

# Nos. 19- 4254(L), 20-31, 20-32, 20-41

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IN THE UNITED STATES COURT OF APPEALS  
FOR THE SECOND CIRCUIT

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STATE OF NEW YORK; CITY OF NEW YORK; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; DISTRICT OF COLUMBIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF MARYLAND; COMMONWEALTH OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF OREGON; COMMONWEALTH OF PENNSYLVANIA; STATE OF RHODE ISLAND; STATE OF VERMONT; COMMONWEALTH OF VIRGINIA; STATE OF WISCONSIN; CITY OF CHICAGO; AND COOK COUNTY, ILLINOIS,

Plaintiffs-Appellees,

*(Caption continued on inside cover)*

On Appeal from the United States District Court  
for the Southern District of New York

**JOINT APPENDIX VOLUME VII OF X**

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*Of Counsel:*

ROBERT P. CHARROW  
*General Counsel*

SEAN R. KEVENEY  
*Deputy General Counsel*  
*U.S. Department of Health & Human Services*

JOSEPH H. HUNT  
*Assistant Attorney General*

MICHAEL S. RAAB  
LOWELL V. STURGILL JR.  
SARAH CARROLL  
LEIF OVERVOLD  
*Attorneys, Appellate Staff*  
*Civil Division, Room 7226*  
*U.S. Department of Justice*  
*950 Pennsylvania Avenue NW*  
*Washington, DC 20530*  
*(202) 532-4631*  
*Counsel for Defendants-Appellants and Consolidated-  
Defendants-Appellants*

PLANNED PARENTHOOD FEDERATION OF AMERICA, INC.; PLANNED PARENTHOOD OF  
NORTHERN NEW ENGLAND, INC.; NATIONAL FAMILY PLANNING AND REPRODUCTIVE  
HEALTH ASSOCIATION; AND PUBLIC HEALTH SOLUTIONS, INC.

Consolidated-Plaintiffs-Appellees,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR, II, in  
his official capacity as Secretary of the United States Department of Health and Human Service; AND  
UNITED STATES OF AMERICA,

Defendants-Appellants,

DR. REGINA FROST AND CHRISTIAN MEDICAL AND DENTAL ASSOCIATIONS,

Intervenors-Defendants-Appellants,

ROGER T. SEVERINO, in his official capacity as Director, Office for Civil Rights, United States  
Department of Health and Human Services; AND OFFICE FOR CIVIL RIGHTS, UNITED STATES  
DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Consolidated-Defendants-Appellants.

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# Exhibit 82

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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 Kentucky Voices for Health, 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.”<sup>1</sup>

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, while cloaked in the language of non-discrimination, is designed to deny care and

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<sup>1</sup> 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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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.”<sup>2</sup>

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.<sup>3</sup> 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.<sup>4</sup> 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.<sup>5</sup> Women of color experience health care disparities such as high rates of cervical cancer and are disproportionately impacted by HIV.<sup>6</sup>

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

<sup>3</sup> 83 Fed. Reg. 3917.

<sup>4</sup> *Id.*

<sup>5</sup> 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>.

<sup>6</sup> 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,<sup>7</sup> 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.<sup>8</sup> Notably, immigrant, Latina women have far higher rates of uninsurance than Latina women born in the United States (48 percent versus 21 percent, respectively).<sup>9</sup>

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.<sup>10</sup> 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.<sup>11</sup>

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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>.

<sup>7</sup> 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>.

<sup>8</sup> 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).

<sup>9</sup> *Id.* at 8, 16.

<sup>10</sup> 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](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](http://blackrj.org/wp-content/uploads/2017/06/FINAL-InOurVoices_Report_final.pdf).

<sup>11</sup> *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.<sup>12</sup> In nineteen states, women of color are more likely than white women to give birth in Catholic hospitals.<sup>13</sup> 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.<sup>14</sup> 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.<sup>15</sup> 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,<sup>16</sup> with over 75 percent of chief executive officers of rural hospitals reporting physician shortages.<sup>17</sup> 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.<sup>18</sup> 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

<sup>12</sup> 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>.

<sup>13</sup> *Id* at 12.

<sup>14</sup> *Id* at 9.

<sup>15</sup> 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/>.

<sup>16</sup> 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).

<sup>17</sup> 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/>.

<sup>18</sup> 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.<sup>19</sup> 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.<sup>20</sup> 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.<sup>21</sup>

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.<sup>22</sup> 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.<sup>23</sup> 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.<sup>24</sup> 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.<sup>25</sup> These women often lack access to transportation and may have to travel great distances to get the care they need.<sup>26</sup> 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.

<sup>19</sup> 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/>.

<sup>20</sup> 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/>.

<sup>21</sup> *Id.*

<sup>22</sup> 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>.

<sup>23</sup> 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/>.

<sup>24</sup> 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>.

<sup>25</sup> 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>.

<sup>26</sup> 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."<sup>27</sup> 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.<sup>28</sup> 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.<sup>29</sup> 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.<sup>30</sup>

*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.<sup>31</sup> Numerous federal courts have found that federal sex discrimination

<sup>27</sup> *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).

<sup>28</sup> 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>.

<sup>29</sup> 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.

