

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.¹

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

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.

Exhibit 95



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

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

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](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

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 counseling³² 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

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

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

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

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

Protecting Statutory Conscience
Rights in Health Care Proposed Rule
RIN 0945-ZA03
March 27, 2018
Page 2 of 13

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

* * *

Protecting Statutory Conscience
Rights in Health Care Proposed Rule
RIN 0945-ZA03
March 27, 2018
Page 3 of 13

**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.

Protecting Statutory Conscience
Rights in Health Care Proposed Rule
RIN 0945-ZA03
March 27, 2018
Page 4 of 13

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:

Protecting Statutory Conscience
Rights in Health Care Proposed Rule
RIN 0945-ZA03
March 27, 2018
Page 5 of 13

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).

Protecting Statutory Conscience
Rights in Health Care Proposed Rule
RIN 0945-ZA03
March 27, 2018
Page 6 of 13

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

Protecting Statutory Conscience
Rights in Health Care Proposed Rule
RIN 0945-ZA03
March 27, 2018
Page 7 of 13

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

Protecting Statutory Conscience
Rights in Health Care Proposed Rule
RIN 0945-ZA03
March 27, 2018
Page 8 of 13

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

Protecting Statutory Conscience
Rights in Health Care Proposed Rule
RIN 0945-ZA03
March 27, 2018
Page 9 of 13

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.

Protecting Statutory Conscience
Rights in Health Care Proposed Rule
RIN 0945-ZA03
March 27, 2018
Page 10 of 13

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.

Protecting Statutory Conscience
Rights in Health Care Proposed Rule
RIN 0945-ZA03
March 27, 2018
Page 11 of 13

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

Protecting Statutory Conscience
Rights in Health Care Proposed Rule
RIN 0945-ZA03
March 27, 2018
Page 12 of 13

...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

Protecting Statutory Conscience
Rights in Health Care Proposed Rule
RIN 0945-ZA03
March 27, 2018
Page 13 of 13

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

STATE OF CALIFORNIA

Dave Jones, Insurance Commissioner

DEPARTMENT OF INSURANCE

EXECUTIVE OFFICE
300 CAPITOL MALL, SUITE 1700
SACRAMENTO, CA 95814
(916) 492-3500
www.insurance.ca.gov



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

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA0
March 27, 2018
Page 2

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 constitutional 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 explicitly 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).

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA0
March 27, 2018
Page 3

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.

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA0
March 27, 2018
Page 4

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 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

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA0
March 27, 2018
Page 5

position of either enforcing its state constitution² 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.)

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA0
March 27, 2018
Page 6

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>

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA0
March 27, 2018
Page 7

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
Insurance Commissioner

⁵ 72 Fed. Reg. at 9971

Exhibit 98

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®



AAP Headquarters
345 Park Blvd
Itasca, IL 60143
Phone: 630/626-6000
Fax: 847/434-8000
E-mail: kidsdocs@aap.org
www.aap.org

**Reply to
AAP Washington Office**
601 13th St NW, Suite 400N
Washington, DC 20005
Phone: 202/347-8600
E-mail: kids1st@aap.org

Executive Committee

President
Colleen A. Kraft, MD, FAAP

President-Elect
Kyle Yasuda, MD, FAAP

Immediate Past President
Fernando Stein, MD, FAAP

CEO/Executive Vice President
Karen Remley, MD, FAAP

Board of Directors

District I
Wendy S. Davis, MD, FAAP
Burlington, VT

District II
Warren M. Seigel, MD, FAAP
Brooklyn, NY

District III
David I. Bromberg, MD, FAAP
Frederick, MD

District IV
Jane Meschan Foy, MD, FAAP
Winston-Salem, NC

District V
Richard H. Tuck, MD, FAAP
Zanesville, OH

District VI
Pam K. Shaw, MD, FAAP
Kansas City, KS

District VII
Anthony D. Johnson, MD, FAAP
Little Rock, AR

District VIII
Martha C. Middlemist, MD, FAAP
Centennial, CO

District IX
Stuart A. Cohen, MD, FAAP
San Diego, CA

District X
Lisa A. Cosgrove, MD, FAAP
Merritt Island, FL

March 27, 2018

Roger Severino, Director
Office of Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
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 contraceptionⁱ; perform routine neonatal male circumcisionⁱⁱ; 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 $\geq 95\%$ 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.¹ 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.^{liii}

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.^{lxxxix} 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

ⁱ Stein R. Pharmacists' rights at front of new debate; because of beliefs, some refuse to fill birth control prescriptions. *Washington Post*. 2005:A1, A10.

ⁱⁱ British Medical Association. The law and ethics of male circumcision: guidance for doctors. *J Med Ethics*. 2004;30(3):259–263.

ⁱⁱⁱ Pontifical Academy for Life. Moral reflections on vaccines prepared from cells derived from aborted human fetuses. *Natl Cathol Bioeth Q*. 2006;6(3):541–537.

^{iv} Wicclair MR. Conscientious objection in medicine. *Bioethics*. 2000;14(3):205–227.

^v Wicclair MR. Pharmacies, pharmacists, and conscientious objection. *Kennedy Inst Ethics J*. 2006;16(3):225–250.

^{vi} Allen WL, Brushwood DB. Pharmaceutically assisted death and the pharmacist's right of conscience. *J Pharm Law*. 1996;5(1):1–18.

^{vii} American Academy of Pediatrics. Policy Statement. "Recommended Childhood and Adolescent Immunization Schedule—United States, 2017." *Pediatrics*, 2017. <http://pediatrics.aappublications.org/content/139/3/e20164007>.

^{viii} Zhou F, Shefer A, Wenger J, et al. *Economic evaluation of the routine childhood immunization program in the United States, 2009*. *Pediatrics*. 2014;133(4):577–585.

^{ix} Centers for Disease Control & Prevention, *Morbidity & Mortality Weekly Report* 352-55 (Apr. 25, 2014), archived at <https://perma.cc/H78B-4655>.

^x HealthyPeople.gov. Immunization and infectious diseases. Available at: <https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives>.

^{xi} See, e.g., Liberty Counsel, *Compulsory Vaccinations Threaten Religious Freedom* (2007), <http://www.lc.org/uploads/files/pdf/memo-vaccination.pdf> (argument by one of petitioners' amici asserting religious objections to rubella and hepatitis vaccines).

^{xii} Richard K. Zimmerman, *Ethical "Analyses of Vaccines Grown in Human Cell Strains Derived from Abortion: Arguments and Internet Search,"* 22 *VACCINE* 4238, 4238–44 (2004).

^{xiii} Centers for Disease Control & Prevention, *HPV Vaccine Information for Clinicians – Fact Sheet* (July 8, 2012), archived at <https://perma.cc/9ANQ-FWWK>.

- ^{xiv} *Ibid.* See also <https://www.cdc.gov/cancer/cervical/statistics/index.htm>.
- ^{xv} *Ibid.*; American Academy of Pediatrics, *Recommended Childhood and Adolescent Immunization Schedule – United States, 2016* (Mar. 2016), archived at <https://perma.cc/8QWH-LUQV>.
- ^{xvi} Joseph E. Balog, *The Moral Justification for a Compulsory Human Papillomavirus Vaccination Program*, 99 AM. J. PUB. HEALTH 616, 617 (2009).
- ^{xvii} American Academy of Pediatrics. Policy Statement. “Medical Versus Nonmedical Immunization Exemptions for Child Care and School Attendance.” *Pediatrics* 2016. <http://pediatrics.aappublications.org/content/138/3/e20162145>.
- ^{xviii} <http://www.health.state.mn.us/news/pressrel/2017/measles082517.html>
- ^{xix} Centers for Disease Control and Prevention. Questions & Answers: Seasonal Influenza. <http://www.cdc.gov/flu/about/qa/disease.htm>.
- ^{xx} Salgado CD, Farr BM, Hall KK, Hayden FG. *Influenza in the acute hospital setting. [erratum in Lancet Infect Dis. 2002;2(6):383] Lancet Infect Dis. 2002;2(3):145–155* pmid: 11944184
- ^{xxi} Poland GA, Tosh P, Jacobson RM. *Requiring influenza vaccination for health care workers: seven truths we must accept. Vaccine. 2005;23(17–18):2251–2255* pmid: 15755605
- ^{xxii} Committee On Adolescence. Office-based care for lesbian, gay, bisexual, transgender, and questioning youth. *Pediatrics*. 2013;132(1):198–203.
- ^{xxiii} Kann L, Kinchen S, Shanklin SL, et al; Centers for Disease Control and Prevention (CDC). Youth risk behavior surveillance--United States, 2013. *MMWR Suppl.* 2014;63(4):1–168.
- ^{xxiv} Centers for Disease Control and Prevention. CDC Wonder [database]: mortality query. Available at: <http://wonder.cdc.gov>. Accessed April 24, 2015.
- ^{xxv} Brent DA, Perper JA, Allman CJ, Moritz GM, Wartella ME, Zelenak JP. The presence and accessibility of firearms in the homes of adolescent suicides. A case-control study. *JAMA*. 1991;266(21):2989–2995.
- ^{xxvi} American Academy of Pediatrics, Committee on Injury and Poison Prevention. Firearm injuries affecting the pediatric population. *Pediatrics*. 1992;89(4 pt 2):788–790.
- ^{xxvii} Grossman DC, Mueller BA, Riedy C, et al. Gun storage practices and risk of youth suicide and unintentional firearm injuries. *JAMA*. 2005;293(6):707–714.
- ^{xxviii} Gould MS, Greenberg T, Velting DM, Shaffer D. Youth suicide risk and preventive interventions: a review of the past 10 years. *J Am Acad Child Adolesc Psychiatry*. 2003;42(4):386–405.
- ^{xxix} *Ibid.*
- ^{xxx} Swanson SA, Colman I. Association between exposure to suicide and suicidality outcomes in youth. *CMAJ*. 2013;185(10):870–877.
- ^{xxxi} Gould MS, Kleinman MH, Lake AM, Forman J, Midle JB. Newspaper coverage of suicide and initiation of suicide clusters in teenagers in the USA, 1988-96: a retrospective, population-based, case-control study. *Lancet Psychiatry*. 2014;1(1):34–43.
- ^{xxxii} Haw C, Hawton K, Niedzwiedz C, Platt S. Suicide clusters: a review of risk factors and mechanisms. *Suicide Life Threat Behav*. 2013;43(1):97–108.
- ^{xxxiii} Ali MM, Dwyer DS, Rizzo JA. The social contagion effect of suicidal behavior in adolescents: does it really exist? *J Ment Health Policy Econ*. 2011;14(1):3–12
- ^{xxxiv} National Institute of Mental Health. Recommendations for reporting on suicide. Available at: www.nimh.nih.gov/health/topics/suicideprevention/recommendations-forreporting-on-suicide.shtml. Accessed July 27, 2015.
- ^{xxxv} Kaufman M; American Academy of Pediatrics, Committee on Adolescence. Care of the adolescent sexual assault victim. *Pediatrics*. 2008;122(2):462–470.
- ^{xxxvi} Planty M, Langton L, Krebs C, Berzofsky M, Smiley-McDonald H. Female victims of sexual violence, 1994-2010. Washington, DC: US Department of Justice, Office of Justice Programs, Bureau of Justice Statistics; March 2013. Available at: www.bjs.gov/content/pub/pdf/fvsv9410.pdf.
- ^{xxxvii} *Ibid* and Planty M, Langton L. *Criminal Victimization, 2011*. Washington, DC: US Department of Justice, Office of Justice Programs, Bureau of Justice Statistics; 2012. Available at: www.bjs.gov/index.cfm?ty=pbdetail&iid=4494.
- ^{xxxviii} Greenbaum J, Crawford-Jakubiak JE; Committee on Child Abuse and Neglect. Child sex trafficking and commercial sexual exploitation: health care needs of victims. *Pediatrics*. 2015;135(3):566–574.

- xxxix Centers for Disease Control and Prevention. 2015 Sexually transmitted diseases treatment guidelines: sexual assault and abuse and STDs. Available at: www.cdc.gov/std/tg2015/sexualassault.htm.
- ^{xl} Holmes MM, Resnick HS, Kilpatrick DG, Best CL. Rape-related pregnancy: estimates and descriptive characteristics from a national sample of women. *Am J Obstet Gynecol*. 1996;175(2):320–324; discussion 324–325 2003;14(1):1–20.
- ^{xli} Stewart FH, Trussell J. Prevention of pregnancy resulting from rape: a neglected preventive health measure. *Am J Prev Med*. 2000;19(4):228–229.
- ^{xlii} McFarlane J. Pregnancy following partner rape: what we know and what we need to know. *Trauma Violence Abuse*. 2007;8(2):127–134.
- ^{xliii} Miller E, Decker MR, McCauley HL, et al. A family planning clinic partner violence intervention to reduce risk associated with reproductive coercion. *Contraception*. 2011;83(3):274–280.
- ^{xliv} Gottschall JA, Gottschall TA. Are per-incident rape-pregnancy rates higher than per-incident consensual pregnancy rates? *Hum Nat*.
- ^{xlv} Lerand SJ, Ireland M, Boutelle K. Communication with our teens: associations between confidential service and parent-teen communication. *J Pediatr Adolesc Gynecol*. 2007;20(3):173–178.
- ^{xlvi} *Ibid*.
- ^{xlvii} Centers for Disease Control and Prevention. *Sexually Transmitted Disease Surveillance 2015*. Atlanta, GA:US Department of Health and Human Services; 2016. Available at: www.cdc.gov/std/stats15/default.htm. Accessed August 17, 2017.
- ^{xlviii} Perper K, Peterson K, Manlove J. *Diploma Attainment Among Teen Mothers. Fact Sheet. Publication #2010-01*. Washington, DC: Child Trends; 2010.
- ^{xlix} Greenbaum J, Crawford-Jakubiak JE; Committee on Child Abuse and Neglect. Child sex trafficking and commercial sexual exploitation: health care needs of victims. *Pediatrics*. 2015;135(3):566–574.
- ^l Martinez G, Copen CE, Abma JC. Teenagers in the United States: sexual activity, contraceptive use, and childbearing, 2006–2010 national survey of family growth. *Vital Health Stat 23*. 2011; (31):1–35.
- ^{li} Finer LB, Zolna MR. Unintended pregnancy in the United States: incidence and disparities, 2006. *Contraception*. 2011;84(5): 478–485.
- ^{lii} Kost K, Henshaw S, Carlin L. *US Teenage Pregnancies, Births and Abortions: National and State Trends and Trends by Race and Ethnicity*. New York, NY: Guttmacher Institute; 2010.
- ^{liii} Martinez G, Copen CE, Abma JC. Teenagers in the United States: sexual activity, contraceptive use, and childbearing, 2006–2010 national survey of family growth. *Vital Health Stat 23*. 2011; (31):1–35.
- ^{liv} Martinez G, Copen CE, Abma JC. Teenagers in the United States: sexual activity, contraceptive use, and childbearing, 2006–2010 national survey of family growth. *Vital Health Stat 23*. 2011; (31):1–35.
- ^{lv} Ott MA, Rosenberger JG, McBride KR, Woodcox SG. How do adolescents view health? Implications for state health policy. *J Adolesc Health*. 2011;48(4):398–403.
- ^{lvi} Jones RK, Biddlecom AE. The more things change...: the relative importance of the internet as a source of contraceptive information for teens. *Sex Res Soc Policy*. 2011;8(1):27–37.
- ^{lvii} Institute of Medicine, Committee on Preventive Services for Women. *Clinical Preventive Services for Women: Closing the Gaps*. Washington, DC: National Academies Press; 2011.
- ^{lviii} Health Resources and Services Administration. *Women’s Preventive Services: Required Health Plan Coverage Guidelines*. Rockville, MD: Health Resources and Services Administration; 2012.
- ^{lix} The Patient Protection and Affordable Care Act. Pub L No. 111-148 (2010). Available at: www.dol.gov/ebsa/healthreform/. Accessed January 13, 2014.
- ^{lx} American Academy of Pediatrics. *AAP Agenda for Children—Strategic Plan 2015-2016*. Available at: www.aap.org/en-us/about-the-aap/aap-facts/AAP-Agenda-for-Children-Strategic-Plan/Pages/AAP-Agenda-for-Children-Strategic-Plan.aspx.
- ^{lxi} Darney P; One Hundred Professors of Obstetrics and Gynecology. A statement on abortion by 100 professors of obstetrics: 40 years later. *Am J Obstet Gynecol*. 2013;209(3):193–199.
- ^{lxii} Fleming GV, O’Connor KG. Adolescent abortion: views of the membership of the American Academy of Pediatrics. *Pediatrics*. 1993;91(3):561–565.
- ^{lxiii} Miller NH, Miller DJ, Pinkston Koenigs LM. Attitudes of the physician membership of the society for adolescent medicine toward medical abortions for adolescents. *Pediatrics*. 1998;101(5):E4.
- ^{lxiv} *Hodgson v Minnesota*, 497 US 417 (1990).
- ^{lxv} *Planned Parenthood v Casey*, 505 US 833 (1992).

