civil Rights compliance reviews, investigations, and complaints.

The Final Rule should contain guidelines for compliance and a more thorough discussion of how the complaint system and enforcement of these nondiscrimination regulations will operate. The Rule should model guidelines after the policies and procedures in current federal and state employment discrimination laws and regulations. The guidelines should specify who in the Department should be informed of compliance reviews, investigations, or complaints, at what frequency and what information the Department wishes to receive.

**Section 88.7 Enforcement**

Issue:
The section of the Proposed Rule authorizing the Office for Civil Rights to enforce the Rule, inappropriately expands the class of persons who can bring complaints against health care entities.

Recommendations:

Pursuant to the Proposed Rule, anyone may file a complaint with the Office for Civil Rights, not only the person or entity whose rights have been potentially violated. The Department specifies "[t]he complaint filer is not required to be the person, entity, or health care entity whose rights under the Federal health care conscience and associated anti-discrimination laws or this part have been potentially violated."[6] Similarly, the Preamble states, "[u]nder the proposed rule, OCR would also be explicitly authorized to investigate 'whistleblower' complaints, or complaints made on behalf of others, whether or not the particular complainant is a person or entity protected by conscience and associated anti-discrimination laws."[7]

As noted above, the Office for Civil Rights has various remedies, including withholding, denying, suspending payments, awards, and Federal financial assistance, and referral to the Department of Justice. The remedies can be triggered "when there appears to be a failure" or even a "threatened" failure to comply with the underlying laws or the proposed regulation.

The Final Rule should limit those who can file a complaint to those who have suffered harm, as defined by the Rule and the statutes from which the Rule gains its authority. The Final Rule should eliminate the references to the apparent and "threatened" failures to comply with the law and reserve the remedies for those who have failed to comply.

**Section 88.8 Relationship to Other Laws**

Issue:
The Proposed Rule's broad interpretation of the federal statutes from which it derives its authority may create conflicts with other federal and state laws:

- Title VII of the Civil Rights Act of 1964 and other applicable federal and state laws authorize employers to engage in the interactive process with an employee to explore whether the employee's religious practices can be reasonably accommodated without incurring an undue hardship. Under Title VII, there may be instances in which a health care entity is unable to accommodate the employee's refusal to perform, or assist in performing, a health care activity because the accommodation is not reasonable or would pose an undue hardship.

- 42 U.S.C. 5106i(b) requires states to permit child protective services to pursue legal remedies to provide treatment to children whose parents have objected to treatment on religious grounds in certain circumstances. The Proposed Rule interprets 29 U.S.C. 290bb-36(f) as prohibiting requiring a parent or legal guardian to provide a child any medical service or treatment against their religious beliefs or moral objections. Under the Rule, States are neither required to find nor prohibited from finding child abuse or neglect in cases in which parents or legal guardians rely solely or partially on spiritual means rather than medical treatment.

[6] 88.7(b)
[7] 83 F.R. 3898

- Federal and state laws mandate coverage for certain care and treatment. For example, providers who accept Medicare Part A and/or Medicaid must provide transgender individuals equal access to facilities and services and must treat transgender individuals consistent with their gender identity.[8] A provider may assert a religious or moral objection and deny services to transgender individuals in violation of those patients' rights.

- Public health law authorizes federal agencies to establish communicable disease control policies that may impose requirements on providers related to services, counseling or reporting.[9]

- State laws require pharmacists to fill any legal prescription, even those to which he or she has a moral or religious objection.[10]

- State laws may require that patients receive notice about providers or hospitals that do not cover certain services.[11]

- Existing state laws address the following issues: Advanced directives; abortion, sterilization, and contraception; physician assisted suicide; newborn hearing screening; vaccinations and immunizations; privacy; sexual orientation; and transgender care.

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[8] 45 C.F.R. § 92.206 (stating that healthcare services and health coverage may not be denied because a person's gender identity differs from his/her sex assigned at birth. Providers may not limit a transgender person's access to services ordinarily available to people of only one sex based on the transgender person's sex assigned at birth or gender identity).

[9] 42 U.S.C. § 264. The Public Health Services Act authorizes the Secretary of Health and Human Services to make and enforce regulations necessary "to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession."

[10] Recent state laws and proposed legislation have addressed pharmacists' rights and responsibilities in dispensing contraception/emergency contraception. Some states would allow pharmacists to refuse, on moral grounds, to fill a prescription for contraceptives; other states would require pharmacists to fill any legal prescription for birth control. *See* *http://www.ncsl.org/programs/health/conscienceclauses.htm*

[11] *See* California Health & Safety Code 1363.02 (a) The Legislature finds and declares that the right of every patient to receive basic health information necessary to give full and informed consent is a fundamental tenet of good health policy and has long been the established law of this state. Some hospitals and other providers do not provide a full range of reproductive health services and may prohibit or otherwise not provide sterilization, infertility treatments, abortion, or contraceptive services, including emergency contraception. It is the intent of the Legislature that every patient be given full and complete information about the health care services available to allow patients to make well informed health care decisions.
(b) On or before July 1, 2001, a health care service plan that covers hospital, medical, and surgical benefits shall do both of the following:
(1) Include the following statement, in at least 12-point boldface
type, at the beginning of each provider directory:
"Some hospitals and other providers do not provide one or more of the following services that may be covered under your plan contract and that you or your family member might need: family planning; contraceptive services, including emergency contraception; sterilization, including tubal ligation at the time of labor and delivery; infertility treatments; or abortion. You should obtain more information before you enroll. Call your prospective doctor, medical group, independent practice association, or clinic, or call the health plan at (insert the health plan's membership services number or other appropriate number that individuals can call for assistance) to ensure that you can obtain the health care services that you need."

Recommendations:
The Final Rule should contain guidelines and a more thorough discussion of how the provider conscience regulations will intersect with federal and state laws and discuss how situations will be evaluated when there is a federal or state law that is contrary to the provider conscience regulations. Section 88.8, governing the Proposed Rule's relationship to other laws, clarifies that the Rule is not intended to preempt any Federal, State or local law equally protective of religious freedom and moral convictions. It is not clear how it will be determined whether state laws are, in fact, "equally protective." Clarification is needed whether the Department will defer to state and local regulatory interpretation of whether their laws are equally protective of religious freedom and moral convictions.

The preemption standard seems to create the undesirable consequence of preempting state laws that are protective of patients when those protections conflict with the religious freedom and moral convictions of the health care workforce. The Department should discuss how provider conscience objections can be exercised without taking away the ability of states to regulate areas that are traditionally the subject of state jurisdiction.

The Final Rule should clarify how a health care entity should respond to an employee's refusal to participate or assist in participating in a health service in circumstances addressed by an applicable collective bargaining agreement. Where a health care entity has reached a bargained agreement with a union that addresses how to respond to a represented employee's objection to participating in a medical procedure, the Proposed Rule does not clarify whether that bargained agreement can continue to be enforced.

We appreciate the opportunity to comment on these important issues. Please contact Leah Newkirk at (510) 271-5938 or leah.g.newkirk@kp.org with any questions.

Sincerely,

Anthony Barrueta
Senior Vice President
Government Relations
Kaiser Permanente

Stephen M. Parodi, MD
Associate Executive Director
The Permanente Medical Group
Executive Vice President, External Affairs
The Permanente Federation LLC

# Exhibit 93

ALAMEDA COUNTY
**HEALTH CARE SERVICES**
AGENCY
COLLEEN CHAWLA, Director

**OFFICE OF THE AGENCY DIRECTOR**
1000 San Leandro Boulevard, Suite 300
San Leandro, CA 94577
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March 27, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Subject: Docket Number: HHS-OCR-2018-0002
Conscience NPRM: RIN 0945-ZA03
Proposed Rule: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Secretary Azar:

On behalf of the County of Alameda, California, I write today regarding the Department's Notice of Proposed Rule Making (NPRM) that would allow for the Conscience and Religious Freedom division to handle investigations of religious freedom complaints, compliance, and enforcement.

The County of Alameda is committed to providing and supporting services that promote healthy and thriving populations. Our County values and strives to increase access to equity, fairness, and inclusive health services. We appreciate and support efforts to prevent discrimination of health workers, but we are concerned that the proposed rule language could be misinterpreted, allowing for discrimination of those needing essential medical services who could be denied care based on moral or religious convictions of the provider. This denial of care would ultimately perpetuate health care inequalities and health disparities. Additionally, this will deteriorate patient care and puts the health and wellbeing of our residents at risk.

Specifically, our concerns with the proposed rule are the following:

1. **Financial implications –** Our County and community health providers strive to develop effective and efficient ways to provide services at a low cost because adequate health care funding is not provided and oftentimes funding is threatened and/or cut for low-income and indigent individuals. If enacted, the proposed rule would allow for the denial of care and would increase health costs to our County and our providers. Health needs persist. Those who are denied treatment would seek care in emergency rooms and other higher-cost venues. The proposed rule would cause staff shortages. It must also be recognized that many of our community health providers operate on a tight budget and do not have the additional staff on hand to fill in should a colleague refuse to provide care under these regulations. If this rule is implemented, approximately 430,000 individuals in Alameda County enrolled in Medi-Cal could be negatively impacted.
2. **Destroys trust –** Our County and community health providers serve the most in need and vulnerable populations. To effectively serve them, relationships are built and trust is fostered. This proposed rule would destroy the relationships we have developed with individuals that are hard to reach and are unlikely to obtain health services. For example, the County's Health Care for the Homeless Program provides health services to over 9,000 homeless individuals. These clients are facing difficult physical and mental health challenges and denying services will have catastrophic consequences especially those who are suicidal, have substance use disorders (such as opioids), etc.

3. **Endangers public health –** The proposed rule could be a barrier that leads to delays in controlling communicable diseases and endangering public health. For example, recently, there was a Hepatitis A virus outbreak in California and a State of Emergency was declared. Quick response, education, and immunizations are necessary to prevent and control current and future outbreaks. If health workers decline to provide immunizations, containment efforts would be impacted.

The County of Alameda urges the Department of Health and Human Services, Office for Civil Rights to seriously consider our concerns and revise the proposed rule so that it does not restrict access to health care and allow for discrimination that can ultimately cause financial burdens, destroy community trust, and endanger public health.

Sincerely,

Colleen Chawla, Director
Alameda County Health Care Services Agency

# Exhibit 94

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

Office of the President
Haywood Brown, MD, FACOG

March 27, 2018

VIA ELECTRONIC SUBMISSION

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

**Re: RIN 0945-A03; Protecting Statutory Conscience Rights in Health Care; Delegations of Authority**

Dear Secretary Azar:

The American College of Obstetricians and Gynecologists (ACOG) writes in response to the proposed rule, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" (Proposed Rule), published in the Federal Register on January 26, 2018 by the Department of Health and Human Services (HHS) Office for Civil Rights (OCR).

The creation of the Proposed Rule, coupled with the creation of a new division within OCR – the "Conscience and Religious Freedom Division" – suggests a concerning expansion of OCR's authority in a way that threatens to restrict access for patients seeking medical care and support. We are concerned that the Proposed Rule and new office will encourage some providers and institutions to place their personal beliefs over their patients' medical needs, a move that can have real-world, potentially life-and-death consequences for patients. ACOG opposes this expansion and calls on HHS and OCR to immediately withdraw the Proposed Rule.

ACOG believes that respect for an individual's conscience is important in the practice of medicine, and recognizes that physicians may find that providing indicated care could present a conflict of conscience. ACOG is committed to ensuring all women have unhindered access to health care and opposes all forms of discrimination.[i]

As outlined in the American Medical Association's Code of Medical Ethics, responsibility to the patient is paramount for all physicians. ACOG holds that providers with moral or religious objections should ensure that processes are in place to protect access to and maintain a continuity of care for all patients. If health care providers feel that they cannot provide the standard services that patients request or require, they should refer patients in a timely

manner to other providers. In an emergency in which referral is not possible or might negatively impact the patient's physical or mental health, providers have an obligation to provide medically indicated and requested care. Conscientious refusals should be limited if they constitute an imposition of religious or moral beliefs on patients, negatively affect a patient's health, are based on scientific misinformation, or create or reinforce racial or socioeconomic inequalities. The Proposed Rule disregards these rigorous standards of care established by the medical community.

The Proposed Rule demonstrates political interference in the patient-physician relationship. Institutions, facilities, and providers must give patients the full range of appropriate medical care to meet each patient's needs as well as relevant information regarding evidence-based options for care, outcomes associated with different interventions, and, in some cases, transfer to a full-service facility. Communication is the foundation of a positive patient-physician relationship and the informed consent process.[ii,iii] By allowing providers to refuse to provide patients with information, the Proposed Rule makes it impossible for patients to make the health care decision that is right for them. All patients should be fully informed of their options.[iv]

ACOG evaluates policies based on the standard of "first, do no harm" to patients, and the result of the Proposed Rule could be just the opposite. Across the country, refusals of care based on personal beliefs have kept women from needed medical care.[v]

The Proposed Rule expands existing conscientious refusal laws by allowing any entity involved in a patient's care to claim a conflict of conscience, from a hospital board of directors to an individual who schedules procedures, and by allowing the refusal of "any lawful health service or activity."[vi] This threatens patients' access to all health care services, including vaccinations and blood transfusions.