<sup>30</sup> *Id.*

<sup>31</sup> 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.<sup>32</sup> 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.”<sup>33</sup>

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.<sup>34</sup> 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.<sup>35</sup> 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.”

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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).

<sup>32</sup> 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).

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

<sup>34</sup> 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](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).

<sup>35</sup> 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.”<sup>36</sup>

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.<sup>37</sup> 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.<sup>38</sup>

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.<sup>39</sup> Almost ten percent of LGB respondents reported that they had been denied necessary health care expressly because of their sexual orientation.<sup>40</sup> 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:

<sup>36</sup> Sharita Gruberg & 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/>.

<sup>37</sup> 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>.

<sup>38</sup> Mirza, *supra* note 34.

<sup>39</sup> 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](http://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf).

<sup>40</sup> *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.<sup>41</sup>
- Lesbian and bisexual women report poorer overall physical health than heterosexual women.<sup>42</sup>
- 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.<sup>43</sup>
- 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.<sup>44</sup>
- Bisexual people face significant health disparities, including increased risk of mental health issues and some types of cancer.<sup>45</sup>

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]”.<sup>46</sup> 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.<sup>47</sup>

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.<sup>48</sup> The World Professional

<sup>41</sup> 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/>.

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> 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>.

<sup>45</sup> 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>.

<sup>46</sup> HUMAN RIGHTS WATCH, *supra* note 28.

<sup>47</sup> Mirza, *supra* note 34.

<sup>48</sup> *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.<sup>49</sup> The American College of Obstetricians and Gynecologists warns that failure to provide gender-affirming treatment can lead to serious health consequences for transgender individuals.<sup>50</sup> 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.<sup>51</sup> The LGBTQ community is significantly at risk for sexual violence.<sup>52</sup> Eighteen percent of lesbian, gay, bisexual students have reported being forced to have sex.<sup>53</sup> Transgender women, particularly women of color, face high rates of HIV.<sup>54</sup>

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,

<sup>49</sup> *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).

<sup>50</sup> *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>.

<sup>51</sup> Kates, *supra* note 37, at 4.

<sup>52</sup> 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.

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

<sup>54</sup> 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.<sup>55</sup> 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.<sup>56</sup> 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.<sup>57</sup> 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

<sup>55</sup> 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).

<sup>56</sup> 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://nwlrc.org/wp-content/uploads/2015/08/lgbt\\_refusals\\_factsheet\\_05-09-14.pdf](https://nwlrc.org/wp-content/uploads/2015/08/lgbt_refusals_factsheet_05-09-14.pdf).

<sup>57</sup> 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.<sup>58</sup> 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.<sup>59</sup> 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.<sup>60</sup> In order to ensure that patient

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

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

<sup>60</sup> 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."<sup>61</sup> 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."<sup>62</sup> Similarly, pharmacists are called to respect the autonomy and dignity of each patient.<sup>63</sup>

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.<sup>64</sup> 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."<sup>65</sup>

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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).

<sup>61</sup> *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>.

<sup>62</sup> *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](https://www.truthaboutnursing.org/research/codes/code_of_ethics_for_nurses_US.html).

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

<sup>64</sup> 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>.

<sup>65</sup> *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."<sup>66</sup> In addition, the proposed rule undermines principles of quality care. Health care should be safe, effective, patient-centered, timely, efficient, and equitable.<sup>67</sup> 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.<sup>68</sup> 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.

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

<sup>67</sup> INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21<sup>ST</sup> 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>.

<sup>68</sup> *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.<sup>69</sup> 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.<sup>70</sup>

The clear, evidence-based treatment standard for opioid use disorder (OUD) is medication-assisted treatment (MAT).<sup>71</sup> 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."<sup>72</sup> 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.<sup>73</sup> 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.<sup>74</sup> 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.<sup>75</sup> 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

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

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

<sup>71</sup> 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>.

<sup>72</sup> World Health Organization, 19th WHO Model List of Essential Medicines (April 2015), [http://www.who.int/medicines/publications/essentialmedicines/EML2015\\_8-May-15.pdf](http://www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf)

<sup>73</sup> 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>].

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

<sup>75</sup> 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.<sup>76</sup> 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.<sup>77</sup>

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.”<sup>78</sup> 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.”<sup>79</sup> 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.<sup>80</sup> 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.”<sup>81</sup>

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.<sup>82</sup> 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.<sup>83</sup> 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.<sup>84</sup> The current Secretary of the

<sup>76</sup> 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>.

<sup>77</sup> 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](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).

<sup>78</sup> Lopez, *supra* note 75.

<sup>79</sup> Eric Eyre, *Trump officials seek opioid solutions in WV*, CHARLESTON GAZETTE-MAIL, May 9, 2017, [https://www.wvgazette.com/news/health/trump-officials-look-for-opioid-solutions-in-wv/article\\_52c417d8-16a5-59d5-8928-13ab073bc02b.html](https://www.wvgazette.com/news/health/trump-officials-look-for-opioid-solutions-in-wv/article_52c417d8-16a5-59d5-8928-13ab073bc02b.html).

<sup>80</sup> 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>.