-
- ^{lxvi} American College of Obstetricians and Gynecologists, American Academy of Pediatrics. Confidentiality protections for adolescents and young adults in the health care billing and insurance claims process. *Obstet Gynecol.* 2016;58(3):374–377.
- ^{lxvii} American Medical Association, Council on Ethical and Judicial Affairs. Opinion 2.015—Mandatory Parental Consent to Abortion. Available at: www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion2015.page?
- ^{lxviii} American Medical Association, Council on Ethical and Judicial Affairs. Opinion 5.055—Confidential Care for Minors. Available at: www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion5055.page?
- ^{lxix} American Medical Association, Council on Ethical and Judicial Affairs. Mandatory parental consent to abortion. *JAMA.* 1993;269(1):82–86.
- ^{lxx} Ford C, English A, Sigman G. Confidential health care for adolescents: position paper for the society for adolescent medicine. *J Adolesc Health.* 2004;35(2):160–167.
- ^{lxxi} American Academy of Family Physicians. Adolescent health care, confidentiality. Available at: www.aafp.org/about/policies/all/adolescentconfidentiality.html.
- ^{lxxii} American Public Health Association. Ensuring minors’ access to confidential abortion services. Available at: www.apha.org/advocacy/policy/policysearch/default.htm?id=1415.
- ^{lxxiii} AAP Committees on Adolescence and Psychosocial Aspects of Family and Child Health (2016). Sexuality Education for Children and Adolescents. *Pediatrics.* 2016; 138(2). Retrieved from <http://pediatrics.aappublications.org/content/138/2/e20161348>.
- ^{lxxiv} Harris, BR. Veiled in textual neutrality: is that enough? A candid reexamination of the constitutionality of Section 4454 of the Balanced Budget Act of 1997. *Alabama Law Rev.* 2010;61(2):393-423.
- ^{lxxv} *Ibid.*
- ^{lxxvi} *Children’s Health Care Is a Legal Duty Inc v Min de Parle*, 212 F.3d 1084 (8th Cir. 2000), *cert. denied*, 532 US 957 (2001).
- ^{lxxvii} AAP Committee on Bioethics, “Conflicts Between Religious or Spiritual Beliefs and Pediatric Care: Informed Refusal, Exemptions, and Public Funding,” *Pediatrics* October 2013, 2013;132;962; DOI: 10.1542/peds.2013-2716. Retried from <http://pediatrics.aappublications.org/content/pediatrics/132/5/962.full.pdf>.
- ^{lxxviii} <https://www.healthychildren.org/English/ages-stages/baby/Pages/Purpose-of-Newborn-Hearing-Screening.aspx>.
- ^{lxxix} Council on Community Pediatrics. Detention of Immigrant Children. *Pediatrics.* 2017; 139(5). Available at: <http://pediatrics.aappublications.org/content/139/5/e20170483>.
- ^{lxxx} AAP Committee on Psychosocial Aspects of Child and Family Health, “Promoting the Well-Being of Children Whose Parents Are Gay or Lesbian—Policy Statement,” *Pediatrics* Apr 2013, 131 (4) 827-830; DOI: 10.1542/peds.2013-0376.
- ^{lxxxi} *ibid*
- ^{lxxxviii} Szilagyi, M. et al. (2015). Policy Statement: Health Care Issues for Children and Adolescents in Foster Care and Kinship Care. *Pediatrics.* 2015; 136; e1131. Retrieved from <http://pediatrics.aappublications.org/content/pediatrics/136/4/e1131.full.pdf>.
- ^{lxxxix}
- ^{xc} *Ibid.*
- ^{xci} U.S. Department of Health and Human Services, Administration for Children and Families, Administration on Children, Youth, and Families, Children’s Bureau (2017). The AFCARS Report FY 2016. Retrieved from <https://www.acf.hhs.gov/sites/default/files/cb/afcarsreport24.pdf>.

Exhibit 99



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.¹ 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.²

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

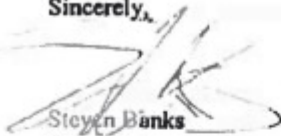
The proposed rule may impact the ability of State and local governments to enforce the full scope of their health- and insurance-related laws and policies by conditioning the receipt of federal funding on compliance with the rule. Similarly, it may leave providers caught between conflicting mandates. 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.

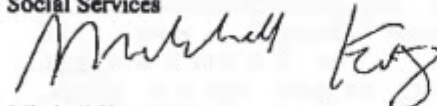
We oppose regulations that allow personal beliefs to trump science at the expense of vulnerable populations' access to health care. We oppose systems that compromise our duty to protect and improve the health of City residents. We oppose actions that sanction discrimination against patients based on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

We urge HHS to rescind the proposed rule.

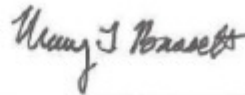
Sincerely,



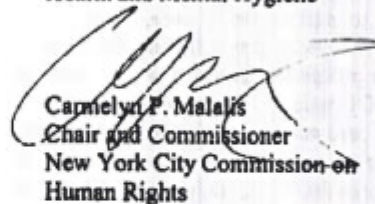
Steven Banks
Commissioner
New York City Department of
Social Services



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



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



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

¹ Substance Abuse and Mental Health Services Administration. Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth. HHS Publication No. (SMA) 15-4928. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015.

*Shellenberg KM, Tsui AO. Correlates of perceived and internalized stigma among abortion patients in the USA: an exploration by race and Hispanic ethnicity. *Int J Gynaecol Obstet.* 2012;118(2):60015-60019.

Case No.	Date	Initials
19-001	09/05/19	[Signature]
19-002	09/05/19	[Signature]
19-003	09/05/19	[Signature]
19-004	09/05/19	[Signature]
19-005	09/05/19	[Signature]
19-006	09/05/19	[Signature]
19-007	09/05/19	[Signature]
19-008	09/05/19	[Signature]
19-009	09/05/19	[Signature]
19-010	09/05/19	[Signature]
19-011	09/05/19	[Signature]
19-012	09/05/19	[Signature]
19-013	09/05/19	[Signature]
19-014	09/05/19	[Signature]
19-015	09/05/19	[Signature]
19-016	09/05/19	[Signature]
19-017	09/05/19	[Signature]
19-018	09/05/19	[Signature]
19-019	09/05/19	[Signature]
19-020	09/05/19	[Signature]
19-021	09/05/19	[Signature]
19-022	09/05/19	[Signature]
19-023	09/05/19	[Signature]
19-024	09/05/19	[Signature]
19-025	09/05/19	[Signature]
19-026	09/05/19	[Signature]
19-027	09/05/19	[Signature]
19-028	09/05/19	[Signature]
19-029	09/05/19	[Signature]
19-030	09/05/19	[Signature]
19-031	09/05/19	[Signature]
19-032	09/05/19	[Signature]
19-033	09/05/19	[Signature]
19-034	09/05/19	[Signature]
19-035	09/05/19	[Signature]
19-036	09/05/19	[Signature]
19-037	09/05/19	[Signature]
19-038	09/05/19	[Signature]
19-039	09/05/19	[Signature]
19-040	09/05/19	[Signature]
19-041	09/05/19	[Signature]
19-042	09/05/19	[Signature]
19-043	09/05/19	[Signature]
19-044	09/05/19	[Signature]
19-045	09/05/19	[Signature]
19-046	09/05/19	[Signature]
19-047	09/05/19	[Signature]
19-048	09/05/19	[Signature]
19-049	09/05/19	[Signature]
19-050	09/05/19	[Signature]
19-051	09/05/19	[Signature]
19-052	09/05/19	[Signature]
19-053	09/05/19	[Signature]
19-054	09/05/19	[Signature]
19-055	09/05/19	[Signature]
19-056	09/05/19	[Signature]
19-057	09/05/19	[Signature]
19-058	09/05/19	[Signature]
19-059	09/05/19	[Signature]
19-060	09/05/19	[Signature]
19-061	09/05/19	[Signature]
19-062	09/05/19	[Signature]
19-063	09/05/19	[Signature]
19-064	09/05/19	[Signature]
19-065	09/05/19	[Signature]
19-066	09/05/19	[Signature]
19-067	09/05/19	[Signature]
19-068	09/05/19	[Signature]
19-069	09/05/19	[Signature]
19-070	09/05/19	[Signature]
19-071	09/05/19	[Signature]
19-072	09/05/19	[Signature]
19-073	09/05/19	[Signature]
19-074	09/05/19	[Signature]
19-075	09/05/19	[Signature]
19-076	09/05/19	[Signature]
19-077	09/05/19	[Signature]
19-078	09/05/19	[Signature]
19-079	09/05/19	[Signature]
19-080	09/05/19	[Signature]
19-081	09/05/19	[Signature]
19-082	09/05/19	[Signature]
19-083	09/05/19	[Signature]
19-084	09/05/19	[Signature]
19-085	09/05/19	[Signature]
19-086	09/05/19	[Signature]
19-087	09/05/19	[Signature]
19-088	09/05/19	[Signature]
19-089	09/05/19	[Signature]
19-090	09/05/19	[Signature]
19-091	09/05/19	[Signature]
19-092	09/05/19	[Signature]
19-093	09/05/19	[Signature]
19-094	09/05/19	[Signature]
19-095	09/05/19	[Signature]
19-096	09/05/19	[Signature]
19-097	09/05/19	[Signature]
19-098	09/05/19	[Signature]
19-099	09/05/19	[Signature]
19-100	09/05/19	[Signature]

Exhibit 100

WASHINGTON
LEGISLATIVE OFFICE



March 27, 2018

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

Submitted electronically

Re: Proposed New 45 CFR Part 88 Regarding Refusals of Medical Care

AMERICAN CIVIL
LIBERTIES UNION
WASHINGTON
LEGISLATIVE OFFICE
915 15th STREET, NW, 6TH FL
WASHINGTON, DC 20005
T/202.544.1681
F/202.546.0738
WWW.ACLU.ORG

The American Civil Liberties Union (“ACLU”) submits these comments on the proposed rule published at 83 FR 3880 (January 26, 2018), RIN 0945-ZA03, with the title “Protecting Statutory Conscience Rights in Health Care; Delegations of Authority” (the “Proposed Rule” or “Rule”).

FAIZ SHAKIR
DIRECTOR

For nearly 100 years, the ACLU has been our nation’s guardian of liberty, working in courts, legislatures, and communities to defend and preserve the individual rights and liberties that the Constitution and the laws of the United States. With more than 2 million members, activists, and supporters, the ACLU is a nationwide organization that fights tirelessly in all 50 states, Puerto Rico, and Washington, D.C. for the principle that every individual’s rights must be protected equally under the law, regardless of race, religion, gender, sexual orientation, gender identity or expression, disability, national origin, or record of arrest or conviction.

NATIONAL OFFICE
125 BROAD STREET, 18TH FL.
NEW YORK, NY 10004-2400
T/212.549.2500

OFFICERS AND DIRECTORS
SUSAN N. HERMAN
PRESIDENT

ANTHONY D. ROMERO
EXECUTIVE DIRECTOR

ROBERT REMAR
TREASURER

In Congress and in the courts, we have long supported strong protections for religious freedom. Likewise, we have participated in nearly every critical case concerning reproductive rights to reach the Supreme Court and advocated for policies that promote access to reproductive health care. The ACLU is also a leader in the fight against discrimination on behalf of those who historically have been denied their rights, including people of color, LGBT (lesbian, gay, bisexual, and transgender) people, women, and people with disabilities. Because of its profound respect for and experience defending religious liberty, reproductive rights, and principles of non-discrimination, the ACLU is particularly well positioned to comment on the Proposed Rule. We steadfastly protect the right to religious freedom. But the right to religious freedom does not include a right to harm others as this Proposed Rule contemplates. And, indeed, when the Bush Administration adopted similar rules, the ACLU challenged them in court. *See National Family Planning & Reproductive Health*

*Association, Inc. v. Leavitt, consolidated in Case No. 3:09-cv-00054-RNC (D. Conn. 2009).*¹

The Proposed Rule grants health care providers unprecedented license to refuse to provide information and health care to patients and puts faith before patients' health. The Rule thus contravenes the core mission of the Department of Health and Human Services [the "Department"] to protect and advance the health of all. The Department's failure even to mention the impact of the rule on patients is clear evidence of its misplaced priorities. The Rule also flies in the face of the longstanding history of the Department to further our nation's health by addressing discrimination in health care, aiming instead to foster discrimination.

Tellingly, the Department justifies the Rule by citing as the "problem" cases in which patients sought remedies after being denied health care—to the detriment of their health and often for discriminatory reasons. *See* 83 FR 3888-89 & n.36. The problem, however, is not that patients want care, but that health care providers denied vital, even life-saving, medical care, discriminated, and imposed their religious doctrine to the detriment of patients' health. Tamesha Means, for example, should not have been turned away from the hospital where she sought urgent care even once, let alone three times, without even being provided with the information that her own life could be in jeopardy if she did not obtain emergency abortion care for her miscarriage.² Rebecca Chamorro should not have been required to undergo the additional stress, health risks, and cost of two surgical procedures, rather than a single one, when her doctor was ready, willing, and able to perform a standard postpartum tubal ligation.³ Evan Minton's scheduled hysterectomy should not have been canceled on the eve of that procedure, despite his doctor's willingness to proceed with that routine operation, because the hospital became aware he was transgender.⁴ These refusals, not the patients seeking justice, are the problem. Yet these are the types of refusals the Department seeks to make more commonplace with this Rule. 83 FR 3888-89 & n.36.

Moreover, if the Department is to adhere to its mission and to address discrimination, its focus should not be on expanding a purported right of institutions to refuse to provide care because of beliefs, but on eliminating the discrimination that continues to devastate communities in this country. 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.⁵ Black women, for example, are three to four times more likely than white women to die during or after childbirth.⁶ Women have long been the subject of discrimination in

¹ That lawsuit was ultimately dismissed when the Obama Administration rescinded virtually all of the regulations. *See* 74 FR 10207, 75 FR 9968, 76 FR 9968, *infra* n.16.

² *See* Health Care Denied 9-10 (May 2016), available at <https://www.aclu.org/report/report-health-care-denied?redirect=report/health-care-denied>.

³ *See id.* at 18.

⁴ *See* Verified Complaint, *Minton v. Dignity Health*, Case No. 17-558259 (Calif. Super. Ct. April 19, 2017).

⁵ *See* Skinner et al., *Mortality after Acute Myocardial Infarction in Hospitals that Disproportionately Treat African-Americans*, NAT'L INSTITUTE OF HEALTH 1 (2005),

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1626584/pdf/nihms13060.pdf>.

⁶ *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>.

health care and the resulting health disparities.⁷ And due to gender biases and disparities in research, doctors offer women less aggressive treatment, or even no treatment, for conditions such as heart disease.⁸ Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.⁹ 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 that aspect of their identity in the year before the survey.¹⁰ The Department should be working to end, not foster, discrimination in health care.¹¹

In the comments below, the ACLU details some of the specific ways in which the Proposed Rule exceeds the Department's authority and in so doing causes significant harm to patients.¹² The non-exhaustive examples of serious flaws in the Rule include:

- The Proposed Rule utterly fails to consider the harmful impact it would have on patients' access to health care.
- The Department lacks *any* legislative rule-making authority under the Church Amendments, 42 U.S.C. § 300a-7, the Coats-Snowe Amendment, 42 U.S.C. § 238n, and the Weldon Amendment, Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, Div. H, Tit. V, § 507(d) (collectively, the "Amendments"), the primary statutory authority for the Rule, and thus it cannot adopt these proposed force-of-law requirements to expand those Amendments.
- The Rule tries to expand the plain language Congress used in the Amendments and over a dozen other laws referenced by this rulemaking (collectively, the "Refusal Statutes"), proposing definitions that distort the ordinary meaning of words and otherwise impermissibly stretching these narrow provisions.
- The Rule's impact is not limited to individual health care providers; it attempts to greatly expand the Refusal Statutes to enable more institutions—e.g., hospitals,

⁷ 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).

⁸ 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).

⁹ 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.

¹⁰ 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.

¹¹ The Department's Office of Civil Rights ("OCR") has a long history of combating discrimination, protecting patient access to care, and eliminating 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.

¹² Although these ACLU comments primarily focus on examples of the Proposed Rule's flaws and harms with reference to the Church, Coats and Weldon Amendments, virtually all of the problems identified in this letter extend to the Rule's similar, unfounded extension of the over a dozen other provisions encompassed within the Rule.

clinics, and other corporate entities—to deny care, even in emergency situations, and even when individual providers at the institutions have no objection to providing the care.

- The Rule is entirely unnecessary as health care providers are already shielded by Title VII’s religion protections, and addressed by the Refusal Statutes, and there is no evidence that existing mechanisms are insufficient to ensure compliance with those Refusal Statutes.
- The Rule purports to seek a “society free from discrimination,” but repeatedly *invites expanded discrimination – through refusals of care –* against women, LGBT patients, and other members of historically-mistreated groups.
- Likewise, the Rule purports to advance “open and honest communication,” yet it *empowers providers to withhold information* from patients about their medical condition and treatment options in contravention of legal and ethical requirements and principles of informed consent.