ACOG believes that the top priority in any federal rulemaking must be ensuring access to comprehensive, evidence-based health care services. Access to comprehensive reproductive health care services is essential to women's health and well-being.[vii] ACOG urges HHS and OCR to put patients first and withdraw the Proposed Rule.

Sincerely,

Haywood L. Brown, MD, FACOG
President
American College of Obstetricians and Gynecologists



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[i] American College of Obstetricians and Gynecologists. Statement of Policy: Racial Bias. Feb 2017. *Accessed online:* https://www.acog.org/-/media/Statements-of-Policy/Public/StatementofPolicy93RacialBias2017-2.pdf?dmc=1&ts=20180326T1531018088

[ii] Informed consent. ACOG Committee Opinion No. 439. American College of Obstetricians and Gynecologists. Obstet Gynecol 2009; 114:401–8.

[iii] Partnering with patients to improve safety. Committee Opinion No. 490. American College of Obstetricians and Gynecologists. Obstet Gynecol 2011;117:1247–9.

[iv] Effective patient–physician communication. Committee Opinion No. 587. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;123:389–93.

[v] American College of Obstetricians and Gynecologists. Position Statement: Restrictions to Comprehensive Reproductive Health Care. April 2016. *Accessed online:* https://www.acog.org/Clinical-Guidance-and-Publications/Position-Statements/Restrictions-to-Comprehensive-Reproductive-Health-Care

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

[vii] Increasing access to abortion. Committee Opinion No. 613. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;124:1060–5.



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# Exhibit 95

NCJW

National Council of Jewish Women

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

**From:**
Carly Manes
Director, Commission on Social Action of Reform Judaism
Associate Director, Religious Action Center of Reform Judaism
1707 L St. NW
Washington, D.C. 20036

**Re:** RIN 0945-ZA03
**DT:** March 27, 2018

To whom it may concern:

I am writing on behalf of the National Council of Jewish Women (NCJW) in response to the proposed rule from the U.S. Department of Health and Human Services, RIN 0945-ZA03, titled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority." Inspired by Jewish values, NCJW strives for social justice by improving the quality of life for women, children, and families and by safeguarding individual rights and freedoms.

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 involved in patient care to use their personal beliefs to deny people the care they need. For the reasons outlined below, the National Council of Jewish Women 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)."[1] 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 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

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[1] *See id.* at 12.

[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.

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

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

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.[7] 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.[8] 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.[9]

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

Across the country refusals of care based on personal beliefs have been invoked in countless ways to deny patients the care they need.[12] One woman experiencing pregnancy complications rushed to the only hospital in her community, a religiously affiliated facility, where she was denied the miscarriage

[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.
[10] *See* Rule *supra* note 1, at 180.
[11] *Id.*
[12] *See, e.g.*, *supra* note 3.

management she needed because the hospital objected to this care.[13] Another woman experiencing pregnancy loss was denied care for ten days at a religiously affiliated hospital outside Chicago, Illinois.[14] In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy.[15] 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.[16] Another woman was sent home by a religiously affiliated hospital with two Tylenol after her water broke at 18 weeks of pregnancy. Although she returned to the hospital twice in the following days, the hospital did not give her full information about her condition and treatment options.[17]

*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

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[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 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, *Nuestra Voz, Nuestra Salud, Nuestro Texas: the Fight for Women's Reproductive Health in the Rio Grande Valley* 1, 7 (2013), http://www.nuestrotexas.org/pdf/NT-spread.pdf.

[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/.

where many health systems 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]

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

By expanding refusals of care the Proposed Rule will exacerbate the barriers to health care services patients need. It is evident that the harm caused by this Proposed Rule will fall hardest on those most in need of care by allowing individuals and health care entities to use their personal beliefs to dictate patient care. The Department should remember, under Executive Order 13563, an agency may only propose regulations where it has made a reasoned determination that the benefits justify the costs and where the regulations are tailored "to impose the least burden on society."[27] The Proposed Rule plainly fails on both counts. Although the Proposed Rule attempts to quantify the costs of compliance, it

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[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-staggering-number-of-people-into-extreme-poverty; *Tracking Universal Health Coverage: 2017 Global Monitoring Report*, WORLD HEALTH ORG. & THE WORLD BANK (2017), http://documents.worldbank.org/curated/en/640121513095868125/pdf/122029-WP-REVISED-PUBLIC.pdf.

[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/gender-sexuality/PRPCP/bearingfaith.pdf.

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

[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/.

[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-catholic-hospitals-2013.pdf.

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

[27] 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.

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.[28]

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.[29] Because the Proposed Rule would cause substantial harm, including to patients, it would violate the Establishment Clause.[30]

**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.[31] For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling[32] and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.[33] 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.[34] 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.[35] 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

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

[29] 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).

[30] 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.

[31] *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.

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

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

[34] *See, e.g.*, Rule *supra* note 1, at 180-185.

[35] *See* NFPRHA *supra* note 34.

under-insured, and uninsured individuals, rely on Title X clinics to access services they otherwise might not be able to afford.[36]

**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.[37] 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.[38] Informed consent requires providers disclose relevant and medically accurate information about treatment choices and alternatives so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.[39] 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.[40]

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.[41] Individuals seeking reproductive health care, regardless of their reasons for

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[36] *See id.*

[37] *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.

[38] *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).

[39] *See id.*

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

[41] 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).

needing these services, should be treated with dignity and respect. Allowing providers to flout established medical guidelines and deny medically accurate, evidence-based care to patients harms them and impairs their ability to make the health care decision that is right for them.

In addition, the Proposed Rule ignores the many providers with deeply held moral convictions that affirmatively motivate them to provide patients with health care, including abortion, transition-related care, and end-of-life care. Moreover, the Proposed Rule fails to acknowledge the Church Amendments' protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce.[42] 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.[43] 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.[44] They will place a significant and burdensome requirement on health care providers and impose unique challenges for those working in other countries by taking resources away from patient care without adding any benefit.

The Department, including OCR, has an important role to play in ensuring equal opportunity to access health care and ending discriminatory practices that contribute to poor health outcomes and health disparities.[45] 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

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

[43] *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.").

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

[45] 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.

care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.[46]

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.[47] 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.[48] Further, the disparity in maternal mortality is growing rather than decreasing,[49] which in part may be due to the reality that women have long been the subject of discrimination in health care and the resulting health disparities. For example, women's pain is routinely undertreated and often dismissed.[50] 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.[51] Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.[52] 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.[53]

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

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

[47] *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.

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

[49] *See id.*

[50] *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).

[51] *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).

[52] *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.

[53] *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.

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.[54]

**Conclusion**

The Proposed Rule will allow personal moral and 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 National Council of Jewish Women calls on the Department to withdraw the Proposed Rule in its entirety.

Sincerely,

Jody Rabhan

Director of Washington Operations, National Council of Jewish Women

# Exhibit 96

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

March 27, 2018

The Honorable Roger Severino
Director
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, DC 20201

Submitted via the Federal Regulations Web Portal, http://www.regulations.gov

**RE: Protecting Statutory Conscience Rights in Health Care Proposed Rule, RIN 0945–ZA03**

Dear Director Severino:

The Blue Cross Blue Shield Association ("BCBSA") appreciates the opportunity to provide comments on the proposed rule, Protecting Statutory Conscience Rights in Health Care, 83 Fed. Reg. 3880 (January 26, 2018; "Proposed Rule").

BCBSA is a national federation of 36 independent, community-based, and locally operated Blue Cross and Blue Shield Plans ("Plans") that collectively provide healthcare coverage for one in three Americans. For more than 80 years, Blue Cross and Blue Shield companies have offered quality healthcare coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare, and Medicaid.

Blue Cross and Blue Shield Plans support federal nondiscrimination laws and have operated in compliance with those laws. However, we are concerned that the Proposed Rule will create significant unwarranted economic and regulatory burdens on Plans and other health insurance issuers and group health plans that are far removed from the actual performance of health care services. The Preamble's examples of situations in which discrimination could occur do not involve health insurance issuers, but focus on health care providers. Therefore, we suggest clarifications in the Proposed Rule to alleviate unnecessary burdens for Blue Cross Blue Shield Plans.

**Recommendations**

Our recommendations are as follows:

- **Scope:** The final rule should limit any obligations and duties under the Weldon Amendment to the governmental entities included in the Weldon Amendment and not

extend these obligations and duties to health insurance issuers and health plans which do not have any duties or obligations under the statute.

- **"Assist in the Performance:"** The final rule should eliminate the complex, expansive proposed definition of "assist in the performance." If this definition is retained, the final rule should use the term "reasonable," which was used in the 2008 Final Rule instead of the word "articulable" in the definition of "assist in the performance."

- **"Referral:"** The definition of "referral" should be narrowed to only include referral by health care providers or their employees, and the final rule should include a specific exemption for health insurance issuer employees performing administrative functions such as answering questions from covered individuals or processing claims.

- **Written Assurance and Certification:** The requirement for written assurances should be eliminated and the final rule should only require a single annual certification.

- **Notice:** The final rule should eliminate the notice requirement for health insurance issuers and group health plans. If health insurance issuers are required to provide notice, the final rule should only require notice to an issuer's workforce, not the public.

- **Effective Date:** The final rule should not be effective prior to January 1, 2019, with the requirement for notices being effective January 1, 2020.

We appreciate your consideration of our comments and we look forward to working with you on implementation of conscience protections provided by federal statutes. If you have any questions or want additional information, please contact Richard White at Richard.White@bcbsa.com or 202.626.8613.

Sincerely,

Kris Haltmeyer
Vice President
Legislative and Regulatory Policy
Blue Cross Blue Shield Association

* * *

**BCBSA DETAILED COMMENTS ON PROTECTING STATUTORY CONSCIENCE RIGHTS IN HEALTH CARE PROPOSED RULE**

## I. Application of Weldon Amendment to Health Insurance Issuers and Health Plans (Proposed §§ 88.2, 88.3)

**Issue:**

The Proposed Rule would extend the nondiscrimination requirements applicable to governmental entities under the Weldon Amendment to private entities.

**Recommendation:**

Revise the rule to limit any obligations and duties under the Weldon Amendment to the governmental entities included in the Weldon Amendment and do not extend it to health insurance issuers and health plans which do not have any duties or obligations under the statute.

**Rationale:**

The Weldon Amendment, by its terms, prohibits a "Federal agency or program, [or]…a State or local government" from discriminating against a health care entity that does not provide, pay for, provide coverage of, or refer for abortions. Weldon Amendment, Consolidated Appropriations Act, 2009, Pub. L. No. 111-117, 123 Stat 3034, section 508. The Amendment defines the term "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." Section 508(d)(2). Thus, under Weldon, a federal agency or program, or a state or local government, cannot receive funding from an act to which Weldon is attached, if the agency, program or government discriminates against health care entities that refuse to provide, pay for or refer for abortions.

The Proposed Rule interprets the statutory definition of "health care entity" to include health insurance issuers and health plans, including the sponsors of health plans. 83 Fed. Reg. 3880, 3890. The Weldon Amendment clearly protects, among others, HMOs and health insurance issuers from discrimination by agencies, programs, or governments that receive funding from an Act to which the Weldon Amendment is attached.

However, the Weldon Amendment does not impose any duties or obligations on HMOs, health insurance issuers, or group health plans. They are protected by the Weldon Amendment, but they are not regulated by the Weldon Amendment. OCR should revise the rule to make clear that the only entities that are subject to duties, requirements, or obligations as the result of the Weldon Amendment are governmental agencies and programs that are funded by an act that includes the Weldon Amendment.

## II. Application of the "Assist in the Performance" Provision (Proposed § 88.2)

**Issue:**

The "assist in the performance" provision is limited to the Church Amendments, but the Proposed Rule creates a complex definition expanding this provision beyond the text of the Church Amendments.

**Recommendation:**

Eliminate the complex, expansive definition of "assist in the performance" or limit the definition to health care providers and researchers.

**Rationale:**

The term "assist in the performance" is used in the text of the Church Amendments. The Church Amendments are one section in the "Population Research and Voluntary Family Planning Programs" subchapter of the Public Health Service Act. The surrounding subchapters describe various grants and contracts available for family planning services organizations.

In this context – population research and voluntary family planning – the Church Amendments specifically and explicitly protect health care providers and researchers from discrimination based on their refusal to provide sterilization or abortion services because of religious beliefs and moral convictions. For example, the Church Amendments refer to performing or assisting in performing abortions, 42 U.S.C. § 300a-7(b)(1), requiring entities to make facilities or personnel available to perform sterilization or abortions, *id.* at (b)(2), discrimination against physicians and other health care personnel who refuse to perform sterilization or abortion, *id.* at (c). Subsections (b) and (c) apply to the direct provision of medical services or medical research.