<sup>81</sup> 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](https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf)

<sup>82</sup> 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>

<sup>83</sup> 42 C.F.R. §8.610.

<sup>84</sup> 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.j1550>; Alex Azar, Secretary, U.S. Dep’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.<sup>85</sup> 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.<sup>86</sup> 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.<sup>87</sup> 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

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

<sup>85</sup> Azar, *supra* note 84.

<sup>86</sup> 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?lvl=4&lvlid=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?lvl=4&lvlid=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?lvl=4&lvlid=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?lvl=4&lvlid=31>.

<sup>87</sup> 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.<sup>88</sup> 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.<sup>89</sup> 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.<sup>90</sup>

*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.<sup>91</sup> 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.<sup>92</sup>

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.<sup>93</sup> 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.<sup>94</sup> The Institute of Medicine has

<sup>88</sup> 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/>.

<sup>89</sup> 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](https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf).

<sup>90</sup> 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>.

<sup>91</sup> 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](http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf)

<sup>92</sup> *Id.* at S114.

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

<sup>94</sup> 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.<sup>95</sup>

*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.<sup>96</sup> 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.<sup>97</sup>

*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.<sup>98</sup> For example, the rate of preeclampsia is 61% higher for Black women than for white women, and 50% higher than women overall.<sup>99</sup> The American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics guidelines state

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

<sup>95</sup> 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).

<sup>96</sup> *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](https://www.cdc.gov/std/stats16/CDC_2016_STDS_Report-for508WebSep21_2017_1644.pdf).

<sup>97</sup> 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](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](https://www.unicef.org/aids/files/2009_position_paper_condoms_en.pdf).

<sup>98</sup> 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=ihp20>.

<sup>99</sup> 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.<sup>100</sup> ACOG and American Heart Association recommend that a pregnancy be avoided or ended for certain conditions such as severe pulmonary hypertension.<sup>101</sup> 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.<sup>102</sup> In addition, some medical guidelines counsel patients to end a pregnancy if they are taking certain medications for thyroid disease.<sup>103</sup>

*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.<sup>104</sup> Twenty three percent of the hospitals limited EC to victims of sexual assault.<sup>105</sup>

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.<sup>106</sup> At the bare

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

<sup>101</sup> 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>.

<sup>102</sup> 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).

<sup>103</sup> 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).

<sup>104</sup> 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)

<sup>105</sup> *Id.* at 105.

<sup>106</sup> *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.<sup>107</sup>

*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.<sup>108</sup> 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.<sup>109</sup> Under the proposed rule, an insurance company could refuse to cover PrEP or PEP

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

<sup>108</sup> 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](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).

<sup>109</sup> *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.<sup>110</sup> 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."<sup>111</sup>

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."<sup>112</sup> Justice Kennedy emphasized that an accommodation must not "unduly restrict other persons, such as employees, in protecting their own interests."<sup>113</sup> 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."<sup>114</sup> 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?

<sup>110</sup> 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).

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

<sup>112</sup> *Hobby Lobby*, 134 S. Ct. 2751, 2760 (2014).

<sup>113</sup> *Id.* at 2786-87 (Kennedy, J., concurring).

<sup>114</sup> 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.<sup>115</sup> 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.<sup>116</sup> 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.<sup>117</sup> Instead, courts have held that the government has a compelling interest in ending discrimination

<sup>115</sup> 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>.

<sup>116</sup> *Id.*

<sup>117</sup> 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.”<sup>118</sup> 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.”<sup>119</sup> In addition, the Department includes activities such as “making arrangements for the procedure.”<sup>120</sup> 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.<sup>121</sup> Biased counseling can contribute to unwanted health outcomes and exacerbate health disparities.<sup>122</sup> 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

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

<sup>119</sup> 83 Fed. Reg. 3892.

<sup>120</sup> *Id.*

<sup>121</sup> 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/>.

<sup>122</sup> 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.<sup>123</sup> 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.<sup>124</sup> 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.”<sup>125</sup> 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

<sup>123</sup> 83 Fed. Reg. 3890-91.

<sup>124</sup> *Id.* at 3895.

<sup>125</sup> *Id.* at 3893.

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

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.”<sup>127</sup> Additionally, the proposed rule incorporates entities as defined in 1 USC 1 which includes corporations, firms, societies, etc.<sup>128</sup> States and public agencies and institutions are also deemed to be entities.<sup>129</sup> 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**

Kentucky Voices for Health 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 any one 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 Emily Beauregard, Executive Director: [emily.beauregard@kyvoicesforhealth.org](mailto:emily.beauregard@kyvoicesforhealth.org).

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<sup>126</sup> 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).

<sup>127</sup> 83 Fed. Reg. 3893.