Because the Proposed Rule harms patient health, encourages discrimination, and exceeds the Department’s rulemaking authority, it should be withdrawn. If the Department refuses to do so, it must, at a minimum, revise the Proposed Rule so that it comes into alignment with the statutory provisions it purports to implement, makes clear that it is not intended to conflict with other state and federal laws that protect patients, and mitigates the harm to patients’ health and well-being.

I. The Proposed Rule Fails Even to Mention Its Impact on Patients, While Inviting More Refusals of Care That Would Fall Disproportionately on Low-Income People and Other Marginalized Groups.

The Department’s mission is “to enhance and protect the health and well-being of all Americans. [It] fulfill[s] that mission by providing for effective health and human services and fostering advances in medicine, public health, and social services.”¹³ The Department administers more than 100 programs, which aim to “protect the health of all Americans and provide essential human services, especially for those who are least able to help themselves.”¹⁴

It is thus extraordinary that this Notice of Proposed Rulemaking (“NPRM”) is devoted solely to increasing the ability of health care entities and professionals to refuse to provide health care information and services to patients. Nowhere in the 50 pages that the NPRM spans in the Federal Register does it discuss the impact that refusals to provide information and denials of care have on patient health and well-being. In fact, patients are not even mentioned in the discussion of “affected persons and entities.” 83 FR 3904. And in the Proposed Rule’s flawed attempt at a cost-benefit analysis, the Department devotes a mere three paragraphs to the Rule’s purported effects on patient-provider communication—and none at all to the direct harms suffered by those who are denied information and care. 83 FR 3916-17.

¹³ See <https://www.hhs.gov/about/index.html>.

¹⁴ See <https://www.hhs.gov/programs/index.html>.

But this failure to address the obvious consequences of giving federally-subsidized providers *carte blanche* to decide whom to treat or not treat based on religious or moral convictions—or indeed, based on any reasoning or none at all¹⁵—does not mean the harm does not exist. Indeed, the harms would be substantial. For example, as set forth in more detail below, the Proposed Rule:

- Appears to provide immunities for health care institutions and professionals who refuse to provide complete information to patients about their condition and treatment options;
- Would result in patients being denied, or delayed in getting, health care to the extent the Rule requires health care facilities to employ people who refuse to perform core functions of their jobs;
- Purports to create new “exemptions,” that would leave patients who rely on federally-subsidized health care programs, such as Title X family planning services, unable to obtain services those programs are required by law to provide;
- Creates confusion about whether hospitals can refuse to provide, and bar its staff from providing, emergency care to pregnant women who are suffering miscarriages or otherwise need emergent abortion care; and
- Invites health care providers to discriminate against individuals based on who they are by, for example, refusing to provide otherwise available services to a patient for the sole reason that the patient is transgender.

These harms will fall most heavily on historically disadvantaged groups and those with limited economic resources. As the ACLU’s own cases and requests for assistance reflect, women, LGBT individuals, and members of other groups who continue to struggle for equality are those who most often experience refusals of care. The Proposed Rule’s unauthorized expansion of the Refusal Statutes will only exacerbate these disparities.

Likewise, people with low and moderate incomes will suffer most acutely under the Proposed Rule. The Refusal Statutes, and therefore the expansive Proposed Rule, are tied to federal funding. Individuals with limited income are more likely to rely on health care that is in some manner tied to federal funding and are therefore more likely to be subject to the refusals to provide care and information sanctioned by the Proposed Rule. Thus, for example, if a health care entity that, under the Proposed Rule, is now able to obtain a government contract to provide Title X family planning services despite its unwillingness to provide the required services, low-income individuals in the area are likely to have few, if any, other options for the care.

¹⁵ Although the NPRM highlights religious freedom and rights of conscience, a number of the Refusal Statutes – and the proposed expansions of those in the Rule – do not turn on the existence of any religious or moral justification. The Proposed Rule would empower not only those acting based on the basis of belief, but others acting, for example, out of bare animus toward a patient’s desired care or any aspect of their identity.

Not only will this result in the outright denial of care to the detriment of patients' health, it will also impose serious economic consequences that the Proposed Rule fails to take into account. For example, the denial of care can result not only in greater health care costs, but also in lost wages (and in some cases loss of employment), increased transportation costs and increased child care costs. For women, immigrant patients, and rural patients, these snowballing effects can be particularly acute. Yet, remarkably, the Proposed Rule finds no effect at all on the "disposable income or poverty of families and children" from expanding denials of health care. 83 FR 3919. Contrary to the Department's conclusions, this Rule would impose new costs on and create new pressures for many families, especially those with the least economic means.

Rather than seek to expand patient protections, the Proposed Rule appears to launch a direct attack on existing federal legal protections that prevent or remedy discrimination against patients. *See, e.g., infra* Part IV. The Rule raises equal concern with regard to its intended effect on state laws that aim to enhance patient protection and address discrimination. The Preamble devotes extensive discussion to "Recently Enacted State and Local health care laws" that have triggered some litigation by "conscientious objectors," 83 FR 3888, characterizing those disputes as part of the rationale for the Rule.¹⁶ But this rulemaking provides no clarity as to preservation of other legal protections and repeatedly evidences an intent to cut back on, for example, important equality safeguards for patients. At the very least, this will create severe confusion, creating competing and contradictory requirements, and in so doing put critical federal funding for vital care at risk. At worst, it targets vulnerable patients for increased refusals of care and the harms described above.

Because it is contrary to the very mission of the Department, attempts to license widespread denials of care and harm to patients, and fosters discrimination, the Proposed Rule should be withdrawn.

II. The Department Lacks the Authority to Promulgate the Proposed Rule.

Not only does the Rule undermine patient's health, it is unauthorized. For example, the Department does not possess *any* legislative rulemaking powers under the Church, Coats-Snowe or Weldon Amendments – the Amendments that form the bases for the bulk of the Rule – and thus it lacks the authority to promulgate this Rule with respect to those statutes.

"It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). With this Proposed Rule, the Department clearly seeks to adopt legislative rules that will impose force-of-law, substantive requirements and compliance procedures that must be followed by covered entities. But there is no authority delegated by Church, Coats-Snowe or Weldon to undertake such rulemaking. Indeed, in prior litigation, the Department itself emphasized that "[i]n the first place, it is not clear that the Weldon Amendment can be said to delegate regulatory authority to the Executive Branch at all." Br. of

¹⁶ *See also* 83 FR 3889 (seeking to "clarify" that conscience protections "supersede conflicting provisions of State law"; pointing to state requirements, for example, that insurers include abortion coverage in health plans as illustrations of "the need for greater clarity concerning the scope and operation" of federal rights of refusal).

Defs. at 35, *National Family Planning and Reproductive Health Association v. Gonzales*, 391 F. Supp. 2d 200 (D.D.C. 2005), available at 2004 WL 3633834; see also 76 FR 9971, 9975 (discussing that the Amendments do not provide for promulgation of regulations).

None of the Amendments includes, or references, *any* explicit delegation of regulatory authority. Compare, e.g., 42 U.S.C. § 2000d-1 (expressly directing all relevant federal agencies to issue “rules, regulations, or orders of general applicability” to achieve the objectives of Title VI). Nor is there any implicit delegation of legislative rulemaking authority for these provisions. As underscored by the decades that Church, Coats-Snowe and Weldon have applied without any legislative rulemaking supplementing their content, those enactments do not give the Department the power to issue force-of-law rules under them, as the Department is now – expansively – trying to do.¹⁷ For this reason alone, the Department cannot properly proceed to adopt the Proposed Rule or any similar variation of it.

III. The Rule Proposes Numerous Expansive Definitions That Defy the Meaning of the Statutory Terms and Would Fuel Confusion, Misinformation, and Denials of Care.

Even if the Department had the necessary rulemaking authority (which it does not), the Proposed Rule’s broad definition of certain terms and expansions of the Refusal Statutes’ reach would far exceed any conceivable authority. An agency cannot use rulemaking to extend the scope of a statute. See *City of Arlington, Tex. v. F.C.C.*, 569 U.S. 290, 297 (2013) (agency must stay within the bounds of the statute under which it acts). Yet that is what this Rule does, through numerous proposed “definitions,” including, among others, those proposed for “assist in the performance,” “referral or refer for,” and “discrimination.”

Indeed, it is telling that the Rule’s Preamble devotes four pages in the Federal Register to trying to justify its over-reaching definitions, but does not attempt to describe the Rule’s proposed substantive requirements at all. Instead, the Preamble claims that the substantive requirements are simply “taken from the relevant statutory language.” 83 FD 3895. But that assertion is belied by, *inter alia*, the Department’s proposed expansion and re-writing of those statutes through impermissible re-definition of numerous statutory terms and other sleights of hand. Any rule-making of this kind needs to attempt to explain not only the definitions of words, but how those definitions and the Rule’s substantive requirements come together to regulate conduct, which the Department utterly fails to do.

For example, the Department proposes to define “assist in the performance” of an abortion or sterilization to include not only assistance *in the performance* of those actual procedures—the ordinary meaning of the phrase—but also participation in any other activity

¹⁷ Although the Bush Administration promulgated similar rules in December 2008, those rules did not take full effect before their reconsideration and rescission commenced. The eventual replacement regulation, which became final in 2011 and remains in force today, consists of just two provisions describing solely that OCR is designated to receive complaints under the Amendments. The Department promulgated that rule under 5 U.S.C. § 301, the Department’s “housekeeping” authority for adopting regulations limited to the conduct of its own affairs. Section 301 does not authorize the promulgation of substantive regulatory requirements like those in the Proposed Rule. See 76 FR 9975-76. Moreover, that we here highlight the lack of regulatory rule-making authority under Section 301 and under the Amendments should not be read to imply that any such authority exists under the other Refusal Statutes referenced in this NPRM; the Proposed Rule does not specify *any* authority for legislative rulemaking.

with “an articulable connection to a procedure[.]” 83 FR 8892, 3923. Through this expanded definition, the Department explicitly aims to include activities beyond “direct involvement with a procedure” and to provide “broad protection”—despite the statutory references limited to “assist[ance] in the performance of” an abortion or sterilization procedure itself. *Id.*; *cf. e.g.*, 42 U.S.C. § 300a-7(c)(1).

This would mean, for example, that simply admitting patients to a health care facility, filing their charts, transporting them from one part of the facility to another, or even taking their temperature could conceivably be considered “assist[ing] in the performance” of an abortion or sterilization, as any of those activities could have an “articulable connection” to the procedure. As described more fully below, *see infra* Part VI, the Proposed Rule would even sanction the withholding of basic information about abortion or sterilization on the grounds that “assist[ing] in the performance” of a procedure “includes but is not limited to counseling, referral, training and other arrangements for the procedure.” 83 FR 3892, 3923.

But the term “assist in the performance” does not have the virtually limitless meaning the Department proposes ascribing to it. The Department has no basis for declaring that Congress meant anything beyond actually “assist[ing] in the performance of” the specified procedure—given that it used that phrase, 42 U.S.C. § 300a-7(c)(1). There is no basis for the Department to interpret that term to mean any activity with any connection that can merely be articulated, regardless of how attenuated the claimed connection, how distant in time, or how non-procedure-specific the activity.

Likewise, the Proposed Rule’s definition of “referral or refer for” impermissibly goes beyond the statutory language and congressional intent. The Rule declares that “referral or refer for” means “the provision of *any* information ... by any method ... pertaining to a health care service, activity, or procedure ... that could provide *any assistance* in a person obtaining, assisting, ... financing, or performing” it, where the entity (including a person) doing so “sincerely understands” the service, activity, or procedure to be a “possible outcome[.]” 83 FR 3894, 3924 (emphasis added). This expansive definition could have dire consequences for patients. For example, a hospital that prohibits its doctors from even discussing abortion as a treatment option for certain serious medical conditions could attempt to claim that the Rule protects this withholding of critical information because the hospital “sincerely understands” the provision of this information to the patient may assist the patient in obtaining an abortion.¹⁸

But by providing a green light for the refusal to provide information that patients need to make informed decisions about their medical care, the Proposed Rule not only violates basic medical ethics, but also far exceeds congressional intent. A referral, as used in common parlance and the underlying statutes, has a far more limited meaning than providing *any* information that *could* provide *any assistance whatsoever* to a person who may ultimately decide to obtain, assist, finance, or perform a given procedure sometime in the future. The meaning of “referral or refer for” in the health care context is to *direct* a patient elsewhere for care. *See* Merriam-Webster, <https://www.merriam-webster.com/dictionary/referral> (“referral” is “the process of directing or redirecting (as a medical case or a patient) to an appropriate specialist or agency for definitive

¹⁸ As explained in Part VI(B), *infra*, the Proposed Rule’s overbroad interpretation of the phrase “make arrangements for,” 83 FR 3895, compounds the problems with the unjustified definition of referral.

treatment”); Medicare.gov, *Glossary: Referral*, <https://www.medicare.gov/glossary/r.html> (defining referral as “[a] written order from your primary care doctor for you to see a specialist or get certain medical services”); HealthCare.gov, *Glossary: Referral*, <https://www.healthcare.gov/glossary/referral/> (same); Ctrs. for Medicare & Medicaid Services Website, *Glossary: Referral*, <https://www.cms.gov/apps/glossary/default.asp?Letter=R&Language> (“Generally, a referral is defined as an actual document obtained from a provider in order for the beneficiary to receive additional services.”); *id.* (a referral is a “written OK from your primary care doctor for you to see a specialist or get certain services”).

In addition, the Proposed Rule’s definition appears to include a subjective element not present in any of the referenced statutes or in the ordinary meaning of “referral”: Under the Rule, an entity’s “sincere understanding” determines whether or not a referral has occurred. 83 FR 3924; *see also* 83 FR 3894 n.46 (claiming that a “referral constitutes moral cooperation with a conscientiously objected activity”). The Proposed Rule states that it is attempting to provide “broad protection for entities unwilling to be complicit in” certain services, 83 FR 3895, but transforming “refer for” into a much looser, subjective notion of being “complicit in” is a significant departure from the actual statutory language of the Refusal Statutes and plainly exceeds the Department’s authority.

These expansive definitions are all the more troubling to the extent the Proposed Rule’s definition of “discrimination” purports to provide unlimited immunity for institutions or employees who refuse to perform essential care. The Rule apparently attempts to provide unlimited immunity for institutions that receive some federal funds to deny abortion care, to block coverage for such care, or to stop patients’ access to information, no matter what the patients’ circumstances or the mandates of state or federal law. Likewise, the definition appears aimed at providing immunity for employees who refuse to perform central parts of their job, regardless of the impact on the ability of a health care entity to provide appropriate care to its patients. This expansion of “discrimination” would apparently treat virtually any adverse action—including government enforcement of a patient non-discrimination or access-to-care law—against a health care facility or individual as *per se* discrimination. Indeed, the definition of discrimination appears designed to provide a tool to stop enforcement of state laws providing more protection of patients, particularly those seeking abortion care. But “discrimination” does not mean any negative action, and instead requires an assessment of context and justification, with the claimant showing unequal treatment on prohibited grounds under the operative circumstances.¹⁹ *See infra* Parts IV-V.

While this comment letter does not attempt to detail all of the unfounded definitional expansions included in the Proposed Rule, other examples abound. *See e.g.*, 83 FR 3893

¹⁹ The Rule should not be expanded even further by an unfounded “disparate impact” concept that has no place in implementing these narrowly-targeted Refusal Statutes. While the Proposed Rule does not explain its proffered “disparate impact” concept, such a concept might empower the Department, for example, to forbid *any* enforcement of a general state government policy that is contrary to a particular institution’s religious dictates, or of a neutral employment rule that is contrary to some employees’ beliefs (rather than accepting that an employer’s obligations are at most reasonable accommodation of particular employees, if possible without undue hardship, *see infra* Part IV).

(proposing to define “health care entity” to include those employers and others who sponsor health plans but “are *not* primarily in the business of health care”) (emphasis added), 3894 (proposing to define “workforce” to include volunteers and contractors, despite those individuals’ independence from any corporate or public entities employing workers), 3894 (erroneously expanding definition of “health service program”), 3923-24.²⁰ The Department has no authority to expand the Refusal Statutes in this way, and these irrational definitions that are contrary to both the Refusal Statutes and congressional intent should be explicitly rejected.

IV. The Proposed Rule Threatens to Upend the Appropriate Balance Struck by Long-Standing Federal Laws.

A. The Proposed Rule Ignores the Careful Balance Title VII Strikes Between Protecting Employees’ Religious Beliefs and Ensuring Patients Can Obtain the Health Care They Need.

The Proposed Rule is not only unauthorized and harmful to patients, it is also unnecessary as federal law already amply protects individuals’ religious freedom—freedom the ACLU has fought to protect throughout its nearly 100-year history.