It follows, then, that the reference to "individual" in paragraph (d) – which says that no individual shall be "required to perform" or "assist in the performance" if the performance or assistance would be contrary to the individual's religious beliefs or moral convictions – refers to the same individuals that Congress referred to in (b) and (c) – physicians, health care personnel, and others (including non-medical personnel) who directly provide health care services related to voluntary family planning programs or perform population research. "Individual", in this context, cannot extend to include every individual that works for an entity that receives federal funds from HHS. "The definition of words in isolation…is not necessarily controlling in statutory construction. A word in a statute may or may not extend to the outer limits of its definitional possibilities. Interpretation of a word or phrase depends upon reading the whole statutory text, considering the purpose and context of the statute." *Dolan v. U.S. Postal Serv.,* 546 U.S. 481, 486 (2006). Here, the purposes and context of the statute is to regulate population research and voluntary family planning programs, not commercial health insurance or group health plans..

In contrast, the Proposed Rule provides, in relevant part, that:

> Any entity that carries out any part of any health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services is required to comply with paragraph (a)(2)(vi) of this section and §§ 88.4, 88.5, and 88.6 of this part.

Proposed § 88.3(a)(v). And the Proposed Rule defines "health service program" to "include[] any plan or program that provides health benefits, whether directly, through insurance, or otherwise, and is funded, in whole or part, by the Department. It may also include components of State or local programs." Proposed § 88.2.

While the Church Amendments do not define "health service program," the context clearly suggests that the Church Amendments are concerned with protecting population researchers and family planning providers – *e.g.,* physicians – who refuse to perform "certain health care procedures" from discrimination by entities that receive funds from HHS administered programs, Proposed Rule, Preamble, 83 Fed. Reg. 3880, 3882, as well as medical researchers. *Jarecki v. G. D. Searle & Co.,* 367 U.S. 303, 307, 81 S. Ct. 1579, 1582, 6 L. Ed. 2d 859 (1961) ("'Discovery' is a word usable in many contexts and with various shades of meaning. Here, however, it does not stand alone, but gathers meaning from the words around it. These words strongly suggest that a precise and narrow application was intended in [section] 456.") The Proposed Rule goes much further however, applying the Church Amendments far beyond health care providers and researchers and as written could be read to apply to employees of commercial health insurance issuers and health plans that have no connection with the context of the amendment.

Because the Church Amendments protect voluntary family planning health care providers and population researchers, there is no need to for the rule to define "assist in the performance" to have an "articulable connection;" the Church Amendments are clear that the provider and researcher do not have to "perform" or "assist" in the provision of a sterilization or abortion. They do not have to have an "articulable connection" – they may simply refuse to perform or assist in the performance of the sterilization, abortion, or medical research. "Assist in the performance" only needs a complex and expansive definition because OCR has mistakenly extended it beyond the statutory text. If OCR includes a definition it should be limited to health care providers and researchers.

Further, including health insurance issuers within the "assist in the performance" provision violates Executive Orders requiring reduction of regulatory burdens. Exec. Order No. 13765, relating to minimizing the economic burdens of the ACA, requires the heads of all executive departments and agencies with responsibilities under the ACA to "…minimize the unwarranted economic and regulatory burdens of the [ACA]…." 82 Fed. Reg. 8351 (January 24, 2017). This approach was echoed in a subsequent Executive Order stating that "…it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations." Exec. Order No. 13771, 82 Fed. Reg. 9339 (February 3, 2017).

## III. Definition of "Assist in the Performance" Under the Church Amendments (Proposed § 88.2)

**Issue:**

The Proposed Rule uses the term "articulable connection," which is so broad that it appears to have no bounds. This is much more expansive than the 2008 Final Rule's use of the term "reasonable connection" and expands the reach of the rule far beyond the rights protected by statute. The change in this one word has significant implications for health insurance issuers, which do not actually have staff that perform or assist in the performance of procedures or services covered by the statute.

**Recommendation:**

The final rule should use the term "reasonable" which was used in the 2008 Final Rule instead of the word "articulable" in the definition of "assist in the performance," and thus should read:

> "Assist in the Performance" means "to participate in any activity with a **reasonable** connection to a procedure, health service or health service program, or research activity, but does not include providing information, assisting with claims or premiums, or addressing any questions under the terms of an applicable group health plan or health insurance policy."

**Rationale:**

The Preamble to the Proposed Rule states:

> The Department proposes that "assist in the performance" means "to participate in any activity with an articulable connection to a procedure, health service or health service program, or research activity, so long as the individual involved is a part of the workforce of a Department-funded entity. This includes counseling, referral, training, and other arrangements for the procedure, health service, or research activity." *This definition mirrors the definition used for this term in the 2008 Rule.*

83 Fed. Reg. 3880, 3892 (January 26, 2018) (emphasis added).

Unfortunately, the Proposed Rule does not "mirror" the 2008 Final Rule, which used the term "reasonable connection." 45 C.F.R. § 88.2, effective January 1, 2009 ("Assist in the Performance means to participate in any activity with a reasonable connection to a procedure, health service or health service program, or research activity, so long as the individual involved is a part of the workforce of a Department-funded entity. This includes counseling, referral, training, and other arrangements for the procedure, health service, or research activity.") As HHS explained at that time,

> As a policy matter, the Department believes that limiting the definition of the statutory term "assist in the performance" only to those activities that constitute direct involvement with a procedure, health service, or research activity, falls

> short of implementing the protections Congress intended under federal law. *However, we recognized the potential for abuse if the term* ***was unlimited****. Accordingly, we proposed – and here finalize – a definition of "assist in the performance" that is limited to "any activity with a reasonable connection to a procedure, health service or health service program, or research activity."*

73 Fed. Reg. 78072, 78075 (December 19, 2008) (emphasis added).

The Department further explained:

> …the Department *sought to guard against potential abuses of these protections* by limiting the definition of "assist in the performance" to only those individuals who have a reasonable connection to the *procedure, health service or health service program, or research activity* to which they object.

73 Fed. Reg. 78072, 78090 (December 19, 2008) (emphasis added).

While we understand that OCR may want to include a definition of "assist in the performance" in the final rule because that definition was completely removed from the rule in 2011 (76 Fed. Reg. 9968, February 23, 2011), introducing the new term "articulable" as opposed to reverting to the term "reasonable" used in the 2008 Final Rule introduces a definition that is in effect **unlimited** and that the 2008 Final Rule recognized as having the potential for abuse. If the term "articulable" were used, issuers would have to implement changes to their operations contemplating the most extreme connection that an employee could articulate, no matter how unreasonable it may be.

For example, "participate in any activity with an articulable connection to" could potentially be read to allow a health insurance issuer's claims processor to refuse to process a claim for a procedure to which they have a conscience objection even though the procedure has already been performed. How is this "assisting in the performance" although an individual could articulate that they felt it was and that they had a conscience objection to participating? Taking this example further, would a member inquiry to a customer service representative as to or whether a claim for sterilization has been received, paid, or how to appeal a decision made by the issuer regarding sterilization be subject to a valid objection by the customer service representative? As noted above, we do not believe that employees of a health insurance issuer who are performing administrative functions were within the scope of what Congress intended when it passed the various conscience protection laws; however, the use of the term "articulable connection," because it has minimal (if any) limitations, would require issuers to prepare for the most unreasonable claims of discrimination by their employees.

We believe that using the term "reasonable connection" and limiting the scope of "assist in the performance" to actual medical procedures and the arrangements for such procedures (including referrals and counseling) is more in line with the scope of the statutory protections, as well as the intent of the 2008 Final Rule. In the Preamble to the 2018 Proposed Rule, the Department noted that

> In interpreting the term "assist in the performance," the Department seeks to provide broad protection for individuals, consistent with the plain meaning of the

> statutes. The Department believes that a more narrow definition of the statutory term "assist in the performance," such as a definition restricted to those activities that constitute direct involvement with a procedure, health service, or research activity, would fall short of implementing the protections Congress provided. But the Department acknowledges that the rights in the statutes are not unlimited, and it proposes to limit the definition of "assist in the performance" to activities with an articulable connection to the procedure, health service, health service program, or research activity in question.

83 Fed. Reg. 3880, 3892.

Recognizing the limits of the statutory protections at issue is not new. For example, in the 2008 Final Rule, the Department recognized that "[t]hese statutory provisions protect the rights of health care entities/entities, both individuals and institutions, *to refuse to perform* health care services and research activities to which they may object for religious, moral, ethical, or other reasons." 45 C.F.R. § 88.1 (emphasis added). The primary focus of the protection is the physical health care service (*i.e.,* medical procedure or research) and not an explanation of the coverage terms of a health insurance policy.

In addition, the comments on the 2008 rule reveal the abuses intended to be addressed by limiting "assist in the performance" to only those individuals who have a "reasonable connection" to the procedure, health service or health service program, or research activity to which they object. For example, one commenter stated that:

> There may be a fine line between a moral conviction that can be accommodated in refusal of care and the harboring of a prejudice. The [2008 proposed rule] invites abuses and prejudicial implementation. It shifts the defining quality of conscience refusal onto a subjective self determined "ethic" and away from or untethered to listed procedures such as those a neutral third party like Congress explicitly enacted Title X of the Public Health Service Act to address.

(Footnotes omitted). The Proposed Rule disregards this type of abuse by using the term "articulable." While the Preamble states the statutory rights named in the Proposed Rule "are not unlimited," 83 Fed. Reg. 3880, 3892, OCR's attempt to impose some limit through its "articulable connection" language in Proposed § 88.2 is unavailing and does not seem to impose any limit at all.

If OCR does not use "reasonable connection" instead of "articulable connection," OCR should provide examples of situations where there is no "articulable connection" between the religious beliefs of a health insurance issuer employee and health care services. For example, if an issuer employee refuses to participate in processing a claim for sterilization due to the employee's religious beliefs, is that an "articulable connection" that would allow that single employee to in effect deny an otherwise covered claim?

As noted above, "articulable connection" is far broader than "reasonable connection." It is possible to articulate an unreasonable connection; it seems less likely that a reasonable connection is inarticulable. Therefore, OCR should define "assist in the performance" as a "reasonable connection" to a procedure, health service or health service program, or research

activity, but does not include providing information, assisting with claims or premiums, or addressing any questions under the terms of an applicable group health plan or health insurance policy.

## IV. "Referral" Included in "Assist in the Performance" (Proposed § 88.2)

**Issue:**

"Referral" as used in the "assist in the performance" definition is very broad and may affect the ability of health insurance issuers to deliver customer service to their members. In some cases, this could impact the ability of these members to obtain information as to coverage of their insurance benefits or coverage for the actual services, thus potentially impacting members' health as well as potentially putting insurers at risk of violating state and federal laws.

**Recommendation:**

The definition of "referral" should be narrowed to only include referral by health care providers or their employees and the final rule should include a specific exemption for health insurance issuer employees performing administrative functions such as answering questions from covered individuals or processing claims.

**Rationale:**

The definition of "referral" in the Proposed Rule is very broad and includes

> …the provision of any information…pertaining to a health care service, activity, or procedure, including related to availability, location, training, information resources, private or public funding or financing, or directions that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity, or procedure, where the entity or health care entity making the referral sincerely understands that particular health care service, activity, or procedure to be a purpose or possible outcome of the referral.

83 Fed. Reg. 3880, 3924.

The term "referral" or "refer for" is referenced in the Weldon Amendment, and as noted above (Part I), the Weldon Amendment protects health insurance issuers and group health plans (as well as providers) from discrimination by a governmental entity, and imposes no obligation on the protected entities. To the extent health insurance issuers and group health plans are protected under the Weldon Amendment, the rule should apply only to health insurance issuers and group health plans as protected entities, but not to their employees. As such, the definitions in the rule should be written in such a way as to limit their use to the appropriate statute and intent of the underlying statute, and not sweep other classes of individuals into the broad requirements and protections under the rule.

The Weldon Amendment prohibits governmental agencies that receive federal funds, like HHS and states that receive Medicaid funding from HHS, from discriminating against a health care entity that does not provide, pay for, provide coverage of, or refer for abortions. Weldon Amendment, Consolidated Appropriations Act, 2009, Pub. L. No. 111-117, 123 Stat 3034, section 508. A governmental agency that discriminates against a health care entity for its failure to provide, pay for, or refer for abortions will lose the federal funds provided under an Act that includes the Weldon Amendment (the funds will not be "available" to the discriminating agency). Application of "referral" or "refer for" beyond these statutory requirements is inappropriate.

The reason for restricting "referral" or "refer for" to their statutory meaning is that a broader definition may affect the care of health insurance issuer members. The proposed definition of "referral" or "refer for" may allow health insurance issuer employees to simply refuse to provide information, for example, in response to questions about claims, benefits, or other administrative matters, including also not *referring* (*i.e.,* transferring) the member to another employee who can answer those questions. This will leave members uncertain about how to pursue their health care and could affect their care.

