

Exhibit 115

NHeLP Draft as of March 22, 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

Introduction

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

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

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

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

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

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

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

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

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

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

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

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

² Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172, 54,194 (Sept. 8, 2015) (codified at 45 C.F.R. pt. 2).

³ 83 Fed. Reg. 3917.

⁴ *Id.*

⁵ Brian P. Ward et al., *Sexual Orientation and Health Among U.S. Adults: National Health Interview Survey*, NAT’L CTR. FOR HEALTH STATISTICS, 2013 9 (2014), <https://www.cdc.gov/nchs/data/nhsr/nhsr077.pdf>.

⁶ In 2014, Latinas had the highest rates of contracting cervical cancer and Black women had the highest death rates. *Cervical Cancer Rates By Rates and Ethnicity*, CTRS. FOR DISEASE CONTROL & PREVENTION, (Jun. 19, 2017), <https://www.cdc.gov/cancer/cervical/statistics/race.htm>. At the end of 2014, of the total

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

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

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

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

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

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

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

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

⁹ *Id.* at 8, 16.

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

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

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

b. The proposed rule will negatively impact rural communities

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

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

¹³ *Id* at 12.

¹⁴ *Id* at 9.

¹⁵ Lori R. Freedman et al., *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/>.

¹⁶ Health Res. & Serv. Admin, *Quick Maps – Medically Underserved Areas/Populations*, U.S. DEP'T OF HEALTH & HUM. SERV., <https://datawarehouse.hrsa.gov/Tools/MapToolQuick.aspx?mapName=MUA>, (last visited Mar. 21, 2018).

¹⁷ M. MacDowell et al., *A National View of Rural Health Workforce Issues in the USA*, 10 RURAL REMOTE HEALTH (2010), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3760483/>.

¹⁸ Carol Jones et al., *Health Status and Health Care Access of Farm and Rural Populations*, ECON. RESEARCH SERV. (2009), available at <https://www.ers.usda.gov/publications/pub-details/?pubid=44427>.

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

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

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

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

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

²¹ *Id.*

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

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

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

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

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

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

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

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

i. Discrimination against the transgender community

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

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

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

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

³⁰ *Id.*

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

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

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

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

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

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

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

³⁴ Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR. FOR AMERICAN PROGRESS, (Jan. 18, 2018),

https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/?link_id=2&can_id=d90c309ac9b5a0fa50d294d0b1cdf0b2&source=email-rx-for-discrimination&email_referrer=&email_subject=rx-for-discrimination.

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

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

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

ii. Discrimination Based Upon Sexual Orientation

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

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

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

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

³⁸ Mirza, *supra* note 34.

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

⁴⁰ *Id.*

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

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

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

⁴¹ David J. Lick, Laura E. Durso & Kerri L. Johnson, *Minority Stress and Physical Health Among Sexual Minorities*, 8 PERS. ON PSYCHOL. SCI. 521 (2013), available at

<http://williamsinstitute.law.ucla.edu/research/health-and-hiv-aids/minority-stress-and-physical-health-among-sexual-minorities/>.

⁴² *Id.*

⁴³ *Id.*

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

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

⁴⁶ HUMAN RIGHTS WATCH, *supra* note 28.

⁴⁷ Mirza, *supra* note 34.

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

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

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

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

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

d. The proposed rule will hurt people living with disabilities

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

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

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

⁵¹ Kates, *supra* note 37, at 4.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

⁶² *Code of ethics for nurses with interpretive statements, Provision 1.4 The right to self-determination*, AM. NURSES ASS'N (2001),

https://www.truthaboutnursing.org/research/codes/code_of_ethics_for_nurses_US.html.

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

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

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

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

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

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

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

⁶⁶ Amy G. Bryant & Jonas J. Schwartz, *Why Crisis Pregnancy Centers Are Legal but Unethical*, 20 AM. MED. ASS'N J. ETHICS 269, 272 (2018).

⁶⁷ INST. OF MED., *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 3* (Mar. 2001), available at <http://www.nationalacademies.org/hmd/~media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf>.