For example, for more than four decades, Title VII has required employers to make reasonable accommodations for current and prospective employers’ religious beliefs so long as doing so does not pose an “undue hardship” to the employer. 42 U.S.C. §§ 2000e(j), 2000e-2(a).²¹ An “undue hardship” occurs under Title VII when the accommodation poses a “more than *de minimis* cost” or burden on the employer’s business. *Trans World Airlines, Inc. v. Hardison*, 432 U.S. 63, 84 (1977); EEOC Guidelines, 29 C.F.R. § 1605.2(e)(1). Thus, Title VII—while protecting employees’ freedom of religion—establishes an essential balance. It recognizes that an employer cannot subject an employee to less favorable treatment solely because of that employee’s religion and that generally an employer must accommodate an employee’s religious practices. However, it does not require accommodation when the employee objects to performing core job functions, particularly to the extent those objections harm patients, depart from standards of care, or otherwise constitute an undue hardship. *Id.*; *see also Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703 (1985). This careful balance between the needs of employees, patients, and employers is critical to ensuring that health care employers are able to provide quality health care.

Despite this long-standing balance, nowhere does the Proposed Rule mention these basic legal standards or the need to ensure patient needs are met. Instead, by presenting a seemingly unqualified definition of what constitutes “discrimination,” 83 FR 3923-24, the Department

²⁰ Moreover, the Proposed Rule not only re-defines words and phrases from the Refusal Statutes, but also adds words. For example, Section 1303 of the Patient Protection and Affordable Care Act (“ACA”), 42 U.S.C. § 18023(b)(1)(A)(i), refers to “abortion services”; the Proposed Rule expands that to “abortion or abortion-related services,” without defining what that added term – found nowhere in the statute – purports to cover. 83 FR 3926; *see also, e.g.*, 83 FR 3924 (defining “health program or activity” without any apparent use of phrase in a Refusal Statute though it is used to protect patients in Section 1557 of the ACA).

²¹ For purposes of Title VII, religion includes not only theistic beliefs, but also non-theistic “moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views.” Equal Employment Opportunity Commission (“EEOC”) Guidelines, 29 C.F.R. § 1605.1.

appears to attempt to provide complete immunity for religious refusals in the workplace, no matter how significantly those refusals undermine patient care, informed consent, or the essential work of health care institutions. Indeed, the Rule is explicit in seeking an unlimited ability to “be[] free not to act contrary to one’s beliefs,” regardless of the harm it causes others. 83 FR 3892. This definition thus raises real concerns that the Proposed Rule could be invoked by employees or job applicants who refuse to perform core elements of the job. For example, job applicants may attempt to claim that a family planning provider is required to hire them as pregnancy options counselors even though they refuse to provide any information about the option of abortion and even where the provision of such information is required by the provider’s federal funding.

However, neither the Refusals Statutes, nor any other federal law, permits such an unprecedented re-definition of “discrimination.” When Congress prohibited discrimination in certain Refusal Statutes, it did not *sub silentio* create an absolute right to a job even if the employee refuses to perform essential job functions, as that has never been the meaning, legal or otherwise, of “discrimination.” *See, e.g., McDonnell Douglas Corp. v. Green*, 411 U.S. 793, 802 (1973) (employment discrimination claim requires proof that employee was qualified for the position, and employer may articulate a legitimate, non-discriminatory job-related reason to defeat such a claim). Such an unfounded definitional shift for “discrimination” improperly expands narrow congressional enactments and attempts to reinterpret federal laws, all long construed to be harmonious, to instead be conflicting and contradictory. It turns the Department’s mission on its head. If the Department does not withdraw the entire Rule, it should explicitly limit its reach and attempt to clarify how Title VII’s balance can continue to have full force and effect in the workplace.

B. Rather than Ensuring Patients Can Get Care in an Emergency, the Proposed Rule Describes the Obligation to Provide Critical Care as Part of the “Problem.”

The Proposed Rule puts patients at risk by ignoring the federal Emergency Medical Treatment and Labor Act (“EMTALA”) and hospitals’ obligations to care for patients in an emergency. As Congress has recognized, a refusal to treat patients facing an emergency puts their health and, in some cases, their lives at serious risk. Through EMTALA, Congress has required hospitals with an emergency room to provide stabilizing treatment to any individual experiencing an emergency medical condition or to provide a medically beneficial transfer. 42 U.S.C. § 1395dd(a)-(c).

The Refusal Statutes do not override the requirements of EMTALA or similar state laws that require health care providers to provide abortion care to a patient facing an emergency. *See, e.g., California v. U.S.*, Civ. No. 05-00328, 2008 WL 744840, at *4 (N.D. Cal. March 18, 2008) (rejecting notion “[t]hat enforcing [a state law requiring emergency departments to provide emergency care] or the EMTALA to require medical treatment for emergency medical conditions would be considered ‘discrimination’ under the Weldon Amendment”). Indeed, after a challenge to the Weldon Amendment was filed on the ground that it could inhibit the enforcement of statutes requiring hospitals to provide emergency abortion care, Representative

Weldon emphasized that his amendment did not disturb EMTALA's requirement that critical-care facilities provide appropriate treatment to women in need of emergency abortions.²²

It is particularly troubling, therefore, to have the Department include the long-standing legal and ethical obligation to provide emergency care to patients in the Rule's Preamble as *justification* for expanding the Refusal Statutes – in other words, as justification to *relieve* hospitals or hospital personnel of any obligation, for example, to perform an emergency abortion when a patient is in the midst of a miscarriage, or even to “refer” a patient whose health is deteriorating for an emergency abortion. 83 FR 3888, 3894. But the ethical imperative is the opposite: “In an emergency in which referral is not possible or might negatively affect a patient's physical or mental health, providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections.” 83 FR 3888 (quoting American Congress of Obstetricians and Gynecologists (“ACOG”) ethics opinion and describing it as part of the problem the Proposed rule is meant to address).

Tragically, such concerns are far from hypothetical. As noted above, Tamesha Means was turned away from critical care three times, exposing her to serious risk and putting her life in jeopardy, and in the midst of being discharged the third time, was finally helped only when she started to deliver. Another miscarrying patient collapsed at home and almost bled to death after being turned away three different times from the only hospital in her community which refused to provide her the emergency abortion she needed.²³ Refusals such as these disproportionately affect women of color who are more likely than other women to receive their care at Catholic hospitals, which follow directives that can keep providers from following standards of care and governing law.²⁴

The Proposed Rule suggests that hospitals that fail to provide patients like these with appropriate emergency care should be given a free pass. Any such license to refuse patients emergency treatment, including emergency abortions, however, would not only violate EMTALA, but also the legal, professional, and ethical principles governing access to health care in this country. For that reason, if not withdrawn in its entirety, the Proposed Rule should, as one of many necessary limitations, clarify that it does not disturb health care providers' obligations to provide appropriate care in an emergency.

²² See 151 Cong. Rec. H176-02 (Jan. 25, 2005) (statement of Rep. Weldon) (“The Hyde-Weldon Amendment is simple. It prevents federal funding when courts and other government agencies force or require physicians, clinics, and hospitals and health insurers to participate in *elective* abortions.”) (emphasis added); *id.* (Weldon Amendment “ensures that in situations where a mother's life is in danger a health care provider must act to protect a mother's life”); *id.* (discussing that the Weldon Amendment does not affect a health care facility's obligations under EMTALA). Nor were the other Refusal Statutes intended to affect the provision of emergency care. See, e.g., 142 Cong. Rec. S2268-01, S2269 (March 19, 1996) (statement of Senator Coats in support of his Amendment) (“a resident needs not to have [previously] performed an abortion ... to have mastered the procedure to protect the health of the mother if necessary”); *id.* at S2270 (statement of Senator Coats) (“[T]he similarities between the procedure which [residents] are trained for, which is the D&C procedure, and the procedures for performing an abortion are essentially the same and, therefore, [residents] have the expertise necessary, as learned in those training procedures, should the occasion occur and an emergency occur to perform an abortion.”).

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 *Id.* at 12 (2018).

C. The Proposed Rule Fosters Discrimination.

The Proposed Rule also puts patients at risk by ignoring the federal Patient Protection and Affordable Care Act (“ACA”), which explicitly confers on patients the right to receive nondiscriminatory health care in any health program or activity that receives federal funding. 42 U.S.C. § 18116. Incorporating the prohibited grounds for discrimination described in other federal civil rights laws, the ACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability. *Id.* at § 18116(a).

The Refusal Statutes must be read to coexist with the nondiscrimination requirements of the ACA and similar state nondiscrimination laws. If a nondiscrimination requirement has any meaning in the healthcare context, it must mean that patients cannot be refused care simply because of their race, color, national origin, sex, age, or disability. And as courts have recognized, the prohibition on sex discrimination under the federal civil rights statutes should be interpreted to prohibit discrimination against transgender people. *See Whitaker by Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1049-50 (7th Cir. 2017) (discrimination against transgender students violates Title IX, which is the basis for the ACA’s prohibition on sex discrimination); *see also EEOC v. R.G. & G.R. Funeral Homes, Inc.*, ___ F.3d ___, 2018 WL 1177669 at *5-12 (6th Cir. Mar. 7, 2018) (Title VII); *Glenn v. Brumby*, 663 F.3d 1312, 1316-19 (11th Cir. 2011) (Title VII); *Rosa v. Park W. Bank & Tr. Co.*, 214 F.3d 213, 215-16 (1st Cir. 2000) (Equal Credit Opportunity Act); *Schwenk v. Hartford*, 204 F.3d 1187, 1201-03 (9th Cir. 2000) (Gender Motivated Violence Act).

Notwithstanding these protections, as well as explicit statutory protections from discrimination based on gender identity and sexual orientation in many states, the Proposed Rule invites providers to discriminate against LGBT patients, particularly transgender people. The Department includes as a *justification* for expanding the Refusals Statutes a California lawsuit—*Minton v. Dignity Health*—in which a transgender patient is suing under the state nondiscrimination law, alleging that he was denied care a religiously-affiliated hospital routinely provided to other patients, simply because he is transgender. 83 FR 3888-89 & n.36. The Proposed Rule thus suggests that discrimination against a patient simply because he is transgender is permissible—in violation not only of California’s nondiscrimination law, but also of the ACA. For that reason, if not withdrawn in its entirety, the Proposed Rule should, as one of many necessary limitations, clarify that it does not disturb health care providers’ obligations to provide nondiscriminatory care.

D. The Proposed Rule Creates Confusion That Threatens to Deprive Title X Clients of Services That the Underlying Statutes and Regulations Require.

Finally, the Proposed Rule threatens to undermine the Title X program, which for more than four decades has provided a safety net upon which millions of low-income, under-insured, and uninsured individuals rely each year for family planning essential to their health and the promise of equality. For example, Congress requires that all pregnancy counseling within the Title X program be neutral and “nondirective.” *See, e.g.*, Pub. L. No. 115-31 at 521. The Department’s own regulations also require that pregnant women receive “neutral, factual

information” and “referral[s] upon request” for prenatal care and delivery, adoption, and/or abortion. 42 C.F.R. § 59.5(a)(5). Yet the Proposed Rule’s unauthorized expansion of the Weldon Amendment, *see infra* Part V(C), creates confusion about whether health care entities that refuse to provide non-directive options counseling (which includes discussion of abortion) and abortion referrals may seek to claim an exemption from these requirements and therefore a right to participate in the Title X program despite their refusal to provide the services to which Title X clients are entitled. The Department cannot promulgate a rule that conflicts with federal law in this manner and if it is not withdrawn, the Department should make explicit that it does not provide an exemption to the Title X requirements.

* * *

None of the Refusal Statutes was intended or designed to disrupt the balance between existing federal laws—such as Title VII, EMTALA, Title X and also later-in-time statutes, such as Section 1557 of the ACA—or to create categorical and limitless rights to refuse to provide basic health care, referrals, and even information. Thus, even if the Department had the authority to promulgate the Proposed Rule (which it does not), the Proposed Rule is so untethered to congressional language and intent that it must be withdrawn or substantially modified.

V. The Rule Attempts Impermissibly Transform the Referenced Statutes Into Shields for Inadequate or Discriminatory Care.

The Proposed Rule not only distorts the definitions of words in the statutes, but also alters their substantive provisions in other ways to attempt to expand the ability of entities and individuals to deny care in contravention of legal and ethical requirements and to the severe detriment of patients. Some of these additional statutory expansions, are highlighted below.

A. Examples of Impermissible Church Amendment Expansions.

Subsection (b) of the Church Amendments, for example, specifies only that the receipt of Public Health Service Act funding *in and of itself* does not permit a court or other public authority to require that an individual perform or assist in the performance of abortion or sterilization, or require that an entity provide facilities or personnel for such performance. *See, e.g.*, 42 U.S.C. 300a-7(b) (“The receipt of any grant, contract or loan guarantee under the Public Health Service Act . . . by any individual does not authorize any court or any public official or other public authority to require . . . such individual to perform or assist in the performance of any sterilization procedure or abortion if [doing so] would be contrary to his religious beliefs or moral convictions.”). The Proposed Rule, however, attempts to transform that limited prohibition – that receipt of certain federal funds alone does not create an obligation to provide abortions or sterilizations – into an across-the-board shield that forbids any public entity from determining that *any* source of law requires that the entities provide these services. 83 FR 3924-25. If the Rule is not withdrawn, the Department should modify the Rule so that it does not exceed the statute.

Similarly, the Proposed Rule apparently aims to vastly expand the prohibitions contained in subsection (d) of the Church Amendments in a manner that is contrary to the legislative language, the statutory scheme, and congressional intent. Congress enacted Subsection (d) of the Church Amendment in 1974 as part of Public Law 93-348, a law that addressed biomedical and behavioral research, and appended that new Subsection (d) to the pre-existing subsections of Church from 1973, which all are codified within 42 U.S.C. § 300a-7: the “Sterilization or Abortion” section within the code subchapter that relates to “Population Research and Voluntary Family Planning Programs.”

Despite this explicit and narrow context for Subsection (d), the Proposed Rule attempts to transform this Subsection into a much more general prohibition that would apply to *any* programs or services administered by the Department, and that would assertedly prevent any entity that receives federal funding through those programs or services from requiring individuals to perform or assistance in the performance of *any* actions contrary to their religious beliefs or moral convictions. *See* 83 FR 3894, 3906, 3925. This erroneous expansion of Church (d) could prevent health care institutions from ensuring that their employees provide appropriate care and information: It would purportedly prevent taking action against members of their workforce who refuse to provide any information or care that they “sincerely understand” may have an “articulable connection” to some eventual procedure to which they object, no matter what medical ethics, their job requirements, Title VII or laws directly protecting patient access to care may require.

The ACLU is particularly concerned that the Proposed Rule’s erroneous expansion of Church (d) could be used to deny services because of the identity of the individual seeking help. To name a few of the many possibilities that could result from the Proposed Rule’s emboldening of personal-belief-based care denials:

- A nurse could deny access to reproductive services to members of same-sex or inter-racial couples, because her religious beliefs condemn them;
- A physician could refuse to provide treatment for sexually transmitted infections to unmarried individuals, because of her opposition to non-marital sex;
- Administrative employees could refuse to process referrals or insurance claims, just as health care professionals could deny care itself, because they object to recognizing transgender individuals’ identity and medical needs.

This inappropriately expanded conception of Church Subsection (d) conflicts with statutory language, the anti-discrimination protections of Section 1557 of the ACA, the requirements of EMTALA, and the balance established by Title VII, and otherwise manifestly overreaches in a number of respects. Instead, the Department should clarify that the Church Amendments are limited to what the statute provides and Congress intended.

B. Examples of Impermissible Coats-Snowe Amendment Expansions.

The Proposed Rule similarly stretches the Coats-Snowe Amendment beyond its language and Congress' clear intent. In 1996, Congress adopted the Coats-Snowe Amendment, entitled "Abortion-related-discrimination in governmental activities regarding training and licensing of physicians," in response to a decision by the Accrediting Council for Graduate Medical Education to require obstetrician-gynecologist residency programs to provide abortion training. The Proposed Rule, however, entirely omits that context.

Rather than being confined to training and licensing activities as the statute is, the Proposed Rule purports to give all manner of health care entities, including insurance companies and hospitals, a broad right to refuse to provide abortion and abortion-related care. In addition, the Rule's expansion of the terms "referral" and "make arrangements for" extends the Coats-Snowe Amendment to shield any conduct that would provide "any information ... by any method ... that could provide *any assistance* in a person obtaining, assisting, ... financing, or performing" an abortion or that "render[s] aid to anyone else reasonably likely" to make such an abortion referral. 83 FR 3894-95, 3924 (emphasis added). This expansive interpretation not only goes far beyond congressional intent and the terms of the statute, it also could have extremely detrimental effects on patient health. For example, it would apparently shield, against any state or federal government penalties, a women's health center that required any obstetrician-gynecologist practicing there who diagnosed a pregnant patient as having a serious uterine health condition to refuse even to provide her with the name of an appropriate specialist, because that person "is reasonably likely" to provide the patient with information about abortion.