This places health insurance issuers in a difficult position. They have an obligation to honor their contracts for coverage and respond to member inquiries. Failure to comply may result in regulatory sanctions by state or federal regulators (or both) as well as private litigation for damages. On the other hand, an issuer requiring an employee to provide information to members due to an "articulable connection" between an employee's religious beliefs and the health care services sought by the member may also expose the issuer to regulatory sanctions and litigation for damages.

The final rule should avoid these multiple and inconsistent obligations by narrowing the definition of "referral" to only include referral by health care providers or their employees and include a specific exemption for health insurance issuer employees performing administrative functions such as answering questions from covered individuals related to benefits or claims.

## V. Written Assurance and Certification (Proposed § 88.4)

**Issue:**

The requirements for written assurances and certification are unnecessarily duplicative.

**Recommendation:**

The requirement for written assurances should be eliminated and only require a single annual certification.

**Rationale:**

The Proposed Rule would require written assurances for every reapplication for funds, but does not explain what these multiple assurances add to the compliance regime. In fact, they add nothing and should be eliminated.

The only stated reasons for the written assurances are that they would inform the "health care industry" of the applicable laws and make the requirements for the statutes listed in the Proposed Rules more like other civil rights laws. 83 Fed. Reg. 3880, 3896. These are inadequate reasons for duplicative paperwork.

First, there is no need for a separate written assurance to provide information about the statutes if affected entities certify compliance. By providing the certification, affected entities know about the statutes in question. Making administration of these statutes more like the administration of other statutes (83 Fed. Reg. 3880, 3896) is no reason to impose unnecessary regulatory requirements.

Second, as noted above (Part II), imposing additional regulatory requirements such as a duplicative, unnecessary written assurance violates Executive Orders requiring reduction of regulatory burdens. Exec. Order No. 13765, relating to minimizing the economic burdens of the ACA, requires the heads of all executive departments and agencies with responsibilities under the ACA to "…minimize the unwarranted economic and regulatory burdens of the [ACA]…." 82 Fed. Reg. 8351 (January 24, 2017). This approach was echoed in a subsequent Executive Order stating that "…it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations." Exec. Order No. 13771, 82 Fed. Reg. 9339 (February 3, 2017).

To avoid the imposition of unneeded regulatory burdens, the final rule should drop the written assurance requirement and require only a single annual certification.

## VI. Notice (Proposed § 88.5)

**Issue # 1:**

The proposed notice requirement has no basis in statute for health insurance issuers and group health plans. Additionally, OCR specifically asked if there are categories of recipients of federal funds that should be exempted from posting notices. 83 Fed. Reg. 3880, 3897.

**Recommendation:**

Eliminate the notice requirement for health insurance issuers and group health plans.

**Rationale:**

As noted above in Parts I and II, the Church and Weldon Amendments *protect* health insurance issuers and group health plans from discrimination in granting funds by government agencies. These amendments do not *regulate* health insurance issuers. Therefore, the notice requirement is unnecessary and should not apply to health insurance issuers in the final rule.

**Issue # 2:**

The Proposed Rule presents the notice requirement in a confusing way. The Preamble states that the Proposed Rule

> …requires the Department and recipients to notify the *public, patients*, and employees, which may include students or applicants for employment or training, of their protections under the Federal health care conscience and associated antidiscrimination statutes and this regulation.

83 Fed. Reg. 3880, 3897 (emphasis added). However, the actual Proposed Rule text (§ 88.5(a)) requires that the notice be provided on "recipient website(s)" and at a "…physical location in every…recipient establishment where notices to the public and notices to their workforce are customarily posted to permit ready observation."

**Recommendation:**

The final rule should only require the notice to be provided where the workforce as defined in the Proposed Rule can view it and should not be provided to the general public. Further, notices in solely electronic form should be permitted.

**Rationale:**

The conscience protection laws primarily impose requirements related to protecting health care providers and other health care staff from having to perform or assist in performing services to which they have a conscience objection. Thus, it is the workforce of health care providers who need to receive the notice, not members of the general public who are not the primary beneficiaries of the statutes relating to the Proposed Rule. As such, notices should only be required to be provided in a manner that is accessible to the workforce as defined in the Proposed Rule and not the public or patients.

Further, notices in solely electronic form should be permitted. Posting paper notices at physical facilities is a holdover from the era before the widespread electronic communications used today. This outmoded form of communication should not be perpetuated in the final rule.

## VII. Effective Date

**Issue:**

The Proposed Rule does not provide a clear effective date nor does it give adequate time for compliance, particularly for the notice requirement.

The Proposed Rule does not specify an effective date for the overall Proposed Rule. The Preamble notes that the Proposed Rule is economically significant, 83 Fed. Reg. 3880, 3902, so it would be a "major rule" and would become effective 60 days after publication in the *Federal Register* if another effective date is not specified. 5 U.S.C. §§ 801(a)(3)(A), 804(2).

The Proposed Rule has confusing provisions on the effective date of compliance with the notice requirement. The Preamble states that notices must be posted 90 days after the date of publication of the final rule in the *Federal Register*. 83 Fed. Reg. 3880, 3897. However, the

actual text of the Proposed Rule (§ 88.5(a)) requires posting of notices by April 26, 2018, or, as to new recipients, within 90 days of becoming a recipient.

For certification and written assurances, the Preamble says that HHS components would be given discretion to phase-in the written assurance and certification requirements by no later than the beginning of the next fiscal year following the effective date of the final rule. 83 Fed. Reg. 3880, 3896. The actual text of the Proposed Rule does not provide for an effective date for providing written assurances and certifications.

**Recommendation:**

The final rule should not be effective prior to January 1, 2019, with the requirement for notices being effective January 1, 2020.

**Rationale:**

While the conscience protection laws are in place and health plans have taken actions to comply, the Proposed Rule has new provisions that would take time to implement, particularly the requirements related to certification, written assurances, and notices.

Having a uniform time for the certification and written assurances requirement would reduce the confusion that would result if each HHS component is allowed to establish its own effective date. A January 1, 2019, effective date would allow adequate time for the HHS components to integrate the new requirements into their application and contracting processes.

Allowing additional time before the notice requirement is effective recognizes that impacted organizations must analyze the materials on their web pages (such as employee manuals, orientation materials, and job posting/application web pages) to determine the necessary modifications. Then they must allocate the programming resources to make the required changes. These resources are very likely working on other projects, so time must be allowed to implement these new requirements so that organizations are able to comply.

Other areas of communication that require review and revision include:

- Certification/written assurances for the qualified health plan (“QHP”) application process;
- Certification/written assurances for the Medicare bid process; and
- Annual maintenance/updates to any of the above items.

Note that providing adequate time for compliance is not a question of delaying the time in which persons may claim conscience protections. These protections are in effect now and may be claimed at any time by affected persons. Our request is that adequate time be given to implement the requirement to provide formal notice, etc., in recognition of the regulatory and administrative burden of providing notices, written assurances, and certifications. This is consistent the Executive Orders cited above (Parts II, V) requiring the reduction of regulatory burdens, especially relating to the ACA.

# Exhibit 97

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*Dave Jones, Insurance Commissioner*

***Submitted via www.regulations.gov***

March 27, 2018

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

**SUBJECT**: Comments on Proposed Rule RIN 0945–ZA03: "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority"

Dear Secretary Azar:

As California's Insurance Commissioner, I lead the largest consumer protection agency in the state and am responsible for regulating California's insurance market, which is the nation's largest. The California Department of Insurance implements and enforces consumer protections such as essential health benefits requirements, anti-discrimination protections, and laws pertaining to timely access to medical care.

Your proposed rule, *Protecting Statutory Conscience Rights in Health Care,* would result in delays in timely access to medical care, denials of access to medically necessary basic health care services, and would likely result in widespread discrimination in our health care system. Simply put, it undermines patient care.

Existing state and federal law provide health care provider conscience protections, but do not allow them to interfere with patient access to care or civil rights protections that prohibit discrimination. I strongly object to the proposed rule *Protecting Statutory Conscience Rights in Health Care* ("Rule"), which encourages discrimination that will harm patients and urge that it be withdrawn by your Department.

**Impacts of the Proposed Rule**

Under the ostensible claim of protecting religious beliefs and moral convictions, the Rule instead would give providers free rein to discriminate against people on the basis of race, sex, sexual orientation, gender, gender identity, and almost any other kind of bias. The very individuals whose rights the Office of Civil Rights ("OCR") was created to protect would now be subject to discrimination under the Rule. A provider could, ostensibly, refuse under this Rule to provide medical care to a biracial couple seeking a medically necessary health service on the grounds

that doing so would be contrary to his or her religious beliefs or moral convictions. A medical facility, provider or insurer – by action of a scheduling assistant, intake personnel, board of directors, or medical provider – could deny treatment to a patient seeking gender reassignment surgery on the basis that he or she finds it morally objectionable. Similarly, under the proposed Rule, a woman could be denied timely access to abortion services; a provider could refuse to treat a child because her parents are lesbians and the doctor objects to their sexual orientation. In this Rule, HHS improperly pits the beliefs of providers, insurers, and other health care entities against the rights of patients.

Additionally, the Rule attacks a fundamental aspect of federalism by preventing the application of state law and consitutional protections. The U.S. Department of Health and Human Services ("HHS") cannot interfere with a state's ability to protect the civil rights of its residents. California law requires health insurance coverage for a comprehensive set of basic health care services, including reproductive health services. California's Unruh Civil Rights Act explictly prohibits discrimination:

> All persons within the jurisdiction of this state are free and equal, and no matter what their sex, race, color, religion, ancestry, national origin, disability, medical condition, genetic information, marital status, sexual orientation, citizenship, primary language, or immigration status are entitled to the full and equal accommodations, advantages, facilities, privileges, or services in all business establishments of every kind whatsoever.[1]

State law further requires that medical providers and others whose licenses are granted by the state under the provisions of the Business and Professions Code are subject to disciplinary action for refusing to provide services based on characteristics protected under the Unruh Civil Rights Act.

The right of health care providers, and entities, to hold private beliefs does not and should not trump the rights of patients to obtain the care to which they are legally entitled. Licensure as a health care provider, facility, or insurer does not provide license to discriminate. Although HHS points to some law in support of this rule, there is a substantial, contrary body of law that supports a woman's right to choose, as well as the right to not be discriminated against on the basis of a person's sex, gender, gender identity, or sexual orientation. For example, California's Supreme Court ruled that the religious freedom of a medical provider does not exempt them from complying with the anti-discrimination protections in Unruh (*North Coast Women's Medical Group, Inc. v. San Diego County Superior Court* (2008) 44 Cal.4th 1145).

[1] California Civil Code section 51, subdivision (b).

**The Rule Exceeds Legal Authority**

Existing law provides sufficient protection to health care entities that refuse to participate in certain health care services, including abortion, where they find such services to be religiously or morally objectionable, as evidenced by section 88.3 of the Rule, subdivisions (a) through (d), which are largely a restatement of existing law. The Department is wrong to expand the statutory protections already provided, and has no clear authority to do so.

By providing new definitions for long-existing terms in the law, the Rule expands and distorts the meaning of these terms. The Rule attempts to redefine "assist in the performance" to include participating in "any program or activity with an articulable connection to a procedure, health services, health program, or research activity…" including, but not limited to "counseling, referral, training, and other arrangements" for the health care service. This definition is so broad as to include even the provision of basic information for a lawful or necessary health care procedure or service. As a result, a provider could refuse to tell a pregnant woman about a health care service that is vital to her health, including her future fertility.

The Rule is so broad that it makes no exception for emergency treatment, meaning that despite a woman's very life being at risk due to a miscarriage, a provider could refuse to even disclose the risk to her life on the basis of the provider's own religious beliefs or moral convictions. This is contrary to the ethical duties owed by physicians to patients, and is contrary to federal law, which allows federal funds to be used to pay for abortions in the cases where the woman's life is in danger. These duties include the doctrine of informed consent which requires a provider to inform a patient of the risks and benefits associated with a health care service or procedure, as well as available alternatives to that service or course of treatment. Informed consent is a legal obligation due from a physician to a patient; failure to receive informed consent constitutes negligence.

The Rule would expand the scope of existing federal refusal laws to almost any entity associated with health care. The Rule's broad definition of "health care entity" expands this term to include "a plan sponsor, issuer, or third-party administrator, or any other kind of health care organization, facility, or plan." Such an expansion of the law would allow an employer to deny coverage of abortion or any number of other health care services to their employees even if otherwise required by law.

The Rule also adds a definition for "referral" where one did not exist. By including public "notices" within this definition, the Rule will prevent the enforcement of California's Reproductive FACT Act, which requires facilities specializing in pregnancy-related care to disseminate notices to all clients about the availability of public programs that provide free or subsidized family planning services, including prenatal care and abortion. This Act is currently subject to ongoing court cases, including a case before the Supreme Court of the United States (*National Institute of Family and Life Advocates v. Becerra*, (9th Cir. 2016) 839 F.3d 823, *cert.*

*granted* (2017) 138 S.Ct. 464) in which the Court heard oral arguments on March 20th, 2018. HHS should allow the litigation process to conclude and permit the courts to decide whether state laws requiring these type of notices comply with the United States Constitution and federal law.