<sup>128</sup> *Id.*

<sup>129</sup> *Id.*

# Exhibit 83

# CALLEN-LORDE

March 27, 2018

**Attention: Conscience NPRM**

U.S. Department of Health and Human Services  
Office for Civil Rights  
RIN 0945-ZA03  
Hubert H. Humphrey Building, Room 209F  
200 Independence Avenue SW  
Washington, DC 20201

**Dear Secretary Azar:**

On behalf of Callen-Lorde Community Health Center, we submit these comments to the federal Department of Health and Human Services ("Department") and its Office for Civil Rights ("OCR") in **strong opposition to the proposed regulation entitled "Protecting Statutory Conscience Rights in Health Care: Delegations of Authority."**<sup>1</sup>

Callen-Lorde is a growing federally qualified health center (FQHC) with three locations in New York City and a mission to serve lesbian, gay, bisexual and transgender communities and people living with HIV in addition to its geographic service areas. As a community-based health center, Callen-Lorde is open to all regardless of ability to pay. Callen-Lorde provides primary care, dental care, behavioral health care, care coordination and case management, as well as health education services, and its current primary care patient base nearly 18,000 people, approximately 25 percent of whom are patients of transgender or gender non-binary experience and 20% of whom are people living with HIV.

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

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<sup>1</sup> 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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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, 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.”<sup>2</sup>

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.<sup>3</sup> 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.<sup>4</sup> 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.<sup>5</sup> Women of color experience health

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

<sup>3</sup> 83 Fed. Reg. 3917.

<sup>4</sup> *Id.*

<sup>5</sup> 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>.

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care disparities such as high rates of cervical cancer and are disproportionately impacted by HIV.<sup>6</sup> 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.

As a federally-qualified healthcare facility that was born out of the Stonewall era, Callen-Lorde knows firsthand the impact stigma and discrimination has on the health outcomes of populations who have been historically marginalized in healthcare and society. For the purposes of these comments, we will focus our response on the impact these proposed regulations will have on the LGBTQ community and LGBTQ health equity.

a. 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."<sup>7</sup> 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.<sup>8</sup> In a recent study published in *Health Affairs*, researchers examined the

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<sup>6</sup> 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 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>.

<sup>7</sup> *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).

<sup>8</sup> 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>.

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intersection of gender identity, sexual orientation, race, and economic factors in health care access.<sup>9</sup> 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.<sup>10</sup>

b. 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.<sup>11</sup> Numerous federal courts have found that federal sex discrimination statutes reach these forms of gender-based discrimination.<sup>12</sup> 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.”<sup>13</sup>

<sup>9</sup> 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.

<sup>10</sup> *Id.*

<sup>11</sup> 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. 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); *Tronetti v. Healthnet Lakeshore Hosp.*, No. 03-CV-0375E, 2003 WL 22757935 (W.D.N.Y. Sept. 26, 2003) (Title VII).

<sup>12</sup> 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).

<sup>13</sup> *Macy v. Holder*, E.E.O.C. App. No. 0120120821, 2012 WL 1435995, \*12 (Apr. 20, 2012).

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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.<sup>14</sup> 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.<sup>15</sup>

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."
- "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."<sup>16</sup>

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.

Callen-Lorde's very existence is a response to provider and systemic discrimination in healthcare as experienced by LGBTQ individuals and communities. So profound was the need for non-judgmental, quality primary care for LGBTQ populations, that we created our own center. Now, nearly 50 years later – when so many human and civil rights advances having been made – LGB and TGNB people still are being mistreated by providers. Sadly, Callen-Lorde's capacity to serve its communities is consistently being stretched. We firmly believe that the care we provide should be the norm and that true liberation will only come when the LGBTQ community and our families can adequately access culturally competent and comprehensive health care in all forms.

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<sup>14</sup> 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](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).

<sup>15</sup> 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*].

<sup>16</sup> Sharita Gruberg & 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/>.

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In the weeks leading up to the deadline for these comments, Callen-Lorde administered a short on-line survey to its patients, staff and community members. The survey confirmed what we know already: LGB and TBNB individuals still face discrimination in health care and are denied care as a result. We surveyed 58 individuals ranging in age from 22- 83 years old and more than 20 percent of respondents indicated that they either may have – or were – denied care by a provider because of the provider's religious or moral objections.

A select few of the written testimonies pulled from the survey are included in these comments.

## Testimonies of Transgender Discrimination

Kyle, 22-year-old transgender man and Callen-Lorde staff person stated: *"I have had psychiatrists refuse to see me because they are uncomfortable with my gender identity and transition. I also had a primary care provider who delayed referral to transition specialists for the same reason. It was very distressing to have my transition delayed and feel like my provider isn't there to help me progress. The psychiatrist denying care makes me worried about mental health professionals more generally and have to be very careful when seeking mental health services. As a person of transgender experience, if I saw signs up in health practices notifying patients of their ability to discriminate if they choose, I would be very hesitant to return. I would feel like I had no protection and a chance of not receiving adequate healthcare."*

Aaron, a, 29 transgender man and patient of Callen-Lorde stated: *"Where I grew up I could not find a provider to prescribe me hormones and during high school I was sent for a psych ER visit for suicidal ideation. One of the clinicians refused to see me and none of the hospital staff knew what transgender was. This was in 2005 in rural New Jersey. I did not receive treatment for my gender dysphoria and depression for many years because there were no providers who would work with me."*

Anonymous, 25 gender non-conforming person, stated: *"Doctors would either completely avoid my gender or would tell me they didn't 'understand it' and to go find a place that does. I was scared by that and never followed up on a different doctor until much later. Freedom of Speech doesn't mean freedom to oppress or discriminate."*

## c. 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.<sup>17</sup> 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.<sup>18</sup>

<sup>17</sup> 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>.