Again, if the Proposed Rule is not withdrawn, it should be pared back and clarified so as to be faithful to both the statutory text and congressional intent.

C. Examples of Impermissible Weldon Amendment Expansions.

The Department attempts the same sort of improper regulatory expansion of the Weldon Amendment, which is not a permanent statutory provision but a rider that Congress has attached to the Labor, Health and Human Services and Education Appropriations Act annually since 2004. As written, the Weldon Amendment is no more than a bar on particular appropriated funds flowing to federal agencies or programs, or state or local government, if any of those government institutions discriminate on the basis that a health care entity does not provide, pay for, provide coverage of, or refer for abortion. But the Proposed Rule attempts to vastly increase the Amendment's reach in multiple ways. First, the Proposed Rule explicitly extends the reach of the Weldon Amendment beyond the appropriations act to which it is attached, by stating that it also applies to any entity that receives any other "funds through a program administered by the Secretary," which would include, for example, Medicaid. 83 FR 3925. Second, although the terms of the Amendment itself bind only federal agencies and programs and state and local governments, the Rule expands Weldon's reach to also proscribe the behavior of any person, corporation, or public or private agency that receives any of this newly enlarged category of funds. *Id.*

The Rule then provides that no one of this greatly expanded universe of parties may subject any institutional or individual health care entity²⁵ to discrimination for refusal to provide, pay for, provide coverage for, or refer for abortions. Such unauthorized expansions of limited appropriations language seem designed to encourage broad and harmful denials of care. For example, under the expanded definitions contained in the Proposed Rule, an employer, even one with no religious or moral objection to abortion, may attempt to claim that it has a right to deny its employees' insurance coverage for abortion irrespective of state law. Or a private health care network that receives Medicaid reimbursement could face employees asserting not only the ability to refuse to participate in certain abortion-related care, but also to remain in their positions without repercussions. This is not implementation of the Weldon Amendment; this is a new scheme. If the Rule is not withdrawn, the Department should modify the Rule so that it does not exceed the statute.²⁶

VI. The Proposed Rule Appears Intended to Provide a Shield for Health Care Providers Who Fail to Provide Complete Information to Patients in Violation of Both Medical Ethics and Federal Law.

The Proposed Rule also appears to allow providers to let their own personal preferences distort provider-patient communications and deprive patients of critical health care information about their condition and treatment options. The Proposed Rule's Preamble suggests the Rule will improve physician-patient communication because it will purportedly "assist patients in seeking counselors and other health-care providers who share their deepest held convictions." 83 FR 3916-17. But patients are already free to inquire about their providers' views and providers must already honor patients' own expressions of faith and decisions based on that faith. *Cf. id.* Allowing *providers* to decide what information to share—or not share—with patients, as the Rule would do, regardless of the requirements of informed consent and professional ethics would gravely harm trust and open communication in health care.

As the American Medical Association's Code of Medical Ethics ("AMA Code") explains, the relationship between patient and physician "gives rise to physicians' ethical responsibility to place patients' welfare about the physician's own self-interest[.]" AMA Code § 1.1.1. Even in instances where a provider opposes a particular course of action based on belief, the AMA states that the provider must "[u]phold standards of informed consent and inform the patient about all relevant options for treatment, including options to which the physician morally objects." *Id.* § 1.1.7(e). Similarly, ACOG emphasizes that "the primary duty" is to the patient, and that without exception "health care providers must impart accurate and unbiased information so that patients can make informed decisions about their health care." ACOG Committee Opinion No. 385, Recommendations 1-2 (Nov. 2007) (Reaffirmed 2016). Therefore, under well-established principles of informed consent and medical ethics, health care providers must provide patients with all of the information they need to make their own decisions; providers

²⁵ Although the Weldon Amendment itself defines "health care entity" to include individual health care professionals or "any other kind of health care facility, organization or plan," the Proposed Rule's definitions, as discussed above, try to further extend "health care entity" to also encompass companies or associations whose primary purpose is *not* health care, but who happen to sponsor a health care plan. This appears to reach employers.

²⁶ Moreover, for any promulgated Rule, the Department must explain its practical operation in detail, so that any affected public or private actors can ascertain the Department's meaning.

may not allow their own religious or moral beliefs to dictate whether patients receive full information about their condition, the risks and benefits of any procedure or treatment, and any available alternatives.

By erroneously expanding the meaning of “assist in the performance of,” “refer for” and “make arrangements for,” as described above, however, the Proposed Rule purports to allow health care providers to refuse to provide basic information to patients in ways that were never contemplated by the underlying statutes. As described above, these broad definitions may be used to immunize the denial of basic information about a patient’s condition as well as her treatment options. Protecting health care professionals when they withhold this vital information from patients violates fundamental legal and ethical principles, deprives patients of the ability to make informed decisions and leads to negligent care. If the Department moves forward with the Proposed Rule, it should modify it to make clear that it does not subvert basic principles of medical ethics and does not protect withholding information from a patient about her condition or treatment options.

VII. The Rule Would Violate the Establishment Clause Because It Authorizes Health Care Providers to Impose their Faith on their Patients, to the Detriment of Patient Health.

The Proposed Rule imposes the significant harms on patients identified above in service of institutional and individual religious objectors. It purports to mandate that their religious choices take precedence over the health care needs of patients. But the First Amendment forbids government action that favors the free exercise of religion to the point of forcing unwilling third parties to bear the burdens and costs of someone else’s faith. As the Supreme Court has emphasized, “[t]he principle that government may accommodate the free exercise of religion does not supersede the fundamental limitation imposed by the Establishment Clause.” *Lee v. Weisman*, 505 U.S. 577, 587 (1992); *accord Bd. of Educ. of Kiryas Joel Village School Dist. v. Grumet*, 512 U.S. 687, 706 (1994) (“accommodation is not a principle without limits”).

Because the Rule attempts to license serious patient harms in the name of shielding others’ religious conduct, it is incompatible with our longstanding constitutional commitment to separation of church and state. *See Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 708-10 (1985) (rejecting, as Establishment Clause violation, law that freed religious workers from Sabbath duties, because the law imposed substantial harms on other employees); *see also Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 14, 18 n.8 (1989) (plurality opinion) (invalidating sales tax exemption for religious periodicals, in part because the exemption “burden[ed] nonbeneficiaries markedly” by increasing their tax bills). The Department should withdraw the Rule to avoid its violation of the Establishment Clause.

VIII. The Proposed Enforcement Scheme Is Excessive and Fails to Adequately Protect the Due Process and Other Rights of Grantees.

As explained above, the Refusal Statutes carve out specific, narrow exemptions that are only relevant and applicable to certain entities and individuals in certain circumstances. Even with its unfounded expansion of the referenced Refusal Statutes, the Department forecasts only

10-50 complaint investigations or compliance reviews arising under the Refusal Statutes each year, all concerning objections to providing certain health care. 83 FR 3915, 3922. As such, these statutes are quite unlike the various provisions of the Civil Rights Act of 1964, or other civil rights or anti-discrimination statutes that provide broad protection against discrimination to the public or across a wide range of society. Despite these differences, the Proposed Rule claims to model its compliance and enforcement mechanisms on those broad “civil rights laws, such as Title VI and Section 504 of the Rehabilitation Act.” 83 FR 3896, 3898. Yet, the Rule’s enforcement provisions exceed the ones in place for civil rights laws and, notably, this proposed rulemaking does not anywhere reference basic constitutional limits or specify important due process protections against overzealous enforcement. Taken together, these provisions are ripe for abuse.

The following provisions, which are not an exhaustive list of the serious enforcement scheme issues, appear particularly problematic:

- Funded entities must disclose any complaints or compliance reviews under the Refusal Statutes or Rule from the last five years in any funding application or renewal request, even if the complaint did not warrant an investigation or the investigation or review closed with no finding of any violation, 83 FR 3930;
- The Rule permits onerous remedies for a “failure or threatened failure to comply,” including withholding or terminating funding or referral to the Attorney General for “enforcement in federal court or otherwise” without waiting for any attempts at voluntary compliance or resolution through informal means, 83 FR 8330-31;
- The Rule allows the Department to employ the full array of punishments against funding recipients for infractions by sub-recipients, no matter how independent those sub-recipients’ actions and no matter how vigorous the recipients’ compliance efforts,²⁷
- The Rule creates violations for failure to satisfy *any* information requests, and grants access to “complete records,” providing especially expansive access with more stringent enforcement than in the Department’s Title VI regulations, without any reference to the Fourth Amendment protections developed under Title VI and other similar laws, 83 FR 3829-30; and
- The Rule’s enforcement scheme also appears to lack the robust administrative review process, including proceedings before a hearing officer and required findings on the

²⁷ As proposed subsection 88.6(a) provides, if a sub-recipient violation is found, the recipient “from whom the sub-recipient received funds shall be subject to the imposition of funding restrictions and other appropriate remedies available under this part.” 83 FR 3930. This language lacks clarity as to whether imposing a penalty is mandatory or an option, but regardless, not every violation by a sub-recipient should open the recipient to the possibility of sanctions. Moreover, fund termination under the Proposed Rule does not appear to be restricted by the “pinpointing” concept that applies under Title VI, which ensures against vindictive, broad funding terminations and excessive harms to program beneficiaries. Neither this proposed subsection nor the other new enforcement provisions should be added to Part 88, but if they are, subsection 88.6(a) should, like the Proposed Rule’s other unfounded enforcement expansions, be clarified and much more strictly limited.

record, that must precede any suspension or termination of federal funding under, for example, Title VI's enforcement regulations. *See* 45 C.F.R. Part 81. If the Rule is not withdrawn, the Department should make clear that those same rigorous protections apply here.

In addition, while claiming such vast, unauthorized enforcement powers, the Department also repeatedly states that it proposes to uphold “the maximum protection” for the rights of conscience and “the broadest prohibition on” actions against any providers acting to follow their own beliefs. 83 FR 3899, 3931. This combination of a pre-ordained inclination in favor of refusers and excessive enforcement powers further threatens to undermine federal health programs by harming funding recipients who are serving patients well.

If the Rule is not withdrawn, it should be modified in accordance with these comments to ensure that providers of health care are not subjected to unduly broad inquiries or investigations, unfairly penalized, or deprived of due process, all to the detriment of focusing on care for their patients.

IX. The Department Has Not Shown the Need for Expanded Enforcement Authority and Requirements, Uses Faulty Regulatory Impact Analyses, and Proposes a Rule That Will Only Add Compliance Burdens and Significant Costs to Health Care.

Finally, the Department itself estimates hundreds of millions of dollars in cost, almost all imposed on entities providing health care, to undertake the elaborate compliance and enforcement actions the Rule contemplates. But the Proposed Rule's regulatory impact analysis severely underestimates the cost and other burdens it would impose. At virtually every step of its purported tallying of costs, the Department grossly underestimates the time that a covered institution's lawyers, management and employees will have to spend to attempt to understand the Rule, interpret its interplay with other legal and ethical requirements, train staff, modify manuals and procedures, certify and assure compliance, and monitor the institution's actions on an ongoing basis. For example, the Rule considers a single hour by a single lawyer enough for covered entities to “familiarize themselves with the content of the proposed rule and its requirements.” 83 FR 3912. It allocates 10 minutes per Refusal Statute, for the roughly two dozen laws referenced, for an entity to execute the assurance and certification of compliance—thus allocating no time for actually reviewing an entity's records or operations in order to do so. 83 FR 3913. Similarly, the impact analysis mentions the time necessary to disclose investigations or compliance reviews, but not the much more significant amount of time needed to respond to and cooperate in those processes. Moreover, the Department does not factor into cost *at all* the cost to the institution when employees refuse to perform care or provide information, or the costs to the refused patients, who must seek help elsewhere and suffer harms to their health.

In estimating benefits, the analysis does not demonstrate barriers to entry for health professionals, or exits from the health profession that are occurring, nor does it substantiate the contention that the medical field does not already include professionals with a wide diversity of religious and other beliefs. As discussed above, it claims benefits to provider-patient

communication and relationships that are non-existent. The Proposed Rule offers no evidence that either greater protection for refusals or expanded enforcement mechanisms are needed.

The Department's prior rulemaking, which emphasized outreach and enforcement, remains in effect and makes clear that OCR has sufficient enforcement authority, consistent with the specific governing statutes, to address any meritorious complaints or other violations. 45 C.F.R. Part 88; 76 FR 9968. In fact, the Department itself estimates that, even with adoption of the Proposed Rule, it would initiate only 10-50 OCR investigations or compliance reviews per year. Since 2008, the number of Refusal Statute complaints per year has averaged 1.25, with 34 complaints filed in the recent November 2016 to mid-January 2018 period.²⁸ The Proposed Rule contemplates an enormous outlay of funds to implement an elaborate and unnecessary enforcement system that will only divert resources away from enforcing patients' civil rights protections and the provision of high-quality health care to those who need it most.

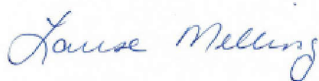
Thus, the Rule's analysis of economic impacts, including under Executive Orders 12866 and 13563, is seriously flawed and fails to demonstrate that any benefits of the Proposed Rule justify its enormous costs, many of which go unacknowledged. In addition, the Secretary proposes to falsely "certify that this rule will not result in a significant impact on a substantial number of small entities." 83 FR 3918. Small health care entities will have to bear the same regulatory analysis and ongoing compliance costs as larger entities, will face the same loss of employee time and effort from religious and other refusals, and yet have fewer resources and other employees to fall back on. While some small entities may be relieved of routinely certifying their compliance in writing, that compliance is still required – and the compliance itself imposes the much more significant cost and interference with its operations. Similarly, the Secretary erroneously "proposes to certify that this proposed rule ... will not negatively affect family well-being." 83 FR 3919, when expanded refusals of medical information and health care by federally funded providers would significantly affect the stability, disposable income, and well-being of low-income families.

The Rule's regulatory impact analyses utterly fail to support its adoption. This expansive rulemaking exceeds any statutory authority and overwhelms any need, and would leave health care institutions, patients, and their families suffering.

* * *

For all these reasons, the Department should withdraw the Proposed Rule.

Sincerely,



Louise Melling
Deputy Legal Director



Faiz Shakir
National Political Director

²⁸ For context, in FY 2017, OCR received a total of 30,166 complaints under all of the federal statutes it enforces.

Exhibit 101

GREATER NEW YORK HOSPITAL ASSOCIATION

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

March 27, 2018

Via Electronic Mail

<http://www.regulations.gov>

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

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

Dear Mr. Severino:

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

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

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



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



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

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

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

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

As set forth in the 2013 edition of *The Hastings Center Guidelines for Decisions on Life-Sustaining Treatment and Care Near the End of Life* (*The Hastings Center Guidelines*), a widely used and cited source of guidance in health care settings, health care providers have a fundamental "duty of care" to patients. This duty prohibits them from "abandoning patients and requires them to meet standards of care and honor patients' rights."^[2] Policies in hospitals and other health care institutions support ethical practice by reflecting the duty of care, which is also reflected in a range of legal and regulatory obligations, e.g., the Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S.C. § 1395dd, and New York State Education Law § 6530 (30) (defining patient abandonment as a form of professional misconduct for physicians and other licensed professionals).

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

The *Hastings Center Guidelines* recommend that health care institutions "should aim to accommodate [providers'] requests to withdraw from a case on religious or other moral grounds without compromising standards of professional care and the rights of patients." The accommodation process should also hold the provider responsible "for maintaining his or her duty of care by assisting in the orderly transfer of the patient to another professional."^[3] This appropriately balances the rights of patients and the rights of providers.

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

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

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

^[3] *Ibid.*

GNYHA

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

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

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

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

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

Comments on Specific Regulatory Proposals

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

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

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

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

^[7] "EEOC Compliance Manual, Religious Discrimination, Section 12-I(A)(1)–Definition of Religion," (July 22, 2008). <https://www.eeoc.gov/policy/docs/religion.html>, (accessed March 26, 2018).

GNYHA

“Assist in the Performance”

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

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

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

“Discriminate” or “Discrimination”

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

Compliance Requirements

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

GNYHA

Enforcement Authority

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

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

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

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

Thank you for taking our comments into consideration.

Very Truly Yours,



Kenneth E. Raske
President

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

Exhibit 102



March 27, 2018

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

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

Dear Mr. Severino:

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

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

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

OCR Enforcement of Provider Conscience Rights:

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



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

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

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

Conflict with Existing Provider Licensure and Standards of Care:

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

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



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

Increase of Unnecessary Regulatory Burdens:

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

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

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

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Anuj K. Goel', written in a cursive style.