Similarly, this Rule would to allow a pharmacist to refuse to fill a birth control prescription or refer such a prescription to another pharmacist because they find it objectionable. HHS is attempting to circumvent settled case law, which has held that a pharmacy may not deny any lawful drug, including emergency contraceptives, to any customer for religious reasons. (*Storman's, Inc. v. Wiesman*, (9th Cir. 2015) 794 F.3d 1064, *cert. denied* (2016) 136 S.Ct. 2433). As in many other areas of the Rule, HHS has failed to narrowly tailor the Rule to apply to the specific conscience objections allowed under existing law. Failure to narrowly tailor the Rule will lead to confusion, denial of access to medically necessary care, and increase the likelihood of discrimination against patients.

**Weldon Amendment Overreach**

In addition to the above noted expansions, the Rule contradicts OCR's previous interpretation of the Weldon Amendment in an attempt to increase its application. As the Rule notes, in 2016 OCR issued a determination on three complaints brought against the California Department of Managed Health Care ("CDMHC") on the basis that the CDMHC required coverage of voluntary abortions as mandated by California law. In its determination in favor of CDMHC, OCR specifically noted that

> "[a] finding that CDMHC had violated the Weldon Amendment might require the government to rescind all funds appropriated under the Appropriations Act to the State of California – including funds provided to the State not only by HHS, but also by the Departments of Education and Labor…such a rescission would raise substantial questions about the constitutionality of the Weldon Amendment."

This determination was made after consultation with the U.S. Department of Justice. In making this determination, OCR pointed to the Court's reasoning in *National Federation of Independent Business v. Sebelius*, (2012) 567 U.S. 519, "that the threat to terminate significant independent grants was so coercive as to deprive States of any meaningful choice whether to accept the condition attached to receipt of federal funds."

With this proposed Rule, however, HHS now specifically intends to apply just such coercion, contrary to its prior, considered findings. HHS is reversing its position with scant legal basis for doing so. In essence, HHS seeks to confer upon health insurers a newly-created ability to make a claim of discrimination against the State of California if they refuse to cover abortions if, for example, they simply don't want to pay for this basic health care service. The Rule's frontal attack on this fundamental aspect of federalism puts the State of California in the impossible

position of either enforcing its state constitution[2] and law, with the loss of federal funding for many programs, or allowing a state-regulated health insurer to flout the state law specifically requiring coverage for all reproductive services, including abortion and sterilization. California will enforce state law. If this Rule is finalized rather than withdrawn, it will result in litigation.

The plain language of the Weldon Amendment allows providers to recuse themselves from participating in or facilitating an abortion. Similarly, existing law in California protects a health care provider who refuses to participate in training for, the arranging of, or the performance of an abortion. The proposed rule, however, goes far beyond these limited accommodations and, in conflict with the state Constitution, instead threatens already-obligated federal funding upon which vital health programs depend.

**Adverse Impact on Consumers**

The Rule's overlap and conflict with existing state and federal law will have a chilling effect on those seeking essential health care services. It will cause confusion for patients as they attempt to exercise their right to access the full range of medically appropriate care, as well as confusion for the very health care entities that the Rule purports to protect. This Rule is evidence of the continuing attempts by HHS to enshrine discrimination against women, LGBTQ individuals, and their families. It is so broad in scope that, under the guise of protecting the personal beliefs of corporations and other health care entities, it condones discrimination based only on a financial objection to providing services, rather than upon actual religious or moral convictions.

In November 2017, I submitted a declaration in the case of *State of California v. Wright* (subsequently renamed on appeal *State of California et al. v. Alex Azar)* regarding federal regulations that implicate both religious and moral exemptions regarding contraceptive coverage. Those rules would allow employers to exclude contraceptive coverage mandated by the Affordable Care Act from their employees' health insurance policies. A preliminary injunction was granted enjoining enforcement of the rule, which is currently under appeal. In my declaration I provided evidence that demonstrated the harm to women if the rule denying women access to contraceptives was permitted to remain in effect. Similarly, on December 15, 2017, the United States District Court for the Eastern District of Pennsylvania granted a preliminary injunction in *Commonwealth of Pennsylvania v. Trump*, a related case. At issue in this proposed Rule is the same grim burden presented by these cases: that the Rule would impose harm to women's health.

[2] *See e.g.* Defend Reproductive Rights v. Myers, (1981) 29 Cal.3d 252 (the California Constitution, on numerous occasions, has been construed to provide greater protection than that afforded by parallel provisions of the United States Constitution. In this case the California Supreme Court held that the California state constitution requires abortion benefits to be provided under MediCal, the state Medicaid program.)

Thanks to the Affordable Care Act, health insurance policies must cover contraceptives. Tens of millions of women across the nation benefit from the ACA provision that requires health insurance coverage of contraceptives without any co-payments or deductibles. Under this new proposed rule, women could be denied their prescribed contraception based on the moral or religious views of the pharmacy owners or employees. The Rule would permit any health care worker to interfere with a woman's constitutionally protected right to make her own reproductive health care decisions. Denying access to contraceptives and other forms of birth control (such as tubal ligation) will result in an increased number of unintended pregnancies and in abortions. Similarly, when a provider's refusal to refer a woman to a health facility where she can obtain an abortion delays the procedure, that provider is increasing health risks for that patient.

As California's Insurance Commissioner, I issued the first regulations in the nation to ensure that transgender Californians would not be discriminated against when seeking health care. We know from the 2015 U.S. National Transgender Survey that 33% 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 appropriate care. The Rule would not only continue this significant problem, but would increase the number of patients who are refused treatment by sanctioning such actions by providers. The survey also brought to light the fact that "[i]n the past year, 23% of respondents did not see a doctor when they needed to because of fear of being mistreated as a transgender person…"[3] Again, under this Rule, that problem would only worsen.

By allowing health care providers to discriminate against LGBTQ persons through this Rule, the Administration risks exacerbating existing health disparities. The Federal Office of Disease Prevention and Health Promotion has determined that LGBT persons already face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights, stating: "Discrimination against LGBT persons has been associated with high rates of psychiatric disorders, substance abuse, and suicide."[4]

**The Rule Imposes a Substantial Regulatory Burden**

Large portions of the Rule are essentially a restatement of existing federal law (*See e.g.* §88.3(a)-(d)). As commentators raised during the rulemaking process in 2011 and HHS acknowledged, "existing law, including Title VII of the Civil Rights Act of 1964 and the federal health care provider conscience protection statutes cited in the Rule already provide protections to

[3] James, S.E., Herman, J.L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016) *The Report of the 2015 U.S. Transgender Survey*, National Center for Transgender Equality, p.10
[4] Office of Disease Prevention and Health Promotion (ODPHP), Healthy People 2020, *Lesbian, Gay, Bisexual, and Transgender Health*, retrieved from https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health

individuals and health care entities."[5] Additionally, the existing rule provides a regulatory enforcement scheme to protect and enforce the rights afforded to health care entities under these laws. The addition of an unnecessary and costly regulation is counter to the intent of Executive Order (EO) 13771. The EO promoted a policy of prudence and fiscal responsibility in the Executive Branch. This Rule satisfies neither goal. This costly Rule is unnecessary to the extent that is merely a restatement of existing law, and, because of such duplication, is likely to cause confusion.

Additionally, this Rule would unduly burden health care entities, including health insurers, states, and providers who would have to keep records to comply with a self-initiated OCR audit or rebut a complaint of discrimination; essentially, the voluminous production, retention, and production of records to prove a negative. The costs and administrative burdens associated with the assurance and certification requirements under this Rule are unnecessary given that existing law already provides sufficient protection to health care entities. Further, the compliance requirements introduce uncertainty into existing, ongoing federal grant programs, inasmuch as the requirements compel violation of state law.

In conclusion, if this rule is implemented, it would deprive women, LGBTQ individuals, their families and others of their civil rights and access to basic health care services. Patients would suffer serious and irreparable harm if this Rule was in place, with no demonstrable or justifiable benefit to providers and health care entities that are adequately protected under existing law. The proposed Rule understandably is opposed by a wide range of stakeholders. I strongly urge you to withdraw the proposed Rule.

Sincerely,

Dave Jones

DAVE JONES
Insurance Commissioner

[5] 72 Fed. Reg. at 9971

# Exhibit 98

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

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March 27, 2018

Roger Severino, Director
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U.S. Department of Health and Human Services
200 Independence Avenue, SW
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Washington, D.C. 20201

**Department of Health and Human Services, Office for Civil Rights**
**RIN 0945-ZA03**
**Docket ID No. HHS-OCR-2018-0002**

Dear Director Severino:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of 66,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents, and young adults, I write to provide input for the Notice of Proposed Rulemaking (NPRM) regarding Protecting Statutory Conscience Rights in Health Care.

America's pediatricians represent all faiths and serve children and families of all faiths. The free exercise of religion is an important societal value, which must be balanced against other important societal values, such as protecting children from serious harm and ensuring child health and well-being.

All children need access to appropriate, evidence-based health services to ensure they can grow, develop, and thrive. The inability to receive needed health care services can have a profound impact on the health of children. The AAP publishes policies and reports based on the best available scientific evidence that are designed to ensure children receive the health and social services they need. The AAP urges the U.S. Department of Health and Human Services (HHS) to ensure that health providers follow evidence-based or evidence-informed practices such as those published by professional medical organizations like the AAP. As HHS considers expanding conscience protections and the enforcement thereof, we respectfully offer these suggestions to ensure that HHS policy facilitates optimal access to services that support healthy children and families.

*Introduction*

Some health care professionals and health care organizations do morally object to particular services or treatments and refuse to provide them. Possible examples of such conscientious objection in pediatric practice include refusals to prescribe contraception, specifically emergency contraception[i]; perform routine neonatal male circumcision[ii]; or administer vaccines developed with virus strains or cell lines derived from voluntarily aborted human fetuses.[iii] Such objections may limit patients' access to information or treatment, and given this, the implementation of such objections is an important issue.

There are morally important reasons to protect the individual's exercise of conscience. Conscience is closely related to integrity. Performing an action that violates one's conscience undermines one's sense of integrity and self-respect and produces guilt, remorse, or shame.[iv,v] Integrity is valuable, and harms associated with the loss of self-respect should be avoided. This view of conscience provides a justification for respecting conscience independent of particular religious beliefs about conscience or morality. Claims of conscience are generally negative (the right to not perform an action) rather than positive (the right to perform an action).[vi]

**Nevertheless, constraints on claims of conscience can be justified on the basis of health care professionals' role responsibilities and the power differential created by licensure.** Health care professionals – and other health care entities – fulfill a particular societal role with associated expectations and responsibilities. For example, health care professionals' primary focus should be on their patients' rather than their own benefit. These role expectations are based in part on the power differential between health care professionals' and patients, which is the result of the providers' knowledge and patients' conditions. Role obligations are generally voluntarily accepted; therefore, health care professionals' claims of conscientious objection may justifiably be limited.

The AAP supports a balance between the individual physician's moral integrity and his or her fiduciary obligations to patients. **A physician's duty to perform a procedure within the scope of his or her training increases as the availability of alternative providers decreases and the risk to the patient increases.** Physicians should work to ensure that health care-delivery systems enable physicians to act according to their consciences and patients to obtain desired and appropriate health care. When an entire health care organization—and not just one provider—objects to providing a specific service, the availability of alternative providers naturally decreases even further.

However, physicians have a duty to disclose to patients and prospective patients standard treatments and procedures that they refuse to provide but are normally provided by other health care professionals. Physicians have a moral obligation to inform their patients of relevant alternatives as part of the informed-consent process. Physicians should convey information relevant to the patient's decision-making in a timely manner, using widely accepted and easily understood medical terminology, and should document this process in the patient's medical record. Physicians who consider certain treatments immoral or who claim a conscience or religious objection have a duty to refer patients who desire these treatments in a timely manner when failing to do so would harm the patients. Such physicians must also provide appropriate

ongoing care in the interim. These same obligations should be applicable to all recipients of federal funds for the provision of health care.

**HHS's NPRM must not induce any health care entity, as defined in the NPRM, to abrogate its moral responsibilities of serving patients. The AAP strongly warns of harms to children's health should HHS not require providers, grantees, or any other entities subject to the NPRM to fulfill the moral obligation to:**

- Ensure that patients obtain desired and appropriate health care;
- Disclose to patients and prospective patients standard treatments and procedures that they refuse to provide which are normally provided by other health care professionals;
- Inform patients of alternative providers as part of the informed-consent process;
- Provide information relevant to the patient's decision-making in a timely manner, using widely-accepted and easily-understood medical terminology, and document this process in the patient's medical record; and
- Refer patients who desire these treatments in a timely manner when failing to do so would harm the patients. Such entities must also provide appropriate ongoing care in the interim.