<sup>18</sup> Mirza, *supra* note 34.

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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.<sup>19</sup> Almost ten percent of LGB respondents reported that they had been denied necessary health care expressly because of their sexual orientation.<sup>20</sup> 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:

- 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.<sup>21</sup>
- Lesbian and bisexual women report poorer overall physical health than heterosexual women.<sup>22</sup>
- 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.<sup>23</sup>
- 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.<sup>24</sup>
- Bisexual people face significant health disparities, including increased risk of mental health issues and some types of cancer.<sup>25</sup>

## Testimonies of Sexual Orientation Discrimination

*Anonymous, 25-year-old cisgender female, stated "Doctor refused to give me an IUD because I am unmarried. I told her I wasn't trying to prevent a pregnancy because I'm a lesbian, but that I wanted the IUD to control painful periods. She told me she couldn't see me as a patient anymore. Luckily I found another provider relatively easily, but it was very upsetting to hear that my doctor refused to see me because of my sexuality."*

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

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<sup>19</sup> 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](http://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf).

<sup>20</sup> *Id.*

<sup>21</sup> 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/>.

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> 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>.

<sup>25</sup> 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>.

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immediate family or them [identifying as LGBTQ]”.<sup>26</sup> 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.<sup>27</sup>

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.<sup>28</sup> The World Professional Association for Transgender Health guidelines provide that gender-affirming interventions, when sought by transgender individuals, are medically necessary and part of the standard of care.<sup>29</sup> The American College of Obstetricians and Gynecologists warns that failure to provide gender-affirming treatment can lead to serious health consequences for transgender individuals.<sup>30</sup> 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.<sup>31</sup> The LGBTQ community is significantly at risk for sexual violence.<sup>32</sup> Eighteen percent of lesbian, gay, bisexual students have reported being forced to have sex.<sup>33</sup> Transgender women, particularly women of color, face high rates of HIV.<sup>34</sup>

<sup>26</sup> HUMAN RIGHTS WATCH, *supra* note 28.

<sup>27</sup> Mirza, *supra* note 34.

<sup>28</sup> *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).

<sup>29</sup> *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).

<sup>30</sup> *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>.

<sup>31</sup> Kates, *supra* note 37, at 4.

<sup>32</sup> 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.

<sup>33</sup> *Health Risks Among Sexual Minority Youth*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/healthyyouth/disparities/smy.htm> (last updated May 24, 2017).

<sup>34</sup> More than 1 in 4 transgender women are HIV positive. Kates, *supra* note 37, at 6.

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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.

### **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.<sup>35</sup> 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.<sup>36</sup> 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.<sup>37</sup> In order to ensure that patient decisions are based on free will, informed

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<sup>35</sup> TOM BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (4th ed. 1994); CHARLES LIDZ ET AL., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY (1984).

<sup>36</sup> BEAUCHAMP & CHILDRESS, *supra* note 58; Robert Zussman, *Sociological perspectives on medical ethics and decision-making*, 23 ANN. REV. SOC. 171-89 (1997).

<sup>37</sup> 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*

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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."<sup>38</sup> 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."<sup>39</sup> Similarly, pharmacists are called to respect the autonomy and dignity of each patient.<sup>40</sup>

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.<sup>41</sup> 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.' 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."<sup>42</sup>

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*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 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).

<sup>38</sup> *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>.

<sup>39</sup> *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](https://www.truthaboutnursing.org/research/codes/code_of_ethics_for_nurses_US.html).

<sup>40</sup> *Code of Ethics for Pharmacists*, AM. PHARMACISTS ASS'N (1994).

<sup>41</sup> 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>.

<sup>42</sup> *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, no maleficence, 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."<sup>43</sup> In addition, the proposed rule undermines principles of quality care. Health care should be safe, effective, patient-centered, timely, efficient, and equitable.<sup>44</sup> 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.<sup>45</sup> 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 living with 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.

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.<sup>46</sup> The latest

<sup>43</sup> Amy G. Bryant & Jonas J. Schwartz, *Why Crisis Pregnancy Centers Are Legal but Unethical*, 20 AM. MED. ASS'N J. ETHICS 269, 272 (2018).

<sup>44</sup> INST. OF MED., *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21<sup>ST</sup> 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>.

<sup>45</sup> *Id.*

<sup>46</sup> Holly Hedegaard M.D., et al. *Drug Overdose Deaths in the United States, 1999-2016*, NAT'L CTR. FOR HEALTH STATISTICS 1-8 (2017).

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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.<sup>47</sup>

The clear, evidence-based treatment standard for opioid use disorder (OUD) is medication-assisted treatment (MAT).<sup>48</sup> 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."<sup>49</sup> 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.<sup>50</sup> 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.<sup>51</sup> 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.<sup>52</sup> 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 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

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<sup>47</sup> *Vital Signs*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/vitalsigns/opioid-overdoses/>.

<sup>48</sup> 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>.