⁶⁸ *Id.*

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The opioid epidemic continues to claim too many lives. According to the Centers for Disease Control and Prevention (CDC), over 63,000 people in the U.S. died from drug overdose in 2016.⁶⁹ The latest numbers show a 2017 increase in emergency department overdose admissions of 30% across the country, and up to 70% in some areas of the Midwest.⁷⁰

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

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

⁶⁹ Holly Hedegaard M.D., et al. *Drug Overdose Deaths in the United States, 1999-2016*, NAT’L CTR. FOR HEALTH STATISTICS 1-8 (2017).

⁷⁰ *Vital Signs*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vitalsigns/opioid-overdoses/>.

⁷¹ U.S. DEP’T HEALTH & HUM. SERV., PUB NO. (SMA)12-4214, MEDICATION-ASSISTED TREATMENT FOR OPIOID ADDICTION IN OPIOID TREATMENT PROGRAMS (2012), <https://store.samhsa.gov/shin/content/SMA12-4214/SMA12-4214.pdf>; National Institute on Drug Abuse, *Effective Treatments for Opioid Addiction*, <https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction>.

⁷² World Health Organization, 19th WHO Model List of Essential Medicines (April 2015), http://www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf

⁷³ OPEN SOC’Y INST., BARRIERS TO ACCESS: MEDICATION-ASSISTED TREATMENT AND INJECTION-DRIVEN HIV EPIDEMICS 1 (2009), <https://www.opensocietyfoundations.org> [<https://perma.cc/YF94-88AP>].

⁷⁴ See James M. Chamberlain & Bruce L. Klein, *A Comprehensive Review of Naloxone for the Emergency Physician*, 12 AM. J. EMERGENCY MED. 650 (1994).

⁷⁵ Ellen M. Weber, *Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance*, 13 J. HEALTH CARE L. & POL’Y 49, 56 (2010); German Lopez, *There’s a highly successful treatment for opioid addiction. But stigma is holding it back.*, Vox, Nov. 15, 2017, <https://www.vox.com/science-and-health/2017/7/20/15937896/medication-assisted-treatment-methadone-buprenorphine-naltrexone>.

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

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

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

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

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

⁷⁸ Lopez, *supra* note 75.

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

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

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

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

⁸³ 42 C.F.R. §8.610.

⁸⁴ Matthais Pierce, et al., *Impact of Treatment for Opioid Dependence on Fatal Drug-Related Poisoning: A National Cohort Study in England*, 111:2 ADDICTION 298 (Nov. 2015); Luis Sordo, et al., *Mortality Risk During and After Opioid Substitution Treatment: Systematic Review and Meta-Analysis of Cohort Studies*, BMJ (2017), <http://www.bmj.com/content/357/bmj.i1550>; Alex Azar, Secretary, U.S. Dept’t of Health & Hum. Serv., Plenary Address to National Governors Association, (Feb. 24, 2018),

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

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

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

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

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

⁸⁵ Azar, *supra* note 84.

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

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

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

a. Pregnancy prevention

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

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

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

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

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

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

⁹² *Id.* at S114.

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

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

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

b. Sexually transmitted infections (STIs)

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

c. Ending a Pregnancy

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

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

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

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

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

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

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

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

d. Emergency contraception

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

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

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

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

¹⁰² ELEANOR BIMLA SCHWARZ M.D. M.S., et al., *Documentation of Contraception and Pregnancy When Prescribing Potentially Teratogenic Medications for Reproductive-Age Women*, 147 ANNALS OF INTERNAL MEDICINE (Sept. 18, 2007).

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

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

¹⁰⁵ *Id.* at 105.

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

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

e. Artificial Reproductive Technology (ART)

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

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

f. HIV Health

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

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

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

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

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

VI. The proposed rule violates the Establishment Clause

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

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

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

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

¹¹⁰ E.g., *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Cutter v. Wilkinson*, 544 U.S. 709, 720, 726 (2005); *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 n.8 (1989).

¹¹¹ *Cutter*, 544 U.S. at 720, 722; see also *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 709-10 (1985).

¹¹² *Hobby Lobby*, 134 S. Ct. 2751, 2760 (2014).

¹¹³ *Id.* at 2786-87 (Kennedy, J., concurring).

¹¹⁴ 83 Fed. Reg. 3894.

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a. Discrimination

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

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

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

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

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

¹¹⁶ *Id.*

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

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

b. Assist in the performance

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

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

¹¹⁸ *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, slip op. at 46 (2014).

¹¹⁹ 83 Fed. Reg. 3892.