*Specific Concerns Regarding the NPRM's Potential Impact on Child Health and Wellbeing*

**Institutional discrimination/HHS grantees/Medicaid and CHIP coverage/access**

The Academy believes that the United States can and should ensure that all children, adolescents, and young adults from birth through the age of 26 years who reside within its borders have affordable access to high-quality and comprehensive health care, regardless of their or their families' incomes. Public and private health insurance should safeguard existing benefits for children and take further steps to cover the full array of essential health care services recommended by the AAP, including reproductive health and pregnancy-related services. CMS funds critical programs to support adolescent health, reduce unintended pregnancy, and provide reproductive health care, and these programs and services are critical to the health of adolescents and adults. The AAP urges HHS to ensure that no individual accessing services through a public health insurance is denied access to essential care.

As HHS considers potential changes to regulations and policy guidance to encourage the provision of grants and contracts to faith-based organizations, we urge you to ensure that federal policy does not undermine children's access to needed care and services. This includes a focus on upholding federal statutory safeguards for Medicaid beneficiaries that ensure access to qualified providers and appropriate and meaningful services. The AAP believes it essential that all states should uphold this fundamental protection affording access to any qualified, willing provider from which a beneficiary wishes to seek care. This essential protection is critical to the health of adolescents and young adults.

**Vaccines**

The Academy strongly supports all children and their families following the recommended childhood vaccination schedule.[vii] Routine childhood immunizations against infectious diseases are an integral part of our public health infrastructure and childhood immunization is one of the greatest accomplishments of modern medicine. In the United States 2009 birth cohort, routine childhood immunization will prevent approximately 42,000 early deaths and 20 million cases of disease, saving $13.5 billion in direct costs and $68.8 billion in societal costs.[viii] For children born in the United States between 1994 and 2013, "vaccination will prevent an estimated 322 million illnesses, 21 million hospitalizations, and 732,000 deaths over the course of their lifetimes."[ix]

However, vaccines are not 100% effective in all individuals receiving them. Certain infants, children, and adolescents cannot safely receive specific vaccines because of age or specific health conditions. These individuals benefit from the effectiveness of immunizations through a mechanism known as community immunity (also known as "herd" immunity). Community immunity occurs when nearly all individuals for whom a vaccine is not contraindicated have been appropriately immunized, minimizing the risk of illness or spread of a vaccine-preventable infectious agent to those who do not have the direct benefit of immunization. Although there is variance for levels of immunization required to generate community immunity specific to each disease and vaccine, it is generally understood that population immunization rates of at least 90% are required, as reflected in the Healthy People 2020 goals.[x] Certain highly contagious diseases, such as pertussis and measles, require a population immunization rate of ≥95% to achieve community immunity. But despite the importance of vaccines to children's health—and public health overall—some religious adherents object to their use.[xi]

For example, some religious adherents object to vaccines for chicken pox, hepatitis A, hepatitis B, polio, and measles, mumps and rubella (MMR) because they all have an attenuated connection to fetal-tissue research conducted in the 1960's.[xii] While the individual doses of these vaccines are not produced using fetal tissue, nor do they contain fetal tissue, the listed vaccines are grown in human cell cultures developed from two cell lines that trace back to two fetuses, both of which were legally aborted for unrelated medical reasons in the early 1960s. In addition, some object to the vaccine against the human papillomavirus (HPV). Certain strains of HPV can cause a variety of cancers, most notably cervical cancer.[xiii] Each year, approximately 11,000 women in the United States are diagnosed with cervical cancer – and almost half that number die from it.[xiv] Because HPV is often transmitted through sexual contact, and because the HPV vaccine is most effective when administered before the patient comes in contact with the virus, medical experts and organizations – including the AAP – recommend that the HPV vaccine be administered at 11 or 12 years of age.[xv] But because HPV can be transmitted sexually, some religious objectors oppose the vaccine on the basis that it allegedly encourages teens to engage in premarital sex, and that the correct way to limit transmission is through abstinence.[xvi]

In addition, all 50 states, the District of Columbia, and Puerto Rico have regulations requiring proof of immunization for child care and school attendance as a public health strategy to protect children in these settings, and to secondarily serve as a mechanism to promote timely immunization of children by their caregivers. Although all states and the District of Columbia

have mechanisms to exempt school attendees from specific immunization requirements for medical reasons, the majority also have a heterogeneous collection of regulations and laws that allow nonmedical exemptions, including those based on one's religious beliefs, from childhood immunizations otherwise required for child care and school attendance.

The AAP supports regulations and laws requiring certification of immunization to attend child care and school as a sound means of providing a safe environment for attendees and employees of these settings. The AAP also supports medically indicated exemptions to specific immunizations as determined for each individual child. The AAP views nonmedical exemptions to school-required immunizations as inappropriate for individual, public health, and ethical reasons and advocates for their elimination.[xvii] HHS policy should support organizations focused on advancing public health, a critical component of which is vaccination. We urge HHS not to make any policy changes that would provide grants or contracts to organizations that advocate for or adhere to vaccine policies not based on the best available evidence and science.

Unfortunately, we have seen the impact when immunization rates decline. In 2015, the United States experienced a large, multi-state outbreak of measles linked in part to exposures at Disneyland in California. The outbreak likely started from a traveler who became infected with measles and then visited the amusement park while infectious. Most of those infected were intentionally unvaccinated, some of them did not know their vaccination status, and a minority of them were vaccinated. Once outbreaks get started even vaccinated people can be affected because no vaccine is 100 percent effective. Analysis by CDC scientists showed that the measles virus type in this outbreak (B3) was identical to the virus type that caused the large measles outbreak in the Philippines in 2014.

Another measles outbreak occurred in Minnesota in the spring and summer of 2017, primarily concentrated within the Somali-American community. At the start of the outbreak, only about 42 percent of Somali-Minnesota 2-year-olds were vaccinated, largely due to many parents in the Somali-American community holding unfounded fears that the measles-mumps-rubella (MMR) vaccine causes autism. In a community with previously high vaccination coverage, the sudden drop in MMR vaccination rates resulted in a coverage level low enough to sustain widespread measles transmission in the community following introduction of the virus. Over the course of the outbreak, more than 8,000 people in Minnesota were exposed to measles, 500 were asked to stay home from work or school, 79 people were confirmed with measles, 73 of which were children under 10 years old, and 71 of the cases were in people who were unvaccinated for measles.[xviii]

In addition, each year, more than 200,000 individuals are hospitalized and 3,000-49,000 deaths occur from influenza-related complications.[xix] Serious morbidity and mortality can result from influenza infection in any person of any age. Rates of serious influenza-related illness and death are highest among children younger than 2 years old, seniors 65 years and older, and people of any age with medical conditions that place them at increased risk of having complications from influenza, such as pregnant women and people with underlying chronic cardiopulmonary, neuromuscular, and immunodeficient conditions. Hospital-acquired influenza has been shown to have a particularly high mortality rate, with a median of 16% among all patients and a range of 33% to 60% in high-risk groups such as transplant recipients and patients in the ICU.[xx]

Transmission from an infected, previously healthy child or adult begins as early as 1 day before the onset of symptoms and persists for up to 7 days; infants and immunocompromised people may shed virus even longer. Some infected people remain asymptomatic yet contagious.[xxi]

Because of the numbers cited above, the AAP also supports mandatory influenza immunization for all health care personnel as a matter of patient safety. Voluntary programs have failed to increase immunization rates to acceptable levels. Large health care organizations have implemented highly successful mandatory annual influenza immunization programs without significant problems. Mandating influenza vaccine for all health care personnel nationwide is ethical, just, and necessary. As such, we urge HHS not to make any policy changes that would weaken existing measures to immunize health care personnel and protect patients from vaccine-preventable infectious diseases.

**Mental Health Services**

Suicide affects young people from all races and socioeconomic groups, although some groups have higher rates than others. American Indian/Alaska Native males have the highest suicide rate, and black females have the lowest rate of suicide. Sexual minority youth (ie, lesbian, gay, bisexual, transgender, or questioning) have more than twice the rate of suicidal ideation compared to the average of all other children in the same age range.[xxii] The 2013 Youth Risk Behavior Survey of students in grades 9 through 12 in the United States indicated that during the 12 months before the survey, 39.1% of girls and 20.8% of boys felt sad or hopeless almost every day for at least 2 weeks in a row, 16.9% of girls and 10.3% of boys had planned a suicide attempt, 10.6% of girls and 5.4% of boys had attempted suicide, and 3.6% of girls and 1.8% of boys had made a suicide attempt that required medical attention.[xxiii]

The leading methods of suicide for the 15- to 19-year age group in 2013 were suffocation (43%), discharge of firearms (42%), poisoning (6%), and falling (3%).[xxiv] Particular attention should be given to access to firearms, because reducing firearm access may prevent suicides. Firearms in the home, regardless of whether they are kept unloaded or stored locked, are associated with a higher risk of completed adolescent suicide.[xxv,xxvi] However, in another study examining firearm security, each of the practices of securing the firearm (keeping it locked and unloaded) and securing the ammunition (keeping it locked and stored away from the firearm) were associated with reduced risk of youth shootings that resulted in unintentional or self-inflicted injury or death.[xxvii]

Youth seem to be at much greater risk from media exposure than adults and may imitate suicidal behavior seen on television.[xxviii] Media coverage of an adolescent's suicide may lead to cluster suicides, with the magnitude of additional deaths proportional to the amount, duration, and prominence of the media coverage.[xxix] A prospective study found increased suicidality with exposure to the suicide of a schoolmate.[xxx] Newspaper reports about suicide were associated with an increase in adolescent suicide clustering, with greater clustering associated with article front-page placement, mention of suicide or the method of suicide in the article title, and detailed description in the article text about the individual or the suicide act.[xxxi] More research is needed to determine the psychological mechanisms behind suicide clustering.[xxxii,xxxiii] The National

Institute of Mental Health suggests best practices for media and online reporting of deaths by suicide.[xxxiv]

Families and children, from infancy through adolescence, need access to mental health screening and assessment and a full array of evidence-based therapeutic services to appropriately address their mental and behavioral needs. In particular, adolescents, including LGBTQ youth, need non-judgmental treatment for mental health disorders. The AAP strongly urges HHS not to permit entities to infringe upon such treatment including through the use of "conversion" or "reparative therapy" which is never indicated for LGBTQ youth (add endnote from the LGBTQ section).

**Sexual Assault**

Sexual assault includes any situation in which there is nonvoluntary sexual contact, with or without penetration and/or touching of the anogenital area or breasts, that occurs because of physical force, psychological coercion, or incapacitation or impairment (e.g., secondary to alcohol or drug use). Sexual assault also occurs when victims cannot consent or understand the consequences of their choice because of their age or because of developmental challenges.[xxxv] National data show that teenagers and young adults ages 12 to 34 years have the highest rates of being sexually assaulted of any age group.[xxxvi] Annual rates of sexual assault were reported in 2012 (for 2011) by the U.S. Department of Justice to be 0.9 per 1000 persons 12 years and older (male and female).[xxxvii]

When an adolescent discloses that an acute sexual assault has occurred, it is incumbent on the health care provider to provide a nonjudgmental response. A supportive environment may encourage the adolescent to provide a clear history of what happened, agree to a timely medical and/or forensic evaluation, and engage in counseling and education to address the sequelae of the event and to help prevent future sexual violence. It is important to obtain the history of what happened from the adolescent, when possible. As in any other medical encounters, the physician should learn about relevant past medical and social history. Physicians should consider the possibility that the adolescent could be a victim of human trafficking and commercial sexual exploitation and ask appropriate questions, such as "Has anyone ever asked you to have sex in exchange for something you wanted?"[xxxviii] In addition, the physician should address the physical, psychological, and safety needs of the adolescent victim of sexual violence and be aware that responses to sexual assault can vary. The health care provider should address the adolescent's immediate health concerns, including any acute injuries, the likelihood of exposure to sexually transmitted infection (STIs), the possibility of pregnancy, and other physical or mental health concerns. Treatment guidelines for STIs from the CDC[xxxix] include recommendations for comprehensive clinical treatment of victims of sexual assault, including emergency contraception and HIV prophylaxis. Sexual assault is associated with a risk of pregnancy; 1 study reported a national pregnancy rate of 5% per rape among females 12 to 45 years of age.[xl,xli,xlii,xliii,xliv] Pregnancy prevention and emergency contraception should be addressed with every adolescent female, including rape and sexual assault victims. The discussion can include the risks of failure of the preventive measures and options for pregnancy management. It is critical that no entities, whether individual health care providers or organizations, be sanctioned by HHS in limiting the range of options that a pediatrician may discuss with sexual assault victims.

**Global Health**

The President's Emergency Plan for AIDS Relief (PEPFAR), the U.S. government's effort to prevent and treat HIV and AIDS worldwide, already includes a broad conscience clause (Leadership Act Section 301(d)) that allows participating organizations to deny patients information or care. This includes barrier means of contraception (e.g., condoms), which are one of the mainstays of HIV prevention. The NPRM would apply provisions of the Church Amendments to other global health programs funded by the Department, thereby allowing global health providers and entities to refuse individuals the care in contexts where suitable alternatives may be hard to find or nonexistent.