<sup>49</sup> World Health Organization, 19th WHO Model List of Essential Medicines (April 2015), [http://www.who.int/medicines/publications/essentialmedicines/EML2015\\_8-May-15.pdf](http://www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf)

<sup>50</sup> 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>].

<sup>51</sup> See James M. Chamberlain & Bruce L. Klein, *A Comprehensive Review of Naloxone for the Emergency Physician*, 12 AM. J. EMERGENCY MED. 650 (1994).

<sup>52</sup> 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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harm and do not increase drug use.<sup>53</sup> 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.<sup>54</sup>

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.”<sup>55</sup> 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.”<sup>56</sup> 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.<sup>57</sup> 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.”<sup>58</sup>

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.<sup>59</sup> 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.<sup>60</sup> 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.<sup>61</sup> The current Secretary of the Department has noted that expanding access to MAT is necessary to save lives and that it will be

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<sup>53</sup> 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>.

<sup>54</sup> 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](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).

<sup>55</sup> Lopez, *supra* note 75.

<sup>56</sup> Eric Eyre, *Trump officials seek opioid solutions in WV*, CHARLESTON GAZETTE-MAIL, May 9, 2017, [https://www.wvgazette.com/news/health/trump-officials-look-for-opioid-solutions-in-wv/article\\_52c417d8-16a5-59d5-8928-13ab073bc02b.html](https://www.wvgazette.com/news/health/trump-officials-look-for-opioid-solutions-in-wv/article_52c417d8-16a5-59d5-8928-13ab073bc02b.html).

<sup>57</sup> 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>.

<sup>58</sup> 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](https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf)

<sup>59</sup> 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>

<sup>60</sup> 42 C.F.R. §8.610.

<sup>61</sup> 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.j1550>; Alex Azar, Secretary, U.S. Dep’t of Health & Hum. Serv., Plenary Address to National Governors Association, (Feb. 24, 2018), <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/plenary-address-to-national-governors-association.html>.

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"impossible" to quell the opioid epidemic without increasing the number of providers offering the evidence-based standard of care.<sup>62</sup> 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.<sup>63</sup> 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.<sup>64</sup> 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 care from physicians who do not believe they have any obligations to refer their patients to other providers.<sup>65</sup>

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<sup>62</sup> Azar, *supra* note 84.

<sup>63</sup> 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 of Women's Health, *Lupus and women*, U.S. DEPT 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. DEPT OF HEALTH & HUM. SERV. (Jul. 13, 2016), <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=18>; Office of Minority Health, *Diabetes and Hispanic Americans*, U.S. DEPT OF HEALTH & HUM. SERV. (May 11, 2016), <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=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. DEPT OF HEALTH & HUM. SERV. (Aug. 25, 2017), <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=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. DEPT OF HEALTH & HUM. SERV. (Nov. 3, 2016), <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=31>.

<sup>64</sup> 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/>.

<sup>65</sup> 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/>.

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a. 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.<sup>66</sup> 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.<sup>67</sup>

b. 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.<sup>68</sup> Under the proposed rule, an insurance company could refuse to cover PrEP or PEP 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 regulations are overly broad, vague, and will cause confusion in the health care delivery system**

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<sup>66</sup> *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](https://www.cdc.gov/std/stats16/CDC_2016_STDS_Report-for508WebSep21_2017_1644.pdf).

<sup>67</sup> 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](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](https://www.unicef.org/aids/files/2009_position_paper_condoms_en.pdf).

<sup>68</sup> *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>.

# CALLEN-LORDE

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."<sup>69</sup> 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?

## 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.<sup>70</sup> 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.<sup>71</sup> 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.

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.<sup>72</sup> Instead, courts have held that the government has a compelling interest in ending discrimination 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

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<sup>69</sup> 83 Fed. Reg. 3894.

<sup>70</sup> 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>.

<sup>71</sup> *Id.*

<sup>72</sup> 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).

# CalLEN-LORDE

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."<sup>73</sup> The uncertainty regarding how the proposed rule will interact with non-discrimination laws is extremely concerning.

## Conclusion

Callen-Lorde Community Health Center 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 the following:

Nala Toussaint  
TGNB Health Advocacy Coordinator  
[ntoussaint@callen-lorde.org](mailto:ntoussaint@callen-lorde.org)  
212-271-7200 ext.7134

Kimberleigh Joy Smith, MPA  
Senior Director for Community Health Planning and Policy  
[ksmith@callen-lorde.org](mailto:ksmith@callen-lorde.org)  
212-271-7184

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<sup>73</sup> *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, slip op. at 46 (2014).

# Exhibit 84



Collaborating to  
Ensure a Healthy Ohio

March 27, 2018

Submitted via Federal eRulemaking Portal at <http://www.regulations.gov>

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

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

Dear Office for Civil Rights, Office of the Secretary, HHS:

On behalf of our 233 member hospitals and 13 health systems, the Ohio Hospital Association (OHA) appreciates the opportunity to provide feedback on the Office of Civil Rights (OCR) proposed rules ensuring the protection of statutory conscience rights in health care. Ohio's hospitals support the need to protect health care workers' deeply held religious beliefs and moral convictions.