Anuj K. Goel, Esq.
Vice President, Legal and Regulatory Affairs

Exhibit 103



2001 Medical Parkway
Annapolis, Md. 21401
443-481-1000
askAAMC.org

March 27, 2018

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

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

To whom it may concern:

I am writing on behalf of Anne Arundel Medical Center (AAMC) in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26. AAMC is a health system based in Annapolis, Maryland. Our health system includes Maryland's third busiest hospital, five outpatient pavilions, a 40-bed substance use and mental health treatment facility, and a medical group with more than 55 locations throughout our service area. Last fiscal year (FY 2017), AAMC saw 26,300 inpatient admissions and did more than 920,000 office visits. We have more than 4,700 employees and 1,100 members of Medical Staff.

Notably, AAMC was recently recognized by the Human Rights Campaign's Healthcare Equality Index as a "2018 LGBTQ Healthcare Equality Top Performer." We are proud that AAMC fosters a culture and environment that is welcoming, fair, and open to all patients, regardless of sexual orientation or gender identity.

Providing quality, consistent patient care is a priority for AAMC. Both federal and state laws already protect individual health care employees from discrimination on the basis of their religious beliefs. These protections are meaningful and familiar to health care providers that have navigated these personnel obligations alongside our commitment to providing seamless, respectful healthcare to patients. The proposed regulation creates a complex, burdensome notice and reporting process for organizations and hospitals that is not only unnecessary, but also threatens to undermine the continuity of patient care at our facility.

These are our concerns:

1. The proposed regulation attempts to inappropriately broaden religious exemptions in a way that would deny patients medically necessary or lifesaving care.

Hospitals and healthcare organizations are in the business of providing healthcare services and information to our patients and communities. The broad and undefined nature of the proposed regulation prioritizes individual providers' beliefs 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 healthcare providers without standards and structures to guide the provision of necessary care to the most vulnerable populations, especially lesbian, gay, bisexual, and transgender (LGBT) people and women.

The scope of the regulation and the health care workers it applies to may make it impossible for some providers to offer certain treatments or to see certain patients. The proposed regulation purports to extend the interpretation of existing statutory exemptions far beyond the current standards. Under the proposed regulation a provider could be seen as empowered to refuse to provide any health care service or information for a religious or moral reason – capturing 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.

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

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

3. The proposed regulation lacks safeguards to ensure patients would receive emergency care as required by federal law (EMTALA) and ethical standards.

The proposed regulation is dangerously silent in regards to ensuring patient wellbeing. The lack of consideration of patients' rights is evidenced by the fact that the proposed regulation 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 regulation also fails to address potential conflicts with emergency care requirements. Under the Emergency Medical Treatment and Active Labor Act (EMTALA), a hospital receiving government funds and providing emergency services is required also to provide medical screening and stabilizing treatment to a patient who has an emergency medical condition (including severe pain or labor). 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.

AAMC's EMTALA policy states, "All patients to whom this Policy applies shall receive an initial screening examination by Qualified Medical Personnel and appropriate treatment within the capabilities of Anne Arundel Medical Center without regard to age, race, color, religion, national origin, sex, sexual orientation, ability to pay, payer, physical or mental condition or handicap." Similar language exists in other AAMC policies, including our Patient Rights and discrimination policies.

Conclusion

Simply put, this proposed regulation is bad policy and will hurt our patients and communities. 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. The sweeping exemption and its undefined boundaries of the proposed regulation will have a chilling effect on the provision of life saving and medically necessary healthcare.

Sincerely,



Maulik Joshi, DrPH
Executive Vice President, Integrated Care Delivery and Chief Operating Officer
Anne Arundel Medical Center
2000 Medical Parkway
Annapolis, MD 21401

Exhibit 104

THE DISABILITY COALITION

A Coalition of Persons with Disabilities, Family Members, and Advocates

In Santa Fe:
P.O. Box 8251
Santa Fe, New Mexico 87504-8251
Telephone: (505) 983-9637

In Albuquerque:
3916 Juan Tabo Boulevard, NE
Albuquerque, NM 87111
Telephone: (505) 256-3100

Reply to: Santa Fe office

March 27, 2018

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

Re: Department of Health and Human Services, Office for Civil Rights RIN 0945–
ZA03, Proposed Regulation on “Protecting Statutory Conscience Rights in Health
Care”, Docket No. HHS-OCR-2018-0002

The Disability Coalition of New Mexico is a broad coalition of persons with disabilities, family members and advocates for the rights of people with disabilities of all kinds, including physical, mental, developmental, intellectual, and sensory. We submit these comments in opposition to the proposed rule on “Protecting Statutory Conscience Rights in Health Care” (“the Proposed Rule”) published in the Federal Register by the Department of Health and Human Services (DHHS) on January 26, 2018. 83 Fed.Reg. 3880.

Our central concern is that the Proposed Rule will allow or even promote discrimination specifically on the basis of disability. However, we note that persons with disabilities would also be subject to increased discrimination on non-disability-specific bases that they share with other individuals, such as discrimination related to reproductive health services or end-of-life care, or that based on sexual orientation or gender identity.

People with disabilities already face significant barriers to obtaining the health care they need, in the form of such obstacles as inaccessible medical offices and equipment, providers who do not understand or address the needs of persons living with disabilities, or those who do not value the lives of individuals with disabilities to the same degree as those of the “able-bodied”. The Proposed Rule would compound those problems by giving license to an extremely broad range of people involved – however tangentially – in the provision of health care services to impose

their individual beliefs on patients, to the extent of entirely depriving them of access to necessary services.

Refusals to provide care are often based on subjective beliefs about the quality of life that a person with a disability experiences – or will experience if allowed to live. For example, life-saving care may be denied to a newborn because treating providers believe that the child's quality of life as an individual with a disability is not worth saving. Or care may be withheld from someone who has been severely injured in an automobile accident based on the belief that his quality of life going forward does not merit providing life-saving services. Or a person with an intellectual disability may be denied services based on a belief that the person does not deserve the same access to services that a person with "normal" functional capacity would receive. The Proposed Rule would give free rein to providers to impose these beliefs on their patients, exacerbating the already difficult situation that people with disabilities face in obtaining health care services.

Health care providers already enjoy ample protection from being forced to participate in services that violate their religious beliefs. The Proposed Rule would constitute an enormous broadening of those protections, to the detriment of patients in need of care.

1. The Proposed Rule would allow any person's individual belief to be the basis of an exemption from providing needed care to a patient, regardless of whether the belief is based on religious precepts.

2. The exemption would extend well beyond clinicians directly involved in the provision of health care services, and allow anyone with any "articulable connection" to service provision to refuse participation. 83 Fed.Reg. at 3892 (preamble) and 3923 (proposed 45 CFR §88.2). For example, a hospital administrator could refuse to process paperwork to admit a patient for a procedure disfavored by that employee, a cafeteria worker could refuse to bring a meal to a patient receiving services the worker does not agree with, or a technician could refuse to prepare equipment to be used in a procedure.

3. The "health care entities" protected under the Proposed Rule would include an extremely broad range of organizations beyond those directly engaged in the provision of health care services. The proposed definition expressly includes, for example, research organizations, insurance plans, and "plan sponsor[s]" such as employers, and goes on to state that the proposed list is intended to be merely illustrative and is not exhaustive. 83 Fed.Reg. at p. 3893 (preamble) and 3924 (proposed 45 CFR §88.2). The extent to which entities or individuals with only the most tangential tie to the care would be permitted to block provision of that care is breath-taking.

4. A provider refusing to participate would be under no obligation to give the patient information on or referral to alternate sources of care that would enable the individual to obtain needed services, or to facilitate the patient's transfer to such a provider. Withholding such information from a patient is a gross violation of the trust relationship that should exist between provider and patient and could lead to serious harm to a patient who is thereby prevented from accessing needed care from an alternative source after a "conscience-based" refusal.

In addition to its extremely broad scope, we have many other concerns about the Proposed Rule, including the following:

1. The Proposed Rule would improperly give the religious, moral or ethical beliefs of health care providers (or other individuals distantly associated with the provision of care) primacy over those of the patient. The Proposed Rule goes well beyond protecting the religious and moral beliefs of health care providers and allows those providers (and others with even a tenuous connection to provision of services) to impose their beliefs on their patients and other third parties.

2. The Proposed Rule would improperly give the religious, moral or ethical beliefs of providers primacy over medical standards of care. All patients have the right to expect that they will be treated in accordance with such generally accepted standards and should not be deprived of that appropriate treatment based on individual provider beliefs.

3. The Proposed Rule would protect the rights of providers to refuse to provide care, but does nothing to protect providers whose consciences call on them to provide services. For example, a physician would have the right to refuse to provide abortion services, but another physician whose moral convictions called for her to provide an abortion as a necessary service for a patient would not have the same protection for her beliefs and could be subjected to retaliation, disciplinary action or outright denial of her right to act on her beliefs by providing appropriate medical care. In so doing, the Proposed Rule appears to privilege some moral convictions as worthy of protection over others that are deemed to be unworthy of such safeguards.

4. The disclosure requirements in the Proposed Rule are inadequate. While it would require health care entities to notify patients of the provider's right to refuse services, it requires no notification of the types of care or services that will be denied. This could lead to a patient unknowingly finding herself in a position where she will be denied services, to her detriment. For example, a patient may mistakenly believe that a full-service hospital offers sterilization services, only to find out that she cannot obtain a tubal ligation at the time she delivers her baby but must instead undergo a second surgical procedure at a separate facility at another time.

5. The Proposed Rule goes beyond protecting the religious and moral beliefs of providers and would constitute government authorization for discrimination.

6. The Proposed Rule would conflict with existing law and does not clarify how its provisions would interact with those other provisions.

a) The Proposed Rule would create a conflict with the Emergency Medical Treatment and Active Labor Act (EMTALA), 42 U.S.C. § 1295dd. That statute requires that a hospital must screen patients to determine the existence of an emergency condition and must provide necessary services to stabilize the individual's condition or, in appropriate cases, transfer the patient to another provider for care. The Proposed Rule appears to encourage providers to flout EMTALA by denying care, disregarding the requirements to screen and stabilize, and refusing to arrange for transfer to an appropriate provider. The Proposed Rule (including the preamble) published in the Federal Register makes neither any mention of EMTALA or any attempt to clarify the intended interaction of the Proposed Rule's provisions with statutory obligations under EMTALA.

b) Title VII of the 1964 Civil Rights Act requires reasonable accommodations for the religious beliefs or practices of employees, including those of health care entities, unless the accommodation imposes a undue burden on the entity's operations. The Proposed Rule would go well beyond such accommodations and thereby put employers in the position of operating within two different and inconsistent sets of rules. As with EMTALA, the Proposed Rule published in the Federal Register neither mentions nor addresses Title VII.

Finally, the Proposed Rule appears to authorize an unconstitutional establishment of religion. Freedom of religion, as enshrined in the U.S. Constitution, is the right to free exercise of one's own religion and is not a license to impose one's religious beliefs on others or to engage in discrimination against others based on one's own beliefs. The U.S. Supreme Court has warned that accommodation of religious beliefs may, if taken too far, become an "unlawful fostering of religion", *Corp. of Presiding Bishop v. Amos*, 483 U.S. 327, 334-35 (1987), and that religious accommodations that unduly burden others are not protected by the Constitution's Establishment Clause. See *Sherbert v. Verner*, 374 U.S. 398 (1963); see also *Burwell v. Hobby Lobby*, 573 U.S. ___, 134 S. Ct. 2751 (2014). The Proposed Rule would authorize individuals and institutions involved in the provision of health care to impose their private beliefs on others who do not share those beliefs and thus unduly burden those other persons, and is therefore unconstitutional.

We strongly urge the Department to withdraw the Proposed Rule. Thank you for your consideration of these comments.

Sincerely,

Ellen Pinnes
for The Disability Coalition
EPinnes@msn.com

Exhibit 105

March 27, 2018

The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) opposes the Department of Health and Human Services proposed rule, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, which seeks to permit discrimination by providers in all aspects of health care without adequately protecting patients from discrimination in accessing health care services. This proposed rule is not necessary to protect the rights of providers. The existing rule issued in 2011 adequately protects the conscience of providers and patients.

As a membership organization of nurses dedicated to improving and promoting the health of women and newborns and strengthening the nursing profession, AWHONN asserts that nurses have the professional responsibility to provide nonjudgmental nursing care to all patients, either directly or through appropriate and timely referrals. However, AWHONN recognizes that some nurses may have religious or moral objections to participating in certain reproductive health care services, research, or associated activities. Therefore, AWHONN supports the existing protections afforded under federal law for a nurse who refuses to assist in performing any health care procedure to which the nurse has a moral or religious objection so long as the nurse has given appropriate notice to his or her employer.

AWHONN considers access to affordable and acceptable health care services a basic human right. With regard to the nurse's role in meeting the health care needs of patients, AWHONN advocates that nurses adhere to the following principles:

- Nurses should not abandon a patient, nor should they refuse to care for someone based on personal preference, prejudice, or bias.
- Nurses have the professional responsibility to provide impartial care and help ensure patient safety in emergency situations and not withdraw care until alternate care is available, regardless of the nurses' personal beliefs.
- At the time of employment, nurses are professionally obligated to inform their employers of any values or beliefs that may interfere with essential job functions. Nurses should ideally practice in settings in which they are less likely to be asked to assist in care or procedures that conflict with their religious or moral beliefs.

By permitting providers to refuse to refer patients based on the provider's religious beliefs or moral convictions, the proposed rule carries severe consequences for patients, making it difficult for many individuals to access the care they need.

The proposed rule will undermine critical federal health programs delivered through the Title X Family Grants. The Proposed Rule would seemingly allow health care entities to receive grants and contracts under Title X, while refusing to provide key services required by those programs.¹ For instance, Congress

¹ 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*

has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling² and current regulations require that pregnant women receive “referral[s] upon request” for prenatal care and delivery, adoption, and/or pregnancy termination.³ 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.⁴ 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.⁵ 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.⁶

The Proposed Rule will carry severe consequences for providers and undermine the provider-patient relationship. AWHONN asserts that any woman’s reproductive health care decisions are best made by the informed woman in consultation with her health care provider. AWHONN believes these personal and private decisions are best made within a health care system whose providers respect the woman’s right to make her own decisions according to her personal values and preferences and to do so confidentially. Therefore, AWHONN supports and promotes a woman’s right to evidence-based, accurate, and complete information and access to the full range of reproductive health care services. AWHONN opposes legislation and policies that limit a health care provider’s ability to counsel women as to the full range of options and to provide treatment and/or referrals, if necessary.

Title VII of the Civil Rights Act of 1964 protects workers (applicants and employees) from employment discrimination based on race, color, religion, sex, national origin, or participation in certain protected activities. With respect to religious protection, Title VII applies to most U.S. employers and requires reasonable accommodation of the religious beliefs, observances, and practices of employees when requested, unless such accommodation would impose undue hardship on business operations. These protections do and should continue to apply to nurses and other health care professionals.

A nurse should retain the right to practice in his or her area of expertise following a refusal to participate in an abortion, sterilization, gender reassignment surgery, or any other procedure. This refusal should not jeopardize the nurse’s employment or subject him or her to harassment. In addition, one’s moral and ethical beliefs should not be used as criteria for employment, unless they preclude the nurse from fulfilling essential job functions. AWHONN asserts that these rights should be protected through written

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>.

² See, e.g., Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).

³ See *What Requirements Must be Met by a Family Planning Project?*, 42 C.F.R. § 59.5(a)(5) (2000).

⁴ See, e.g., Rule *supra* note 1, at 180-185.

⁵ See NFPRHA *supra* note 34.

⁶ See *id.*

institutional policies that address reasonable accommodations for the nurse and describe the institution's required terms of notice to avoid patient abandonment.

Sincerely,

Seth A. Chase, MA
Director, Government Affairs
Association of Women's Health, Obstetric & Neonatal Nurses (AWHONN)
1800 M Street NW
Suite 740 South
Washington, DC 20036

Exhibit 106



March 27, 2018

Alex Azar
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, SW.
Washington, DC 20201

Re: RIN 0945-ZA03

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

Dear Secretary Azar:

On behalf of more than 37,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the draft rule relating to protecting conscience rights in health care, as it affects our practice of emergency medicine and the patients we serve.

While we believe that enforcement of existing federal conscience protections for health care providers is important, we strongly object to this proposed rule and do not believe it should be finalized. As written, it does not reflect nor allow for our moral and legal duty as emergency physicians to treat everyone who comes through our doors. Both by law¹ and by oath, emergency physicians care for all patients seeking emergency medical treatment. Denial of emergency care or delay in providing emergency services on the basis of race, religion, sexual orientation, gender identity, ethnic background, social status, type of illness, or ability to pay, is unethical².

ACEP has specific comments on multiple sections of the proposed rule, which are found below.