¹²⁰ *Id.*

¹²¹ RM Haynes et al., *Contraceptive Use at Last Intercourse Among Reproductive-Aged Women with Disabilities: An Analysis of Population-Based Data from Seven States*, CONTRACEPTION (2017), <https://www.ncbi.nlm.nih.gov/pubmed/29253580>; See generally Alex Zielinski, *Why Reproductive Health Can Be A Special Struggle for Women with Disabilities*, THINKPROGRESS, Oct. 1, 2015, <https://thinkprogress.org/why-reproductive-health-can-be-a-special-struggle-for-women-with-disabilities-73eacea23c4/>.

¹²² In one study in Massachusetts, women living with intellectual and developmental disabilities, including those who were Black and Latina, faced increased risks of preterm delivery and very low and low birth weight babies. M. Mitra et al., *Pregnancy Outcomes Among Women with Intellectual and Developmental Disabilities*, AM. J. PREV. MED. (2015), <https://www.ncbi.nlm.nih.gov/pubmed/25547927>.

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

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

c. Referral

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

d. Health Care Entity

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

¹²³ 83 Fed. Reg. 3890-91.

¹²⁴ *Id.* at 3895.

¹²⁵ *Id.* at 3893.

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

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

Conclusion

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

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

¹²⁶ Office for Civil Rights, Decision Re: OCR Transaction Numbers: 14-193604, 15-193782 & 15-195665, 4 (Jun. 21, 2016) (letter on file with NHeLP-DC office).

¹²⁷ 83 Fed. Reg. 3893.

¹²⁸ *Id.*

¹²⁹ *Id.*

Exhibit 116



March 27, 2018

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

Dear Secretary Azar:

On behalf of the National Association of County and City Health Officials (NACCHO) and nearly 3,000 local health departments, thank you for the opportunity to provide comments on the proposed Department of Health and Human Services (HHS) regulation entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority."

Local public health departments are the governmental agencies that work every day in their communities to prevent disease, promote wellness, and protect health. They organize community partnerships and facilitate important conversations with a number of stakeholders about how to create the conditions in which all people can be healthy.

NACCHO has several concerns about the proposed rule and its effect on access to necessary primary care services. **The rule's emphasis on accommodating religious beliefs could interfere with delivery of appropriate care and services.** As proposed, the rule will give health care providers a license based on religious beliefs 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.

NACCHO calls on HHS to include explicit language making clear that religious beliefs will not be used to deny access to health services or to discriminate against people based on reproductive health decisions, gender identity or sexual orientation. In addition, NACCHO calls on HHS to continue activities to identify and address health disparities with the ultimate goal of eliminating them. In activities spanning the Office for Civil Rights, Office of Minority Health, Office of Women's Health as well as the Centers for Medicare & Medicaid Services, all of HHS' endeavors must ensure that disparities are not heightened but are prevented.

Teen births are decreasing and abortion rates are the lowest they have been since the Roe v Wade Supreme Court decision, in large part because of increased access to evidence-based health education and health services. We cannot afford to turn back the clock on this progress. The proposed rule may open the door to discrimination by health care providers based on individually held beliefs. To protect the public's health, the patient's needs must come first. Furthermore, these new priorities are worrisome as they reflect an ideology that aims to dictate the decisions people can make about their bodies and health care.

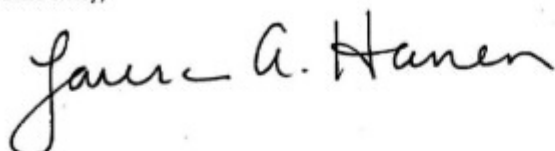


Lesbian, gay, bisexual and transgender (LGBT) people are considered a vulnerable population as it concerns their health. LGBT people face higher rates of HIV/AIDS, depression, an increased risk of some cancers, and are twice as likely as their heterosexual peers to have a substance use disorder. Transgender people in particular are at higher risk for a range of poor health outcomes. For example, the 2015 U.S. Transgender Survey, a national study of nearly 28,000 transgender adults, found that respondents were nearly five times more likely to be living with HIV than the general population, with even higher rates for some populations: for example, nearly one in five (19%) Black transgender women living with HIV, more than 63 times the rate in the general population. Transgender respondents were nearly eight times more like than the general population to be living with serious psychological distress based on the Kessler 6 scale, with higher rates correlating with experiences of discrimination, violence, and rejection.