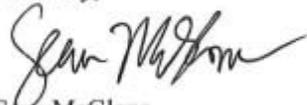
As health care organizations, Ohio hospitals' fundamental goal is to provide safe and effective care to all patients who present for care in the hospital, including those who present in the hospital emergency department. At the same time, conscience protections for health care professionals are long-standing under current law and hospitals have policies in place to accommodate differing religious and moral convictions of their workforce. Though OHA largely supports the goals to be achieved by the proposed rule, we have a concern that strict application or enforcement of the rule as proposed could result in unpredictable and adverse consequences for some patients. For example, the rule could be read to allow a health care professional to refuse to deliver care to a patient even in an emergency situation, based on the health care professional's religious beliefs or moral convictions.

OHA believes the needs of the patient must be met to the greatest extent possible in all cases. Accordingly, OHA believes there is a solution that will both respect and accommodate a caregiver's beliefs and moral convictions while at the same time ensuring patients get the care they need. Specifically, OHA suggests the rule require the caregiver to provide advance written notification of their religious beliefs or moral convictions to their employer prior to any such encounter, so that an accommodation of those beliefs can be made while also allowing for a developed contingency plan to be put in place to ensure patients get the timely and uninterrupted care they need. Such a requirement would also ensure that a patient in need of emergency care is not refused care by a caregiver whose beliefs do not permit them to care for the patient. And the requirement would allow the employer sufficient notice to put a plan in place to ensure the patient receives the necessary care, while accommodating the caregiver's beliefs, and without undue embarrassment for any of the parties.

Office for Civil Rights  
March 27, 2018  
Page 2

OHA appreciates your consideration of its proposed solution, which both respects the beliefs of caregivers and ensures all patients can receive whatever care they need in whatever circumstance they present themselves for care, including in cases of emergency.

Sincerely,

A handwritten signature in black ink, appearing to read "Sean McGlone". The signature is fluid and cursive, with the first name "Sean" being more prominent.

Sean McGlone  
Sr. V.P. & General Counsel

# Exhibit 85



March 27, 2018

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

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

To Whom It May Concern:

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

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

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

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

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



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

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

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

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

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

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

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

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

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

<sup>3</sup> See Rule *supra* note 1, at 12.

<sup>4</sup> Hardaway, Lisa, *Settlement Reached in Case of Lambda Legal Lesbian Client Denied Infertility Treatment by Christian Fundamentalist Doctors*, Lambda Legal, September 29, 2009, accessed at [https://www.lambdalegal.org/news/ca\\_20090929\\_settlement-reached](https://www.lambdalegal.org/news/ca_20090929_settlement-reached).

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



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

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

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

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

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

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

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

<sup>8</sup> Stein, Rob, *Religious hospitals’ restrictions sparking conflicts, scrutiny*, The Washington Post, January 3, 2011, accessed at [https://www.washingtonpost.com/health-environment-science/religious-hospitals-restrictions-sparking-conflicts-scrutiny/2011/01/03/ABVVxmD\\_story.html?utm\\_term=.cc34abebb928](https://www.washingtonpost.com/health-environment-science/religious-hospitals-restrictions-sparking-conflicts-scrutiny/2011/01/03/ABVVxmD_story.html?utm_term=.cc34abebb928)

<sup>9</sup> 42 U.S.C. § 1295dd(a)-(c) (2003).

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



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

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

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

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

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

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

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

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

<sup>11</sup> The notice requirement is spelled out in section 88.5 of the proposed rule.

<sup>12</sup> See, for example, Freedman, Lori R., Luciana E. Hebert, Molly F. Battistelli, and Debra B. Stulberg, *Religious hospital policies on reproductive care: what do patients want to know?* American Journal of Obstetrics & Gynecology 218, no. 2 (2018): 251-e1, accessed here: [http://www.ajog.org/article/S0002-9378\(17\)32444-4/fulltext](http://www.ajog.org/article/S0002-9378(17)32444-4/fulltext); also Guialhi, Maryam, Jeanelle Sheeder, and Stephanie Teal, *Are women aware of religious restrictions on reproductive health at Catholic hospitals? A survey of women's expectations and preferences for family planning care*, Contraception and Stulberg, D., et al, accessed here: [http://www.contraceptionjournal.org/article/S0010-7824\(14\)00358-8/fulltext](http://www.contraceptionjournal.org/article/S0010-7824(14)00358-8/fulltext); *Do women know when their hospital is Catholic and how this affects their care? Restrictions in Catholic Hospitals (PARRCH) national survey*, Contraception, Volume 96, Issue 4, 268-269, accessed here: [http://www.contraceptionjournal.org/article/S0010-7824\(17\)30235-4/fulltext](http://www.contraceptionjournal.org/article/S0010-7824(17)30235-4/fulltext); a

<sup>13</sup> 42 U.S.C. § 2000e-2 (1964).

<sup>14</sup> *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>.