Application of Proposals in Emergency Situations

As emergency physicians, we are surprised and concerned that the proposed rule does not in any way address how conscience rights of individuals and institutions interact

WASHINGTON, DC OFFICE
2121 K Street NW, Suite 325
Washington, DC 20037-1886

202-728-0610
800-320-0610
www.acep.org

BOARD OF DIRECTORS

Paul D. Kivela, MD, MBA, FACEP
President
John J. Rogers, MD, CPE, FACEP
President-Elect
Debra G. Perins, MD, FACEP
Chair of the Board
Victor E. Friedman, MD, FACEP
Vice President
Stephen H. Anderson, MD, FACEP
Secretary-Treasurer
Rebecca B. Parker, MD, FACEP
Immediate Past President
James J. Augustine, MD, FACEP
Aileen J. Haddock, MD, FACEP
Jan Mark Hirshon, MD, PhD, MPH, FACEP
Christopher S. Kang, MD, FACEP
Kevin M. Klauer, DO, EJD, FACEP
Aisha T. Liferidge, MD, FACEP
Mark S. Rosenberg, DO, MBA, FACEP
Gillian R. Schmitz, MD, FACEP

COUNCIL OFFICERS

John G. McManus, Jr, MD, MBA, FACEP
Speaker
Gary R. Katz, MD, MBA, FACEP
Vice Speaker

EXECUTIVE DIRECTOR

Dean Wilkerson, JD, MBA, CAE

¹ 42 U.S. Code § 1395dd - [Examination and treatment for emergency medical conditions and women in labor](#)

² ACEP Code of Ethics for Emergency Physicians; Approved Jan 2017;

<https://www.acep.org/clinical---practice-management/code-of-ethics-for-emergency-physicians>

with the mandated provision of emergency services. The Emergency Medical Treatment and Labor Act (EMTALA) requires clinicians to screen and stabilize patients who come to the emergency department. Such patients have every right to expect the best possible care and to receive the most appropriate treatment and information about their condition.

Patients with life-threatening injuries or illnesses may not have time to wait to be referred to another physician or other healthcare professional to treat them if the present provider has a moral or religious objection. Likewise, emergency departments operate on tight budgets and do not have the staffing capacity to be able to have additional personnel on hand 24 hours a day, 7 days a week to respond to different types of emergency situations that might arise involving patients with different backgrounds, sexual orientations, gender identities, or religious or cultural beliefs. The proposed rule seems to demand that, in order to meet EMTALA requirements, an emergency department anticipate every possible basis for a religious or moral objection, survey its employees to ascertain on which basis they might object, and staff accordingly. This is an impossible task that jeopardizes the ability to provide care, both for standard emergency room readiness and for emergency preparedness. Emergency departments serve as the safety-net in many communities, providing a place where those who are most vulnerable and those in need of the most immediate attention can receive care. By not addressing the rights and needs of patients undergoing an emergency, the legal obligations of emergency physicians, and the budget and staffing constraints that emergency departments face, this rule has the potential of undermining the critical role that emergency departments play across the country.

Definition of Referrals

Under the proposed rule, health care providers could refuse not only to perform any given health care service, but also to provide patients access to information about or referrals for such services. The Department of Health and Human Services (HHS) defines a referral broadly in the rule as “the provision of any information... by any method... pertaining to a service, activity, or procedure, including related to availability, location, training, information resources, private or public funding or financing, or direction that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity, or procedure, when the entity or health care entity making the referral sincerely understands that particular health care service, activity, or procedure to be a purpose or possible outcome of the referral.”

Such a broad definition of referral as referenced under the proposed rule’s prohibition could create unintended consequences, such as preventing patients from getting appropriate care now or even in the future. For example, this definition would allow a primary care physician with a moral or religious objection to abortion to deny referring a pregnant woman (who may not have any immediate intentions or desire for an abortion) to a particular obstetrician-gynecologist out of fear that the woman could eventually receive an abortion from that obstetrician-gynecologist, whether at some point in the future of this pregnancy or even for a future pregnancy.

Another situation where this definition could lead to an undesirable outcome for a patient is when a provider has an objection to a patient’s end-of-life wishes expressed in an advance directive. Emergency physicians often treat patients with advanced illness, and ACEP strongly believes that providers should respect the wishes of dying patients including those expressed in advance directives. Most States today allow for a conscience objection and the right to refuse to comply with a patient’s advance directive, but they all impose

an obligation to inform such patients and, more importantly, to make some level of effort to transfer the patient to another provider or facility that will comply with the patient's wishes. However, under this proposed rule, providers with a religious or moral objection to their patients' end-of-life or advanced care wishes would have no obligation to either treat these patients in accordance with their wishes or refer them to another provider who would. Unfortunately, it is unclear how such State laws would interact with or be impacted by the federal enforcement aspects of this proposed rule, were it to be finalized. What is clear however, is that if this proposed rule is finalized, the patient's wishes could be ignored and the patient ultimately loses.

In all, the proposed rule's far-reaching definition of referral will likely cause confusion about when a referral may or may not be appropriate, thereby increasing the chances that patients do not receive accurate or timely information that may be critical to their overall health and wellbeing. The proposed rule therefore threatens to fundamentally undermine the relationship between providers and patients, who will have no way of knowing which services, information, or referrals they may have been denied, or potentially whether they were even denied medically appropriate and necessary services to begin with. Additionally, given that many insurance plans such as HMOs require referrals before coverage of specialty services, the proposed rule could place patients at financial risk based on the refusal of their primary care physician to provide a referral.

The definition of referral is representative of one of the major, unacceptable flaws in the rule: it does not focus on the needs of patients or our responsibility as providers to treat them. The rule does not mention the rights of patients even once or seek comment on how patients can still be treated if providers have a moral and religious objection to their treatment. It seems to imply that these providers have no responsibility to their patients to make sure they receive the best possible care when they are unable to provide it themselves, and there is no process or guidance in place for these providers to still try to serve their patients. The lack of attention to protecting and serving patients is one of the major reasons we believe that the rule should be withdrawn.

Requirement to Submit Written Assurances and Certifications of Compliance

HHS would require certain recipients of federal funding (including hospitals that provide care to patients under Medicare Part A) to submit annual written assurances and certifications of compliance with the federal health care conscience and associated anti-discrimination laws as a condition of the terms of acceptance of the federal financial assistance or other federal funding from HHS. There are several exceptions from the proposed requirements for written assurance and certification of compliance, including physicians, physician offices, and other health care practitioners participating in Part B of the Medicare program. However, "excepted" providers could become subject to the written certification requirement if they receive HHS funds under a separate agency or program, such as a clinical trial.

ACEP finds the lack of clarity around this requirement extremely concerning, as we believe that it will pose a significant burden on health care professionals including emergency physicians.

First, the rule does not account for all the possible circumstances or arrangements that would potentially force "excepted" physicians to file certifications. For example, some emergency physicians who are participating in Medicare Part B also have joined an accountable care organization (ACO) led by a hospital where they see patients. In many cases, the ACO has entered into a contract with the Centers for Medicare

& Medicaid Services (CMS) to be part of the Medicare Shared Savings Program or a Center for Medicare & Medicaid Innovation (CMMI) ACO model. Since the ACO includes both physicians and a hospital and therefore receives payments from both Parts A and B of Medicare, it is unclear whether emergency physicians who are part of the ACO would lose their exemption status. Numerous other alternative payment models besides ACO models are operated by CMS and involve participation from both hospitals and physicians. HHS should clarify whether physicians who are part of these models would still be exempted from the certification requirement.

Second, it is unclear whether clinicians who treat Medicaid patients are exempt from the requirement. In the rule, HHS includes Medicaid in the list of examples for why some exemptions may be appropriate³, but does not actually list reimbursement from the program as one of the exceptions. Some of our members may see only patients with Medicaid, so this lack of clarity is of great concern to them.

Third, ACEP is concerned about the cost-burden that this proposal will have on the hospitals, free-standing emergency departments, and emergency physicians who are subject to the requirement. CMS estimates that the assurance and certification requirement alone could cost health care entities nearly \$1,000 initially and \$900 annually thereafter to sign documents, review policies and procedures, and update policies and procedures and conduct training. This substantial cost is on top of the cost of posting a notice, which is estimated to be \$140 per entity. Since emergency physicians by law must provide services to patients regardless of their insurance status, their total reimbursement, if any, rarely covers the full cost of providing the services. By adding more burdensome government mandates that emergency departments must cover out of their own constrained budgets, the proposed rule could potentially jeopardize the financial viability of the emergency care safety net. While we believe the proposed rule should be withdrawn because it is so problematic, in the event the rule is finalized, ACEP requests that at minimum emergency departments, and the physicians and other health care providers that furnish care within them, be exempt from the written assurances and certifications of compliance requirement.

Notice Requirement

The proposed rule requires all health entities to post a notice on their websites and in locations in their organizations where public notices are typically posted. This notice advises people about their rights and the entity's obligation to abide by federal health care conscience and associated anti-discrimination laws. The notice also provides information about how to file a complaint with the Office of Civil Rights within HHS. The rule requires entities to use a prescribed notice, found in "Appendix A" of the rule, but seeks comment on whether to permit entities to draft their own notices.

ACEP objects to this posting requirement. Beyond our concerns with the burden of having to adhere to another government-imposed mandate as discussed above, we also are troubled by the fact that the notice in no way addresses the needs of patients or our responsibilities as providers to treat them. It does not provide any information about the fundamental rights of patients to receive the most accurate information and best available treatment options for their conditions. We therefore have grave concerns about posting the notice as currently drafted.

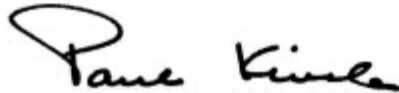
³ On pages 73- 74 of the proposed rule, HHS states "Furthermore, the Department believes that, due primarily to their generally smaller size, several of the excepted categories of recipients of Federal financial assistance or other Federal funds from the Department are less likely to encounter the types of issues sought to be addressed in this regulation. For example, State Medicaid programs are already responsible for ensuring the compliance of their sub-recipients as part of ensuring that the State Medicaid program is operated consistently with applicable nondiscrimination provisions."

It is also unclear whose exact responsibility it is to post the notice(s). Most emergency physicians are employed by a group independent from the hospital that houses the emergency department where they see patients. Therefore, would the hospital's posted notice be sufficient, or would the group that the hospital's emergency physicians are employed by need to also take on this responsibility as a separate entity, with a separate, additional posting in the emergency department?

If so, posting this notice in the emergency department could potentially be considered a violation of EMTALA. EMTALA requires providers to screen and stabilize patients who come to the emergency department. Therefore, notices that could potentially dissuade patients from receiving care that is mandated by Federal law cannot be posted publicly in the emergency department. Since the notice proposed in this rule explicitly states that providers have the right to decline treatment for patients based on their conscience, religious beliefs, or moral convictions, some patients may become concerned that they would not be treated appropriately and decide to leave before they treated—a violation of EMTALA.

In light of the above concerns, ACEP urges the Department to withdraw the proposed rule. We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at jdavis@acep.org.

Sincerely,

A handwritten signature in black ink that reads "Paul Kivela". The signature is written in a cursive, flowing style.

Paul D. Kivela, MD, MBA, FACEP
ACEP President

Exhibit 107



BOARD of DIRECTORS

Sara K. Gould
Chair

Hiroshi Motomura
Vice Chair
University of California,
Los Angeles School of Law

Inez Gonzalez
Treasurer
California State University,
Fullerton

Ghazal Tajmiri
Secretary
Blank Rome LLP

Julissa Arce
Ascend Educational Fund

Adnan Bokhari
Prosperity Now

J. Anthony Borrego
Spring Street Business Law, PC

Kevin M. Cathcart, Esq.

Muzaffar Chishti
Migration Policy Institute at New
York University School of Law

Robert J. Horsley
Fragomen, Del Rey,
Berssen, & Loewy, LLP

Cindy Mann
Manatt, Phelps & Phillips, LLP

Robert Pauw
Gibbs Houston Pauw

Bradley S. Phillips
Munger, Tolles & Olson LLP

Alexandra Suh
Koreatown Immigrant
Workers Alliance

*Organizations listed for
identification purposes only*

EXECUTIVE DIRECTOR
Marielena Hincapié

VIA ELECTRONIC SUBMISSION AT 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 209F
200 Independence Avenue SW
Washington, DC 20201

RE: RIN 0945-ZA03
Comments on DHHS Notice of Proposed Rulemaking Concerning
“Protecting Statutory Conscience Rights” in Health Care; Delegations
of Authority

Dear Director Severino:

The National Immigration Law Center (“NILC”) submits the following comments to the federal Department of Health and Human Services (“Department”) and its Office for Civil Rights (“OCR”) in opposition to the proposed regulation entitled “Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (83 Fed. Reg. 3880 (Jan. 26, 2018)).

NILC specializes in the intersection of health care and immigration laws and policies, providing technical assistance, training, and publications to government agencies, labor unions, non-profit organizations, and health care providers across the country. For over 30 years, NILC has worked to promote and ensure access to health services for low-income immigrants and their family members.

As an organization focused on defending and advancing the rights of low income immigrants, we are deeply concerned with the ways in which these regulations fail to account for the significant burden that will fall disproportionately on immigrants and all people of color. Immigrant women and immigrants who identify as Lesbian, Gay, Bisexual, Transgender, and Queer (“LGBTQ”) already experience severe health disparities and discrimination, conditions that will be exacerbated by the proposed rule, resulting in in poorer health outcomes.

LOS ANGELES (Headquarters)
3450 Wilshire Blvd. Box #108 – 62
Los Angeles, CA 90010
213 639-3900
213 639-3911 fax

WASHINGTON, DC
1121 14th Street, NW, Suite 200
Washington, DC 20005
202 216-0261
202 216-0266 fax

www.nilc.org

NILC Comments, RIN 0945-ZA03

We object to the proposal that OCR direct its limited resources toward the subject of this rule, and to the newly created “Conscience and Religious Freedom Division” 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. Immigrant communities rely on OCR to enforce regulations implementing the Title VI protection that individuals with Limited English Proficiency (LEP) are not subject to discrimination based on national origin.¹ According to the Pew Research Center 49 percent of foreign born individuals are not proficient English speakers (data from the 2010 Census and 2013-15 American Community Surveys).² Yet OCR’s enforcement of the Title VI protection is inadequate, with the result that LEP patients have been consistently shown to receive lower quality health care than English-proficient patients on various measures: understanding of treatment plans and disease processes, satisfaction, and incidence of medical errors resulting in physical harm.³ For these reasons, NILC calls on the Department and OCR to withdraw the proposed rule in its entirety.

I. The proposed regulation would divert OCR from its agency mission by shifting resources that should be used to address the rights of populations subject to acute discrimination and health disparities.

The proposed regulation would inappropriately favor the supposed protection of individuals with certain religious and moral convictions at the expense of protections against the kind of documented experiences of discrimination leading to health disparities which OCR is designed by statute to address, notably under Title VI and Section 1557 of the Patient Protection and Affordable Care Act (“ACA”).⁴ With its origin in protecting against this type of discrimination, the agency must look closely at how any changes would affect this mission before creating new regulations.

As many other commentators will likely note, discrimination based on gender identity, gender expression, gender transition, transgender status, or sex-based stereotypes is necessarily a form of sex discrimination.⁵ Numerous federal courts have found that

¹ 42 U.S.C. §2000d (stating that “no person in the United States shall, on the grounds of race, color, or national origin” be subject to discrimination in federally funded program), § 2000d-1 (authorizing the establishment of the regulations and offices for civil rights within federal agencies to enforce prohibitions on discrimination).

² Gustavo López and Kristen Bialik, *Key findings about U.S. immigrants*, PEW RESEARCH CENTER (May 3, 2017), <http://www.pewresearch.org/fact-tank/2017/05/03/key-findings-about-u-s-immigrants>.

³ Alexander R. Green, MD, MPH, and Chijioke Nze, *Language-Based Inequity in Health Care: Who Is the “Poor Historian”?*, *AMA Journal of Ethics*, March 2017, Volume 19, Number 3: 263-271.

⁴ 42 U.S.C. § 18116 (tasking HHS with enforcing a number of civil rights laws which ban discrimination on additional discriminations, such as gender).

⁵ *See, e.g., EEOC v. R.G. & G.R. Harris Funeral Homes*, No. 16-2424 (6th Cir. Mar. 7, 2018).

NILC Comments, RIN 0945-ZA03

federal sex discrimination statutes reach these forms of gender-based discrimination.⁶ In 2012, the Equal Employment Opportunity Commission (“EEOC”) likewise held that “intentional discrimination against a transgender individual because that person is transgender is, by definition, discrimination based on sex and such discrimination therefore violates Title VII.”⁷ This is a serious civil rights violation that OCR, under Section 1557 of the ACA, should be addressing.

The agency must therefore consider the impact on these populations in considering whether the proposed regulation is an appropriate action for the agency. As national advocates focused on the health of immigrants, NILC urges OCR and the Department to consider how particular sectors of the immigrant population would be harmed by this rule. Immigrants are among the most disproportionately uninsured people in the United States, a harm which is compounded by disparities in health disparities among women and LGBTQ persons. The uninsured rates for citizens (9 percent) is nearly half of lawfully present immigrants (17 percent), even though many of the latter are eligible for health coverage programs but not enrolled. In fact, according to the Kaiser Family Foundation, a larger percentage of unenrolled citizens have a factor making them ineligible for coverage or financial assistance (38 percent) than lawfully present immigrants (31 percent).⁸ This is compounded by dynamics of an individual’s race and sexual orientation: among adult women, 15.2 percent of those who identified as lesbian or gay reported being unable to obtain medical care in the last year due to cost, as compared to 9.6 percent of straight individuals.⁹ These are documented health disparities, which OCR can and should be doing more to investigate under Section 1557 of the ACA.