The medical community and scientific research has repeatedly demonstrated that the poor health outcomes that LGBT people face are not associated with any inherent pathology, but rather high rates of poverty, discrimination in the workplace, schools, and other areas, and barriers to nondiscriminatory health care that meets their needs. Refusals to treat individuals according to medical standards of care put patients' health at risk, particularly for women and LGBT individuals. Expanding religious refusals will further put needed care, including reproductive health care, out of reach for many. Given the broadly-written and unclear language of the proposed rule, if implemented, some providers may misuse this rule to deny services to LGBT individuals on the basis of perceived or actual sexual orientation and gender identity. Allowing providers to flout established medical guidelines and deny medically accurate, evidence-based care impairs the ability of patients to make a health decision that expresses their self-determination.

Thank you again for the opportunity to comment on "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority." NACCHO and local health departments look forward to continued opportunities to partner with the federal government to protect the public and ensure optimal health. Please contact me at lhane@naccho.org/202-507-4255 for any further information.

Sincerely,

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

Laura A. Hanen, MPP
Interim Executive Director & Chief of Government Affairs

Exhibit 117

Roger Severino
March 27, 2018

While the freedom to practice religion – including which medical services to receive – is a fundamental right in the U.S. guaranteed by the First Amendment to our Constitution, we are concerned that some that may abuse this right by making decisions about immunizations on the pretext of religion when the large majority of religious support immunizations. As a nation, we have an ethical responsibility to protect the community from potentially harmful disease outbreaks by seriously considering the possible impact of such claims.

State Authority

The threat of infectious disease outbreaks cannot be taken lightly. These outbreaks occur at the community level where vaccination rates have fallen below the thresholds needed to prevent disease. For example, Minnesota experienced a major outbreak of measles this past spring – in one community, measles vaccination rates had dropped to 42 percent among a group of preschool-aged children, despite a statewide immunization rate of 93 percent. As a result, 8,000 people were exposed to measles, 79 contracted the disease, and 22 were hospitalized. States and communities are most aware of the circumstances facing their residents, and they must be able to enforce policies that protect their populations.

The proposed rule states in multiple places that its intent is not to interfere with state law. In its analysis of the impact of Executive Order 13132, the OCR states “The proposed rule makes clear that it is not intended to interfere with the operation of State law, except as required by existing Federal health and safety protections.” There is no federal law addressing school immunization requirements. NAPNAP urges the Department to clarify that the rule is not intended to be used against schools following state laws by adding the following language to section 88.8: “Nothing in this part shall be construed as preempting or interfering with existing and valid state law, for example, state school immunization requirements.”

Health Care Providers’ Responsibility

Just as states are in the best position to create vaccination policies to protect their residents, health care providers are in the best position to determine what is required to meet the needs of their patients. In the case of immunizations, vaccines protect both the individuals vaccinated and those around them from dangerous diseases (a concept known as “community immunity”). Most vaccine-preventable diseases are transmitted from person to person, so if a high proportion of the population is vaccinated and immune, then the chains of transmission are broken. For example, a child can be protected against measles or whooping cough, even if they have not yet reached the recommended age for vaccination, if enough people around them have been vaccinated and are less likely to carry or transmit the disease. Conversely, if not enough individuals are vaccinated, diseases can once again spread through a community, affecting even those who were vaccinated. Thus, the medical community strongly supports vaccination according to the U.S. Centers for Disease Control and Prevention’s recommended immunization schedule.

However, the evidence is clear that disease outbreaks can be initiated and spread in clinical settings by unvaccinated children. A 2008 measles outbreak sparked in a San Diego pediatric clinic waiting room when an unvaccinated child returned from a vacation in Switzerland with measles, leading to the exposure of 839 people, 11 additional cases (all in unvaccinated children), and the hospitalization of an infant below the age at which the measles vaccine is recommended. Pediatric APRNs believe it is important to provide all children with appropriate medical care, but providers are also best placed to assess the risks to their community and decide which risks should be taken and which should be avoided.