**Sexuality Education and Reproductive Health**

Pediatricians are an important source of health care for adolescents and young adults, especially younger adolescents, and can play a significant role in continuously addressing sexual and reproductive health needs during adolescence and young adulthood. Office visits present opportunities to educate adolescents on sexual health and development; to promote healthy relationships and to discuss prevention of sexually transmitted infections (STIs) including HIV, unintended pregnancies, and reproductive health-related cancers; to discuss planning for the timing and spacing of children, planning for pregnancy, and delivering preconception health care, as appropriate; and to address issues or concerns related to sexual function and fertility.[xlv] Pediatricians can help adolescents sort out whether they feel safe in their relationships as well as how to avoid risky sexual situations. Pediatricians also can facilitate discussion between the parent and adolescent on sexual and reproductive health.[xlvi] Pediatricians are in an important position to identify patients who are at risk for immediate harm (e.g., abuse, sex trafficking) and work collaboratively as part of a team of professionals from a number of disciplines to address these needs.

Sixty-five percent of reported *Chlamydia* and 50% of reported gonorrhea cases occur among 15- to 24-year-olds.[xlvii] Teen-aged birth rates in the United States have declined to the lowest rates seen in 7 decades yet still rank highest among industrialized countries. Pregnancy and birth are significant contributors to high school dropout rates among female youth; only approximately 50% of teen-aged mothers earn a high school diploma by 22 years of age versus approximately 90% of females who did not give birth during adolescence.[xlviii] Child sex trafficking and commercial sexual exploitation of children (CSEC) is increasingly being identified as a public health problem in the United States, and victims of sex trafficking and CSEC may present for medical care for a variety of reasons related to infections, reproductive issues, and trauma and mental health.[xlix]

The AAP believes that all children and adolescents should have access to developmentally appropriate, evidence-based, comprehensive, and medically accurate human sexuality education that empowers them to make informed, positive, and safe choices about healthy relationships, responsible sexual activity, and their reproductive health. This includes information about methods of contraception and sexual consent, as well as information that affirms gender identity and sexual orientation. The Academy supports approaches to sexual and reproductive health that are based on evidence and medical consensus. As such, the AAP recommends that pediatricians counsel their patients to use the most effective methods of contraception, starting with long-

acting reversible contraception such as implants and intrauterine devices. The AAP also strongly encourages the delivery of sexuality education that is based on modern conceptions of human sexuality. Access to accurate reproductive health care and sexual health information is critical to the overall development and well-being of children and adolescents.

The Academy's policy statement on Sexuality Education for Children and Adolescents recognizes that the development of healthy sexuality depends on forming attitudes and beliefs about sexual behavior, which can be influenced by religious concerns in addition to ethnic, racial, cultural, and moral ones. It is imperative that the administration of programs that pertain to reproductive health and education be done with respect for a multiplicity of religious values and belief systems, while prioritizing adolescents' right to accurate sexual health information.

The federal government oversees several programs that fund the delivery of evidence-based sexuality education. These programs help states implement innovative approaches to preventing unintended teen pregnancy, HIV, and other sexually transmitted infections, as well as youth development and adulthood preparation. The AAP urges HHS to continue to prioritize the funding of evidence-based or evidence-informed models in the administration of these programs, and to ensure that federal dollars for these programs are granted to organizations that meet the criteria laid out in these federal programs. The AAP also urges HHS to ensure that all programs that provide access to reproductive health care services prioritize access to the most effective methods of contraception.

**Contraception**

Pediatricians play an important role in adolescent pregnancy prevention and contraception. Nearly half of US high school students report ever having had sexual intercourse.[l] Each year, approximately 750 000 adolescents become pregnant, with more than 80% of these pregnancies unplanned, indicating an unmet need for effective contraception in this population.[li][lii]

Although condoms are the most frequently used form of contraception (52% of females reported condom use at last sex), use of more effective hormonal methods, including combined oral contraceptives (COCs) and other hormonal methods, was lower, at 31% and 12%, respectively, in 2011.[liii] Use of highly effective long-acting reversible contraceptives, such as implants or intrauterine devices (IUDs), was much lower.[liv] Adolescents consider pediatricians and other health care providers a highly trusted source of sexual health information.[lv][lvi] Pediatricians' long-term relationships with adolescents and families allow them to ask about sensitive topics, such as sexuality and relationships, and to promote healthy sexual decision-making, including abstinence and contraceptive use for teenagers who are sexually active. Additionally, medical indications for hormonal contraception, such as dysmenorrhea, heavy menstrual bleeding or other abnormal uterine bleeding, acne, and polycystic ovary syndrome, are often uncovered during adolescent visits. A working knowledge of contraception will assist the pediatrician in both sexual health promotion and treatment of common adolescent gynecologic problems. Contraception has been inconsistently covered as part of insurance plans. However, the Institute of Medicine has recommended contraception as an essential component of adolescent preventive care,[lvii] and the Patient Protection and Affordable Care Act of 2010 (Pub L No. 111–148) requires coverage of preventive services for women, which includes contraception, without a copay.[lviii,lix]

**Abortion**

Ensuring that adolescents have access to health care, including reproductive health care, has been a long-standing objective of the AAP.[lx] Timely access to medical care is especially important for pregnant teenagers because of the significant medical, personal, and social consequences of adolescent childbearing. The AAP strongly advocates for the prevention of unintended adolescent pregnancy by supporting comprehensive health and sexuality education, abstinence, and the use of effective contraception by sexually active youths. For 2 decades, the AAP has been on record as supporting the access of minors to all options regarding undesired pregnancy, including the right to obtain an abortion. Membership surveys of pediatricians, adolescent medicine specialists, and obstetricians confirm this support.[lxi,lxii,lxiii]

In the United States, minors have the right to obtain an abortion without parental consent unless otherwise specified by state law. State legislation that mandates parental involvement (parental consent or notification) as a condition of service when a minor seeks an abortion has generated considerable controversy. U.S. Supreme Court rulings, although upholding the constitutional rights of minors to choose abortion, have held that it is not unconstitutional for states to impose requirements for parental involvement as long as "adequate provision for judicial bypass" is available for minors who believe that parental involvement would not be in their best interest.[lxiv, lxv] Subsequently, there has been renewed activity to include mandatory parental consent or notification requirements in state and federal abortion-related legislation.

The American Medical Association, the Society for Adolescent Health and Medicine, the American Public Health Association, the American College of Obstetricians and Gynecologists, the AAP, and other health professional organizations have reached a consensus that a minor should not be compelled or required to involve her parents in her decision to obtain an abortion, although she should be encouraged to discuss the pregnancy with her parents and/or other responsible adults.[lxvi,lxvii,lxviii,lxix,lxx,lxxi,lxxii] These conclusions result from objective analyses of current data, which indicate that legislation mandating parental involvement does not achieve the intended benefit of promoting family communication but does increase the risk of harm to the adolescent by delaying access to appropriate medical care or increasing the rate of unwanted births.

Beliefs about abortion are deeply personal and are shaped by class, culture, religion, and personal history, as well as the current social and political climate. The AAP acknowledges and respects the diversity of beliefs about abortion. The AAP affirms the value of parental involvement in decision-making by adolescents and the importance of productive family communication in general. The AAP is foremost an advocate of strong family relationships, and holds that parents are generally supportive and act in the best interests of their children. We strongly urge HHS policy not to enable entities to infringe on the ability of parents and children to act in their best interests.

**Medical Neglect**

The AAP asserts that every child should have the opportunity to grow and develop free from preventable illness or injury. Children also have the right to appropriate medical evaluation when it is likely that a serious illness, injury, or other medical condition endangers their lives or threatens substantial harm or suffering. Under such circumstances, parents and other guardians have a responsibility to seek medical treatment, regardless of their religious beliefs and preferences. The AAP emphasizes that all children who need medical care that is likely to prevent substantial harm or suffering or death should receive that treatment.[lxxiii]

The U.S. Constitution requires that government not interfere with religious practices or endorse particular religions. However, these constitutional principles do not stand alone and may, at times, conflict with the independent government interest in protecting children. Government obligation arises from that interest when parental religious practices subject minor children to possible loss of life or to substantial risk of harm. Constitutional guarantees of freedom of religion do not permit children to be harmed through religious practices, nor do they allow religion to be a valid legal defense when an individual harms or neglects a child. As HHS considers the implementation, expansion, and enforcement of religious objections to medical care, we urge you to avoid policy changes that would result in financial support for organizations that encourage or engage in faith-based medical neglect.

**Religious Nonmedical Health Care Institutions**

Medicare and Medicaid cover care provided at religious nonmedical health care institutions (RNHCIs) and exempt these institutions from medical oversight requirements.[lxxiv] RNHCIs provide custodial rather than skilled nursing care. Given patients' exemptions from undergoing medical examinations, it is not possible to determine whether patients of RNHCIs would otherwise qualify for benefits.[lxxv,lxxvi] Because providing public funding for unproven alternative spiritual healing practices may be perceived as legitimating these services, parents may not believe that they have an obligation to seek medical treatment. Although the AAP recognizes the importance of addressing children's spiritual needs as part of the comprehensive care of children, it opposes public funding of religious or spiritual healing practices.[lxxvii]

**Newborn Hearing Screening**

Although most infants can hear normally, 1 to 3 of every 1,000 children are born with some degree of hearing loss.[lxxviii] Without newborn hearing screening, it is difficult to detect hearing loss in the first months and years of an infant's life. About half of the children with hearing loss have no risk factors for it. Newborn hearing screening can detect possible hearing loss in the first days of a child's life. If a possible hearing loss is found, further tests will be done to confirm the results. When hearing loss is confirmed, treatment and early intervention should start as soon as possible. Studies show that children with hearing loss who receive appropriate early intervention services by age 6 months usually develop good language and learning skills. That is why the AAP recommends that all babies receive newborn hearing screening before they go home from the hospital. We would thus strongly urge HHS to support hearing screenings for all newborns, without exception.

**Unaccompanied Children**

Children, unaccompanied and in family units, seeking safe haven in the United States often experience traumatic events in their countries of origin, during their journeys to the United States, and throughout the difficult process of resettlement. Upon arriving in the U.S., unaccompanied immigrant children are transferred to the custody of HHS's Office of Refugee Resettlement (ORR) and placed in shelters, many of which are run by faith-based organizations. Children, especially those who have been exposed to trauma and violence, should not be placed in settings that do not meet basic standards for children's physical and mental health and that expose children to additional risk, fear, and trauma. Children in federal custody and in the custody of sponsors, whether unaccompanied or accompanied, should receive timely, comprehensive medical care, including reproductive services and abortion care, that is culturally and linguistically sensitive by medical providers trained to care for children.[lxxix] This care should be consistent throughout all stages of the immigration processing pathway.

Recent actions by the Office of Refugee Resettlement in the case of "Jane Doe" are quite troubling. No woman or girl should face political interference in their health care decisions, including while she is in an ORR shelter, or held in any federally-funded detention facility. Safe, legal abortion is a necessary component of women's health care. When abortion care is illegal or highly restricted, women resort to unsafe means to end an unwanted pregnancy, including self-inflicted abdominal and bodily trauma, ingestion of dangerous chemicals, self-medication with a variety of drugs, and reliance on unqualified abortion providers. By obstructing basic access to safe and legal abortion, ORR is risking the health and lives of women and adolescents in its custody. ORR's action also appears to be a violation of the terms of the *Flores v. Reno* Settlement Agreement.

We urge HHS to ensure that no grantee of the federal government be permitted to deny any child, especially a child who has been exposed to trauma and violence, access to timely, comprehensive medical care, including reproductive services and abortion care.

**Adoption and Foster Care**

The AAP supports families in all their diversity, because the family has always been the basic social unit in which children develop the supporting and nurturing relationships with adults that they need to thrive. Children may be born to, adopted by, or cared for temporarily by married couples, nonmarried couples, single parents, grandparents, or legal guardians, and any of these may be heterosexual, gay or lesbian, or of another orientation. Children need secure and enduring relationships with committed and nurturing adults to enhance their life experiences for optimal social-emotional and cognitive development. Scientific evidence affirms that children have similar developmental and emotional needs and receive similar parenting whether they are raised by parents of the same or different genders.[lxxx] If two parents are not available to the child, adoption or foster parenting remain acceptable options to provide a loving home for a child and should be available without regard to the sexual orientation of the parent(s).[lxxxi] We urge HHS not to permit entities to discriminate against prospective or current adoptive or foster parents on the basis of sexual orientation of the parents.

**LGBTQ Children**

All children and adolescents deserve the opportunity to learn and develop in a safe and supportive environment. Lesbian, gay, bisexual, transgender, and questioning (LGBTQ) youth face high rates of bullying and other factors that contribute to health disparities such as higher rates of depression and suicidal ideation, higher rates of substance use, and more sexually transmitted and HIV infections.[lxxxii] Supportive and affirming communities, schools, friends and families can buffer all young people – especially LGBTQ youth – from negative experiences and outcomes while simultaneously promoting positive health and well-being.[lxxxiii] Policies that single-out or discriminate against LGBTQ youth are harmful to social-emotional health and may have lifelong consequences.[lxxxiv] All health care entities receiving federal funding, including those that are faith-based, should be welcoming to children who are members of the LGBTQ community.