II. The proposed regulation would harm the health outcomes of immigrant women and women of color by allowing further divergence of access to certain services for these populations.

Among individuals with access to health care, women’s race and immigration status play a role in how they receive health services, access which would be harmed further by this rule. 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

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

⁷ *Macy v. Holder*, E.E.O.C. App. No. 0120120821, 2012 WL 1435995, *12 (Apr. 20, 2012).

⁸ *Health Coverage of Immigrants*, KAISER FAMILY FOUNDATION (Dec. 13, 2017), <https://www.kff.org/disparities-policy/fact-sheet/health-coverage-of-immigrants>.

⁹ Brian P. Ward et al., *Sexual Orientation and Health Among U.S. Adults: National Health Interview Survey*, NAT’L CTR. FOR HEALTH STATISTICS, 2013 9 (2014), <https://www.cdc.gov/nchs/data/nhsr/nhsr077.pdf>.

NILC Comments, RIN 0945-ZA03

stereotypes about black women's sexuality and reproduction.¹⁰ Young black women noted that they were shamed by providers when seeking sexual health information and contraceptive care in part, due to their age, and in some instances, sexual orientation.¹¹ Moreover, the Centers for Disease Control and Prevention reports that black mothers experience maternal mortality at three times the rate of whites.¹²

New research also shows that women of color in many states disproportionately receive their care at Catholic hospitals.¹³ These hospitals as well as many Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs), which provide guidance on wide range of hospital matters, including reproductive health care. In practice, the ERDs prohibit the provision of emergency contraception, sterilization, abortion, fertility services, and some treatments for ectopic pregnancies. Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals and as a result, women were delayed care or transferred to other facilities, risking their health.¹⁴ The proposed rule will give health care providers, such as Catholic hospitals, a license to opt out of evidence-based care that the medical community endorses. If this rule were to be implemented, more women, particularly women of color, will be put in situations where they will have to decide between receiving compromised care or seeking another provider to receive quality, comprehensive reproductive health services. For many, this choice does not exist.

This problem is particularly acute for immigrant, Latina women and their families who often face cultural and linguistic barriers to care, especially in rural areas.¹⁵ These women often lack access to transportation and may have to travel great distances to get the care

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

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

¹² Centers for Disease Control and Prevention, Trends in Pregnancy-Related Deaths, available at <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pmss.html>

¹³ Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, Pub. Rights Private Conscience Project (2018), available at <https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf>.

¹⁴ Lori R. Freedman et al., *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/>.

¹⁵ Michelle M. Casey et al., *Providing Health Care to Latino Immigrants: Community-Based Efforts in the Rural Midwest*, AM. J. PUB. HEALTH (2011), available at <http://ajph.aphapublications.org/doi/full/10.2105/AJPH.94.10.1709>.

NILC Comments, RIN 0945-ZA03

they need.¹⁶ In rural areas there may simply be no other sources of health and life-preserving medical care. When these women encounter health care refusals, they have nowhere else to go. This is the kind of discrimination OCR should be protecting against.

III. The proposed regulation would allow OCR to turn a blind eye to the rampant discrimination faced by LGBTQ individuals, which would cause particular harm to LGBTQ immigrants.

LGBTQ people continue to face discrimination in many areas of their lives, including health care, on the basis of their sexual orientation and gender identity. The Department's Healthy People 2020 initiative recognizes, "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights."¹⁷ A survey conducted by Lambda Legal found that in 2009, lesbian, gay, and bisexual immigrants and immigrants living with HIV reported higher levels of discrimination than non-immigrant individuals, and the numbers were especially high for immigrants of color.¹⁸ In a recent study published in *Health Affairs*, researchers examined the intersection of gender identity, sexual orientation, race, and economic factors in health care access.¹⁹ They concluded that discrimination as well as insensitivity or disrespect on the part of health care providers were key barriers to health care access and that increasing efforts to provide culturally sensitive services would help close the gaps in health care access.²⁰

There are documented outcomes of discrimination against LGBTQ people:

- Twenty-nine percent of transgender individuals experienced a health care provider's refusal to see them on the basis of their perceived or actual gender identity, and 29 percent experienced unwanted physical contact from a health care provider.²¹

¹⁶ NAT'L LATINA INST. FOR REPROD. HEALTH & CTR. FOR REPROD. RIGHTS, NUESTRA VOZ, NUESTRA SALUD, NUESTRO TEXAS: THE FIGHT FOR WOMEN'S REPRODUCTIVE HEALTH IN THE RIO GRANDE VALLEY, 7 (2013), *available at* <http://www.nuestrotexas.org/pdf/NT-spread.pdf>.

¹⁷ *Healthy People 2020, Lesbian, Gay, Bisexual, and Transgender Health*, U.S. DEPT. HEALTH & HUMAN SERV., <https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health>, (last accessed on Mar. 8, 2018).

¹⁸ *LGBT Immigrants and Immigrants living with HIV*, LAMBDA LEGAL, https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-insert_lgbt-immigrants-and-immigrants-living-with-hiv.pdf.

¹⁹ Ning Hsieh and Matt Ruther, HEALTH AFFAIRS, *Despite Increased Insurance Coverage, Nonwhite Sexual Minorities Still Experience Disparities In Access To Care* (Oct. 2017) 1786–1794.

²⁰ *Id.*

²¹ Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR. FOR AMERICAN PROGRESS, (Jan. 18, 2018),

NILC Comments, RIN 0945-ZA03

- 23 percent of respondents did not see a provider for needed health care because of fears of mistreatment or discrimination.²²
- According to one survey, 8 percent of lesbian, gay, bisexual, and queer individuals had an experience within the year prior to the survey where a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation and 7 percent experienced unwanted physical contact and violence from a health care provider.²³
- Almost ten percent of lesbian, gay, or bisexual respondents reported that they had been denied necessary health care expressly because of their sexual orientation.²⁴

Many LGBTQ people lack insurance and providers are not competent in health care issues and obstacles that the LGBTQ community experiences.²⁵ LGBTQ people still face discrimination and often avoid care due to fear of discrimination. This discrimination based on lack of competent care is only furthered when the addition of language and cultural differences exist.

This is the kind of discrimination that OCR has been successful in opposing, and it must continue to do so. As data obtained by the Center for American Progress shows, when the agency was enforcing its regulation against these forms of discrimination from 2012-16, it was effective at identifying discrimination, including 30 percent of cases that were based on denial of care because of gender identity, not related to gender transition.²⁶ The proposed rule allowing providers to deny needed care would reverse recent gains in combatting discrimination and health care disparities for LGBTQ persons. Refusals also implicate standards of care that are vital to LGBTQ health. Medical professionals are expected to provide LGBTQ individuals with the same quality of care as they would anyone else, and OCR should ensure that this happens.

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

²² NAT'L CTR. FOR TRANSGENDER EQUALITY, *The Report of the 2015 U.S. Transgender Survey 5* (2016), available at <https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf> [hereinafter *2015 U.S. Transgender Survey*].

²³ Mirza, *supra* note 21.

²⁴ LAMBDA LEGAL, *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination Against LGBT People and People with HIV 5* (2010), available at http://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf.

²⁵ Medical schools often do not provide instruction about LGBTQ health concerns that are not related to HIV/AIDS. Jen Kates et al., *Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender Individuals in the U.S.*, KAISER FAMILY FOUND.12 (2017), <http://files.kff.org/attachment/Issue-Brief-Health-and-Access-to-Care-and-Coverage-for-LGBT-Individuals-in-the-US>.

²⁶ Mirza, et al., note 21.

NILC Comments, RIN 0945-ZA03

IV. The proposed rule is overly broad, vague, and will cause confusion

NILC supports the comments submitted by the National Health Law Program, particularly in their analysis of the ways in which the proposed rule is broad, vague, and will cause confusion in the health care delivery system. The regulations as proposed would introduce broad and poorly defined language to the existing law that already provides ample protection for the ability of health care providers to refuse to participate in a health care service to which they have moral or religious objections. The regulations dangerously expand the application of the underlying statutes by offering an extremely broad definition of who can refuse to provide health services and what they can refuse to do.

While the proposed regulations purport to provide clarity and guidance in implementing existing federal religious exemptions, in reality they are vague and confusing. This lack of clarity may make it more difficult for people experiencing discrimination to understand and enforce their rights. This concern is particularly relevant to immigrant populations who have limited English proficiency and may be unfamiliar with the U.S. health care system.

V. Conclusion

NILC opposes the proposed rule as it expands religious refusals in a way that fails to protect immigrant women and LGBTQ immigrants from discrimination, to the detriment of patients' health and well-being. The outcome of this regulation will harm communities who already lack access to care and endure discrimination. For these reasons, we urge the agency to withdraw the rule in its entirety.

Thank you for your attention to our comments. If you have any questions, reach out to Matthew Lopas at lopas@nilc.org or 202-609-9962.

Sincerely,

Matthew Lopas
Health Policy Attorney
National Immigration Law Center

Exhibit 108



March 27, 2018

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

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, RIN 0945-ZA03, Docket ID: HHS-OCR-2018-0002

Dear Secretary Alex Azar,

The New York State Lesbian, Gay, Bisexual, and Transgender (LGBT) Health & Human Services Network (The Network), a coalition of 72 LGBT-serving organizations across New York State, strongly opposes the proposed rule titled, “Protecting Statutory Conscience Rights in Health Care; Delegations of Authority,” as published by the Office for Civil Rights in the January 26, 2018 Federal Register.

The Network’s mission is to address and eliminate LGBT-related health disparities and empower LGBT communities to access affordable and culturally informed health services, resulting in a stronger and safer healthcare environment for all LGBT people. This regulation would permit and promote discrimination by healthcare providers, under the guise of moral or religious protections. In particular, we are concerned that this regulation would formally and explicitly allow health care providers to deny healthcare services to LGBT people who already face health disparities due to discrimination and bias in healthcare.

The Network strongly urges against the proposed Protecting Statutory Conscience Rights in Health Care rule for three (3) main reasons: 1) religious liberty cannot override patient autonomy or anti-discrimination principles; 2) this regulation would contribute to increased levels of discrimination for already medically vulnerable communities, particularly LGBT communities; and 3) this regulation does not reflect the viewpoint of the majority of voters.

Religious liberty cannot override patient autonomy or anti-discrimination principles. Religious exemption policies like this one would allow health care workers to prioritize their



own religious beliefs above patient care. These regulations allow providers to base the course of a patient's medical treatment on their own personal beliefs, not on what is best for the patient's health and circumstances. The proposed rule "ensure[s] that persons or entities are not subjected to certain practices or policies that violate conscience, coerce, or discriminate," however, medical providers are already protected and supported through their code of ethics and law. The United State Equal Employment Opportunity Commission (EEOC) protects medical providers in the workplace; they can already refuse to provide treatment that violates their religious, moral, or ethical values under religious discrimination & reasonable accommodation, as long as this does not place undue hardship on the employer.¹

Additionally, the American Medical Association (AMA) Principles of Medical Ethics states that, "A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care." Medical providers already can choose not to provide care based on moral, religious, or other objections. However, formalizing this code of ethics into law would legally permit discrimination and prevent patients who have experienced refusal of care from pursuing legal action. It is the government's duty to ensure that all people have access to healthcare services, free from discrimination. While this regulation claims to protect religious freedom, it is actually a thinly veiled attempt to devalue women and LGBTQ people.

This regulation would contribute to increased levels of discrimination for already medically vulnerable communities, particularly LGBT communities. LGBT people often experience difficulty finding affirming and competent care. In the 2015 United States Trans Survey, 33% of transgender and gender non-conforming people 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, with increased rates for people of color.² Medical negligence and mistreatment led to the death of Robert Eads, a transgender man with ovarian cancer whom over 20 different doctors refused to treat; one provider claimed the diagnosis should make Robert Eads "deal with the fact that he is not a real man."³

¹ United States. Equal Employment Opportunity Commission. (1992). *EEOC compliance manual*. Washington, DC: U.S. Equal Employment Opportunity Commission.

² James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016). *The Report of the 2015 U.S. Transgender Survey*. Washington, DC: National Center for Transgender Equality.

³ Lambda Legal. (2013). *Transgender Rights Toolkit: Overcoming Health Care Discrimination*. New York: Lambda Legal



Furthermore, 50% of LGB people and 90% of transgender people believe there are not enough medical personnel who are properly trained to care for them. Over 50% of LGB and 85% of transgender people indicated that overall community fear or dislike of people like them is a barrier to care.⁴ This proposed rule would likely exacerbate the fear, mistreatment, harassment, and barriers to care for this already vulnerable population.

This regulation does not reflect the viewpoint of the majority of voters. In a March 2017 nationally representative survey done on behalf of the National Women's Law Center, 61% of voters showed opposition to religious exemption laws. In particular, voters express strong concerns that religious exemption laws do not allow patients to access to optimal medical care, information, and referrals without interference. The majority of constituents (60%) also emphasize that hospitals, medical providers, or public health programs that receive public funding should not be allowed to deny medical care based on religious beliefs.⁵ Given that religious exemption policies are not supported by the majority of voters, they should not be implemented.

In closing, The Network strongly opposes the proposed regulation, Protecting Statutory Conscience Rights in Health Care. The Office for Civil Rights has a duty to ensure that LGBTQ individuals are not targeted with this discriminatory regulation.

We appreciate the opportunity to provide these comments. Please contact Corey Westover, the Director of The Network, at cwestover@gaycenter.org or 646.358.1733 with any questions or concerns.

Sincerely,
The New York State LGBT Health & Human Services Network

⁴ Lambda Legal. (2010). *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination Against LGBT People and People with HIV*. New York: Lambda Legal.

⁵ Greenberg Quinlan Rosner Research. (2017). *Voters Oppose Religious Exemption Laws: Findings from a National Survey of Voters*. Washington, DC: Greenberg Quinlan Rosner Research.



**Members of The Network who oppose the proposed ruling,
“Protecting Statutory Conscience Rights in Health Care; Delegations of Authority”**

ACR Health - Q Center
Albany Damien Center
Ali Forney Center
Alliance for Positive Health
Apicha Community Health Center
Audre Lorde Project
Bassett Healthcare Network - The Gender Wellness Center
Binghamton University - Lesbian and Gay Family Building Project/Pride and Joy Families
Callen-Lorde Community Health Center
Community Awareness Network for a Drug-Free Life and Environment (CANDLE)
Chinese American Planning Council - Project Reach
Community Health Action of Staten Island
Cortland LGBT Resource Center
CRUX Climbing
DBGM, Inc.
Destination Tomorrow
Empire Justice Center - LGBT Rights Project
Gay & Lesbian Youth Services of Western New York
GMHC
Grand Street Settlement
GRIOT Circle, Inc.
Harm Reduction Coalition
Hetrick-Martin Institute
Hispanic AIDS Forum - Latino Pride Center
Hudson Valley LGBTQ Community Center
In Our Own Voices
Institute for Human Identity (IHI)
Latino Commission on AIDS
Long Island Crisis Center - Pride for Youth
Long Island Gay and Lesbian Youth (LIGALY)
Long Island LGBT Center
Make the Road New York - LGBTQ Program
Metropolitan Community Church of New York
Montefiore Medical Center- Adolescent AIDS Program
Mount Sinai - Institute for Advanced Medicine
New York City Anti-Violence Project



New York Legal Assistance Group (NYLAG) - LGBT Law Project
New York Transgender Advocacy Group (NYTAG)
Northwell Health - Center for Transgender Care
Out Alliance
Planned Parenthood Mohawk Hudson
Planned Parenthood of the North Country New York - LGBTQ Services, Education, & Outreach
Planned Parenthood of the Southern Finger Lakes - Out For Health
Pride Center of Staten Island
Pride Center of the Capital Region
Pride Center of Western New York
Princess Janae Place, Inc.
Queens Community House- Queens Center for Gay Seniors/Generation Q
Queens LGBT Community Center (Q-Center)
Rainbow Access Initiative
Rainbow Heights Club
Rockland County Pride Center
Safe Horizon - Streetwork Project
SAGE
SAGE Long Island
SAGE Upstate
Southern Tier AIDS Program - Identity Youth
St. Lawrence University - SAFE Project
State University of New York (SUNY) - The HEAT Program
Sylvia Rivera Law Project
The Legal Aid Society - LGBT Law and Policy Initiative
The Lesbian, Gay, Bisexual, Transgender Community Center
The LOFT: LGBT Community Services Center
Translatina Network
The National LGBT Cancer Network
The Trevor Project
Transgender Legal Defense and Education Fund (TLDEF)
Trillium Health
Unity Fellowship Breaking Ground
Urban Justice Center - Peter Cicchino Youth Project