It is therefore appropriate for APRNs and other pediatric providers to have policies that prevent voluntarily unimmunized children from exposing other patients to potential infection, without regard to the reason why parents may choose not to immunize their child. NAPNAP believe OCR should make it clear in the proposed rule that such policies that are adopted for reasons of patient and community safety that have nothing to do with religion are not discriminatory when they are applied to all patients equally.

Headquarters
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March 27, 2018

Roger Severino
Director, Office for Civil Rights
ATTN: Conscience NPRM, RIN 0945-ZA03
U.S. Department of Health and Human Services
Room 509F, 200 Independence Avenue, SW
Washington, DC 20201

Re: RIN 0945-ZA03 – Protecting Statutory Conscience Rights in Health Care; Delegations of Authority
(Submitted electronically via www.regulations.gov)

Dear Director Severino:

On behalf of more than 8,000 pediatric nurse practitioners (PNPs) and fellow pediatric-focused advanced practice registered nurses (APRNs) committed to providing optimal health care to children, the National Association of Pediatric Nurse Practitioners (NAPNAP) appreciates the opportunity to provide its comments on the Department of Health and Human Services Office for Civil Rights (OCR) January 26, 2018, notice of proposed rulemaking, *Protecting Statutory Conscience Rights in Health Care: Delegations of Authority* (RIN 0945-ZA03). We are concerned that the proposed rule could put children, families and communities at serious risk depending on how it is interpreted. Specifically, although OCR intends to respect state law, it troubles us that some individuals and officials might attempt use the rule to challenge existing state school immunization requirements, undermining state responsibility and autonomy to protect public health based to its assessment of local conditions. In addition, we are worried that it is possible for some to incorrectly interpret the rule as prohibiting private practices serving their own clientele. We are also concerned that explicitly naming vaccine administration and reception as a category of discrimination could encourage health care workers to make decisions that may put children at risk.

As you may know, APRNs who concentrate on children’s care, including PNPs, have attained enhanced education in pediatric nursing and health care using evidence-based practice guidelines. Committed to improving children’s health, they practice in primary care, specialty, and acute care. Pediatric-focused APRNs have provided high quality health care to children and families for more than 40 years in an extensive range of practice settings such as pediatric offices, clinics, schools, and hospitals – reaching millions of patients across the country each year. The administration of vaccines to immunize children from disease is a critical part of their practices.

Our nation has made tremendous progress in protecting its children and citizens from deadly infectious diseases, ranging from smallpox to chicken pox. The Centers for Disease Control and Prevention (CDC) estimates that vaccines given to children born between 1994 and 2016 will prevent approximately 381 million illnesses, 24.5 million hospitalizations, 855,000 deaths, and \$1.65 trillion in total costs to society. For example, the CDC reports that the Hib vaccine prevents over 20,000 of cases of serious disease and a thousand deaths each year, while the rubella vaccine protects the unborn from harm and prevents tens of thousands of miscarriages, still births, and birth defects that used to result from infections in pregnancy.

Unfortunately, we know that when children are not immunized, they are at higher risk of deadly infectious diseases. Researchers have found that children exempt from vaccination requirements are more than 15 times more likely to contract measles and nearly six times more likely to contract pertussis, compared to vaccinated children. A 2006 study found that states with loose exemption policies had roughly 50 percent more cases of whooping cough compared to those states with stricter policies.

Roger Severino
March 27, 2018

Putting Children's Health First

As you know, many geographic regions of our country are struggling with insufficient access to health care providers. The Georgetown University Public Health Institute reported that more than 20 million rural Americans live in areas that have a provider-to-patient ratio of 1 to 3,500 or less and are federally designated as health professional shortage areas (HPSAs). Pediatric APRNs are often essential primary care providers for children in these areas, where many families have few options for receiving medical care including vaccinations.

If the only health care provider in such an area refuses to administer vaccines because of his or her personal religious beliefs, entire communities could be left vulnerable to devastating infectious diseases. Similarly, an unvaccinated provider in a health professional shortage area could spread vaccine-preventable diseases throughout an entire community. It is critical that health care providers immunize themselves against vaccine-preventable diseases in order to better protect their patients.