The AAP advocates for policies that are gender-affirming for children – an approach that is supported by other medical professional organizations. In 2016, the AAP joined with other organizations to produce the document, "Supporting & Caring for Transgender Children," a guide for community members and allies to ensure that transgender young people are affirmed, respected, and able to thrive.[lxxxv] Section 1557 of the ACA contains essential nondiscrimination provisions for LGBTQ youth including prohibitions for discrimination on the basis of gender identity. These protections should be maintained and all covered entities, including faith-based organizations, should be required to comply.

All children and adolescents deserve the opportunity to learn and develop in a safe and supportive environment. “Conversion” or “reparative therapy” is never indicated for LGBTQ youth.[lxxxvi] This type of therapy is not effective and may be harmful to LGBTQ individuals by increasing internalized stigma, distress, and depression.[lxxxvii] We urge HHS to refrain from supporting entities who do not treat LGBTQ youth as they do all others, who discriminate or condone discrimination against them, their families, or LGBTQ parents, or who support, condone, or provide “conversion” or “reparative therapy”.

**Child Welfare Services**

Children in foster care have such unique vulnerabilities and health disparities that the AAP classifies them as a population of children with special health care needs. Children in foster care face greater health needs because of their experiences of complex trauma, including abuse, neglect, witnessed violence, and parental substance use disorders (SUD). Children in foster care have typically experienced multiple caregivers, impacting their ability to form a safe, stable, and nurturing attachment relationship with a caregiver. One third of children in foster care have a chronic medical condition, and 60 percent of those under age 5 have developmental health issues.[lxxxviii, lxxxix] Up to 80 percent of children entering foster care have a significant mental health need.[xc] Ensuring access to appropriate and trauma-informed services is critical to meeting the needs of this vulnerable population.

In FY 2016, the number of children entering foster care increased to over 270,000, up from 251,352 in FY 2012. This is the fourth year in a row that removals have increased after declining over the past decade. Parental substance use was a factor for the removal in over a third of those

cases, second only to neglect as a factor for placement in foster care. Of note, infants represented nearly a fifth of all removals from families to foster care, totaling 49,234 in FY 2016. A total of 437,465 children were in foster care on the last day of FY 2016.[xci] As the opioid epidemic continues to contribute to rising foster care placements, we need federal policies that support child and family healing and that provide a sufficient number of nurturing, high-quality foster and adoptive families.

Children fare best when they are raised in families equipped to meet their needs. Child welfare services can support the intensive family preservation services and parental SUD treatment needed to help families heal when it is possible to keep children together with their parents. When out-of-home placements are necessary for a child's health and safety, access to quality parenting from foster or kinship care providers can support a child's healing. High-quality foster parent training and recruitment is essential to ensure sufficient access to families with the necessary background and training in trauma, child development, and parenting skills. In light of the ongoing opioid epidemic and its impact on rising foster care placements, there is a significant need to expand recruitment broadly to meet growing need and to also better support and retain foster families and kinship caregivers.

Given the uniquely vulnerable health needs of children in foster care, and the need for expanded capacity for foster and adoptive homes, the AAP recommends that HHS not make any changes in federal child welfare policy that would result in discrimination against LGBTQ children and youth in foster care, or LGBTQ families seeking to serve as foster or adoptive parents. Faith-based organizations play an important role in providing child welfare services and families to provide nurturing homes for children. However, no federal policy changes should allow for discrimination against children or families in child welfare services on the basis of religion, sexual orientation, or gender identity. All children who enter the child welfare system should receive compassionate, high-quality, and trauma-informed care and support services.

HHS should not support entities involved in child welfare services that engage in discrimination against children or families based on sexual orientation, gender identity, marital status, or faith.

*Conclusion*

The AAP wishes to underscore its recognition of the important role of religion in the personal, spiritual, and social lives of many individuals, including health providers. Balancing that role with efforts to ensure children have appropriate access to needed health and social services is critical to meeting their health needs and supporting their health and wellbeing. As HHS considers potential changes to regulations and policy guidance to encourage the provision of grants and contracts to faith-based organizations, we urge you to ensure that federal policy does not undermine children's access to needed care and services.

Thank you again for the opportunity to provide feedback on this important issue. If you have any questions, please reach out to Ami Gadhia in our Washington, D.C. office at 202/347-8600 or agadhia@aap.org.

Sincerely,

Colleen A. Kraft MD, FAAP
President
CAK/avg

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# Exhibit 99

NYC

March 27, 2018

Via electronic submission

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (Docket No.: HHS-OCR-2018-0002)

To Whom It May Concern:

The New York City Commission on Human Rights, the New York City Department of Health and Mental Hygiene, the New York City Department of Social Services, and NYC Health + Hospitals write to express our opposition to the United States Department of Health and Human Services' (HHS) proposed regulations entitled, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority.

HHS' proposed rule will cause serious harm to the health and well-being of New Yorkers. It will erect barriers to the delivery and receipt of timely, high quality health care. It will foster a new standard of selective and discriminatory treatment for many of our most vulnerable populations. It will also multiply the administrative burdens that health care organizations shoulder to address time-sensitive health conditions. Finally, it will infringe on the ability of state and local governments to enforce their laws and policies. In the face of these significant harms, we urge HHS to rescind this rule.

**The Proposed Rule Will Harm Patients**

The proposed rule elevates healthcare providers' personal beliefs over patient health. It gives providers wide latitude in opting out of treating patients. Undoubtedly, providers will deny care to patients who need it. At a minimum, a denial will mean that patients who are turned away will experience delays and increased expenses in receiving care. But in many cases, delay will effectively mean denial, particularly where time is of the essence or locating a suitable alternate provider is not feasible. The denial of care will be the end of the road in many patients' search for treatment.

Indeed, finding an alternate provider is no simple task. Health plans have limited provider networks, caps on the number of specialty visits, and steep cost-sharing obligations. Workers have limited or no sick leave, and forcing them to visit a second provider to accommodate the first provider's beliefs means that many patients will have to decide between taking care of their health and making a living. That is no choice at all, and many patients will forego care that they otherwise would have received.

Similarly, many people live in areas with a limited number of primary care doctors, specialists, and specialty care facilities. They may be forced to travel great distances to find a provider willing to treat them. Patients who are elderly, patients with disabilities, and patients under the age of majority may be completely unable to access an alternate healthcare provider if refused

care. During an emergency such as a national disaster, there may be only one accessible provider.

The denials of care that will result if the proposed rule is adopted will have severe and often irreversible consequences: unintended pregnancies, disease transmission, medical complications and anguish in the last days of life, and death. For example:

- Post-exposure prophylaxis for HIV should be initiated within 36 hours, but not beyond 72 hours after potential exposure.
- Emergency contraception is most effective at preventing pregnancy if taken as soon as possible after sexual intercourse.
- Contraceptives and pre-exposure prophylaxis for HIV are effective only if accessed prior to a sexual encounter.
- There is a window for a safe, legal abortion, and a narrower window for medication abortion. In the case of ectopic pregnancy or other life-threatening complication, an abortion may need to be performed immediately.
- Opiate users denied methadone or buprenorphine remain at increased risk of overdose, and naloxone must be administered quickly to reverse drug overdose.
- Persons with suicidal ideation need immediate care to prevent self-harm.
- Refusing to honor a person's end-of-life wishes prolongs suffering.

In short, the proposed rule will cause long-lasting and irreparable harm to patients.

The breadth of the proposed rule is extraordinary, all but guaranteeing that patients will be denied essential health care. Extending protections to health plans, plan sponsors, and third-party administrators that receive federal funds may prompt health plans to cease coverage for abortion, contraceptives, health care related to gender transition, and other services. Allowing anyone "with an articulable connection to a procedure, health service, health program or research activity" to raise an alleged conscience objection, means that the myriad of participants in a healthcare encounter—from intake and billing staff to pharmacists, translators, radiology technicians, and phlebotomists—can refuse to participate in service delivery. This will cause untold disruptions and delays for patients. And the expansive definitions of "assist in the performance" and "referral" mean that healthcare providers – after refusing to care for a patient – will not even need to provide a referral or other necessary information for a patient to seek care elsewhere.

The negative health impact of denied care is profound. In the case of infectious disease, there is societal impact: delays in diagnosis, prophylaxis and treatment increase the likelihood of individual disease progression and transmission to others. The consequences of untreated substance use disorders are likewise far-reaching. Compounding matters, the harmful effects of the proposed rules will be felt most acutely by individuals and communities that already face great challenges accessing the care that they need: people of color, low-income persons, women, children, people with substance use disorders, and lesbian, gay, bisexual, transgender, queer, intersex and gender nonconforming ("LGBTQI") persons.

**The Proposed Rule Will Lead to Discrimination Against Already Vulnerable Populations**

The rule gives healthcare providers a free pass to discriminate based on a patient's identity and against any patient whose actions or decisions conflict with the provider's alleged conscience objection.

Discrimination by health care providers marginalizes and stigmatizes patients, driving them away from care systems. It has long-term destructive consequences for the health and well-being of patients and communities that already bear the brunt of discrimination. Women and LGBTQI people will find themselves denied care at alarming rates. Providers may refuse to prescribe contraceptives to women who are not married, fertility treatment to same-sex couples, pre-exposure prophylaxis to gay men, or counseling to LGBTQI survivors of hate or intimate partner violence. Transgender patients are likely to be refused medically necessary care like hormone therapy, and substance users may be denied medications to treat addiction or reverse drug overdose.

The impact of such discrimination extends far beyond the individual patient encounter. For example, LGBTQI youth that are denied services and psychosocial support show a lasting distrust of systems of care.[i] Concerns regarding stigma may also make patients reluctant to reach out to loved ones for support, as has been shown with women who have had abortions.[ii]

This never-before-seen license to pick and choose the type of patient and nature of care that a clinician or organization will provide runs counter to principles of comprehensiveness and inclusion that have long guided the federal government's oversight of key health care programs and the operation of the country's health care delivery system.

**The Proposed Rule Creates New Administrative Burdens for a Strained Health Care System**

The extraordinary breadth of the proposed rule will result in significant and costly administrative burdens on an already-strained healthcare system. The proposed rule places healthcare entities in the precarious position of having to accommodate various ethical beliefs held by thousands of staff, regardless of how tenuous those staffs' connection to the clinical encounter. Also, by prohibiting employers from withholding or restricting any title, position or status from staff that refuse to participate in care, healthcare entities are limited in being able to move staff into positions where they will not disrupt care and harm patients. Thus, doctors in private practice will be prohibited from firing any staff who refuses to assist, and thereby stigmatizes and harms, LGBTQI patients. Emergency departments, ambulance corps, mental health hotlines, and other urgent care settings may need to increase the number of shift staff to ensure sufficient coverage in case of a refusal to work with a patient. This will have a very real financial impact on healthcare facilities, including government-run and subsidized clinics and hospital systems. This is a costly proposition that flies in the face of the federal government's stated goal of reducing administrative burdens within the health care system.

**The Proposed Rule Infringes on State and Local Governments' Ability to Enforce Their Laws and Policies and Conflicts with Patient Protections**

The proposed rule may impact the ability of State and local governments to enforce the full scope of their health- and insurance-related laws and policies by conditioning the receipt of federal funding on compliance with the rule. Similarly, it may leave providers caught between conflicting mandates. The New York City Human Rights Law ("City Human Rights Law"), for example, like many state and local nondiscrimination laws, protects patients from discrimination based on sexual orientation, gender (including gender identity), marital status, and disability.

Protecting vulnerable populations from discrimination and misinformation is of paramount importance to New York City. The City Human Rights Law is one of the most comprehensive civil rights laws in the nation, prohibiting discrimination in health care settings based on, among other things, a patient's race, age, citizenship status, and religion. A provider's refusal to serve a patient pursuant to the proposed rule may be a violation of state and local laws, some of which are enforced through the imposition of injunctive relief and substantial financial penalties. Violations of the City Human Rights Law, for example, can lead to the imposition of penalties of up to $250,000 per violation.

We oppose regulations that allow personal beliefs to trump science at the expense of vulnerable populations' access to health care. We oppose systems that compromise our duty to protect and improve the health of City residents. We oppose actions that sanction discrimination against patients based on who they are or what health conditions they have.

We urge HHS to rescind the proposed rule.

Sincerely,

Steven Banks
Commissioner
New York City Department of
Social Services

Mary T. Bassett, MD, MPH
Commissioner
New York City Department of
Health and Mental Hygiene

Mitchell Katz, MD
President and Chief Executive Officer
New York City Health and Hospitals

Carmelyn P. Malalis
Chair and Commissioner
New York City Commission on
Human Rights

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