In describing situations where health care providers or entities "may be coerced or suffer discrimination," the proposed rule specifically refers to providers and entities who do not support the use of fetal cells in vaccines. However, NAPNAP believes that it would be unethical for a health care provider to allow a disease such as rubella, which can cause miscarriages, stillbirths, and birth defects when contracted by pregnant women, to spread through a community because of personal religious beliefs. For health care professionals and entities, the best interests of the patient's health must come first. We urge the OCR to delete from the proposed language the reference to "being required to administer or receive certain vaccinations derived from aborted fetal tissues as a condition of work or receipt of educational services." "Aborted fetal tissue" has¹ been collected to manufacture vaccines for more than five decades, and the language in the proposed rule could lead to misinformed decisions to not vaccinate, resulting in decreased community immunity and putting those most vulnerable at risk.

In summary, NAPNAP appreciates the OCR's effort to protect conscience rights in the delivery of health care, but we strongly believe that the needs of patients must always be foremost in the conscience of health care professionals. Before you proceed to final rulemaking, we urge you to:

1. Clarify that the regulations are not intended to, and will not be used to, interfere with existing state statutes that do not violate federal law, specifically including school immunization requirements and state vaccination requirements for health care professionals.
2. Clarify that the regulations are not intended to limit the freedom of individual, independent health care professionals to implement policies that prevent voluntarily unimmunized children from exposing other patients to potential infection, as long as they are adopted solely to protect the health of patients and the community and are applied equally to all patients without regard to religion.
3. Remove language that would allow health care professionals to refuse to administer or receive medically appropriate vaccinations, specifically on the erroneous rationale of being derived from aborted fetal tissue.

We are grateful for the opportunity to provide these comments and hope you will contact NAPNAP for assistance on any issues or policies related to children's health and immunization policies. We have a wide range of experts eager to assist you in framing these policies.

Sincerely,



Tressa E. Zielinski, DNP, RN, APN-NP, CPNP-PC
President

Exhibit 118



National Association of Social Workers
Comments on
Department of Health and Human Services Proposed Rule:
Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

The National Association of Social Workers (NASW) is the nation's largest social work professional organizations in the nation. We have over 120,000 members and chapters in every state. With that in mind, NASW is deeply concerned about all federal, state, and local policies that have the potential to deny access to services or to participation in programs due to discriminatory governmental policies. For those reasons, we strongly urge the Department of Health and Human Services (HHS) to set the proposed rule titled, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" as published by the Office for Civil Rights (OCR) in the January 26, 2018 Federal Register.

In this rule, OCR proposes to revise regulations ostensibly to ensure that health care professionals have the right to decline to participate in medical procedures to which they are opposed on moral or religious grounds. As a mechanism for overseeing the implementation and monitoring compliance with this rule, HHS also announced the creation of the Conscience and Religious Freedom Division.

NASW realizes that some health and behavioral health care professionals feel obligated to decline to participate in care that conflicts with their personal ethics. However, social workers' code of ethics demand that, among other things, members of the profession should not practice, condone, facilitate, or collaborate with any form of discrimination based on race, ethnicity, national origin, color, sex, sexual orientation, gender identity or expression. Therefore, we find it ethically unacceptable for a medical or behavioral health practitioner – or service provider- to deny needed care because of the practitioner's personal religious beliefs.

NASW is further concerned that "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" rule extends to health care entities and providers who receive federal funding through grants and contracts. An interpretation of the rule could suggest that medical or behavioral health grantees could refuse to provide treatment to certain communities. For example, it is conceivable that an provider agency, opposed to same-sex couples adoption or foster care, could deny the child treatment of based on their religious objection to same-sex marriage.

NASW is troubled by the prospect that expansions of providers' right to refuse services based on their religious beliefs could exceed HHS's authority; undermine the ability of states to ensure access to essential medical and behavioral health services, undermine critical HHS programs like Title X; interfere with the provider-patient relationship; and threaten the health and emotional well-being of individuals across the country.

Everyone deserves to be treated with dignity and respect when accessing health care. LGBTQ people, women, and other vulnerable communities in our country already face enormous barriers to getting the care they need. Accessing culturally competent care and overcoming outright discrimination is an even greater challenge for those living in areas with already limited access to health providers. The proposed regulation threatens to make access even harder and for some people nearly impossible.

Thank you for the opportunity to provide comments on the 'Protecting Statutory Conscience Rights in Health Care' proposed rule. We trust that these comments, along with the many others we expect the HHS will receive, will demonstrate to how this rule will put the health and potentially even the lives of patients at risk.

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