<sup>15</sup> See *id.*

<sup>16</sup> See, e.g., *supra* note 2.



management she needed because the hospital objected to this care.<sup>17</sup> Another woman experiencing pregnancy loss was denied care for 10 days at a religiously affiliated hospital outside Chicago, Illinois.<sup>18</sup> In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital, which refused to provide him a hysterectomy.<sup>19</sup> Another patient in Arkansas endured a number of dangerous pregnancy complications and could not risk becoming pregnant again. She requested a sterilization procedure at the time of her Cesarean delivery, but her Catholic hospital provider refused to give her the procedure.<sup>20</sup> Another woman was sent home by a religiously affiliated hospital with two Tylenol after her water broke at 18 weeks of pregnancy. Although she returned to the hospital twice in the following days, the hospital did not give her full information about her condition and treatment options.<sup>21</sup>

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

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

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

<sup>17</sup> See Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 6 (2018), <https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf>.

<sup>18</sup> See Julia Kaye, et al., *Health Care Denied*, AM. CIVIL LIBERTIES UNION 1, 12 (2016), [https://www.aclu.org/sites/default/files/field\\_document/healthcaredenied.pdf](https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf).

<sup>19</sup> See Kira Shepherd, et al., *supra* note 19, at 29.

<sup>20</sup> See *The Patient Should Come First: Refusals to Provide Reproductive Health Care*, NAT'L WOMEN'S L. CTR. (2017), <https://nwlc-civ49tixgw5lbbw.stackpathdns.com/wp-content/uploads/2017/05/Refusals-FS.pdf>; Sandhya Somashekhar, *A Pregnant Woman Wanted her Tubes Tied. Her Catholic Hospital Said No.*, WASH. POST (Sept. 13, 2015), [https://www.washingtonpost.com/national/a-pregnant-woman-wanted-her-tubes-tied-her-catholic-hospital-said-no/2015/09/13/bd2038ca-57ef-11e5-8bb1-b488d231bba2\\_story.html?utm\\_term=.8e022b364b75](https://www.washingtonpost.com/national/a-pregnant-woman-wanted-her-tubes-tied-her-catholic-hospital-said-no/2015/09/13/bd2038ca-57ef-11e5-8bb1-b488d231bba2_story.html?utm_term=.8e022b364b75).

<sup>21</sup> See Kira Shepherd, et al., *supra* note 19, at 27.

<sup>22</sup> In 2016, an estimated 11 percent of women between the ages of 19 to 64 were uninsured. Single mothers, women of color, and low-income women are more likely to be uninsured. *Women's Health Insurance Coverage*, KAISER FAMILY FOUND. 1, 3 (Oct. 31, 2017), <http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage>.

<sup>23</sup> Athena Tapales et al., *The Sexual and Reproductive Health of Foreign-Born Women in the United States*, CONTRACEPTION 8, 16 (2018), [http://www.contraceptionjournal.org/article/S0010-7824\(18\)30065-9/pdf](http://www.contraceptionjournal.org/article/S0010-7824(18)30065-9/pdf); Nat'l Latina Inst. For Reproductive Health & Ctr. For Reproductive Rights, *Nuestra Voz, Nuestra Salud, Nuestro Texas: the Fight for Women's Reproductive Health in the Rio Grande Valley* 1, 7 (2013), <http://www.nuestrotexas.org/pdf/NT-spread.pdf>.

<sup>24</sup> Since 2010, eighty-three rural hospitals have closed. See *Rural Hospital Closures: January 2010 – Present*, THE CECIL G. SHEPS CTR FOR HEALTH SERVS. RES. (2018), <http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/>.

<sup>25</sup> See Kira Shepherd, et al., *supra* note 19, at 12.

<sup>26</sup> See *id.* at 10-13.



of both the types of entities using religious beliefs to discriminate and the number of religiously affiliated entities that provide health care and related services.<sup>27</sup>

### **7. The Department is abdicating its responsibility to patients**

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

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

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

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

### **Conclusion**

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

<sup>27</sup> See, e.g., *Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care*, AM. CIVIL LIBERTIES UNION & MERGER WATCH (2013), <https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf>.

<sup>28</sup> See Nina Martin, *Black Mothers Keep Dying After Giving Birth. Shalon Irving's Story Explains Why*, NPR (Dec. 2017), <https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irving-story-explains-why>.

<sup>29</sup> See, e.g., *When Health Care Isn't Caring*, LAMBDA LEGAL 5 (2010), [https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report\\_when-health-care-isnt-caring\\_1.pdf](https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring_1.pdf).

<sup>30</sup> See Jaime M. Grant et al., *Injustice at Every Turn: a Report of the National Transgender Discrimination Survey*, NAT'L GAY AND LESBIAN TASK FORCE & NAT'L CTR. FOR TRANSGENDER EQUALITY, [http://www.thetaskforce.org/static\\_html/downloads/reports/reports/ntds\\_full.pdf](http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf).

<sup>31</sup> See, e.g., Rule, *Supra* note 1, at 3888-89.

# Exhibit 86

**XAVIER BECERRA**  
*Attorney General*

*State of California*  
**DEPARTMENT OF JUSTICE**



1300 I STREET, SUITE 125  
P.O. BOX 944255  
SACRAMENTO, CA 94244-2550  
Public: (916) 445-9555

March 27, 2018

***Via Federal eRulemaking Portal***

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

RE: Comments on Proposed Rule: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (Jan. 26, 2018), RIN 0945-ZA03

Dear Secretary Azar:

I write today to urge the U.S. Department of Health and Human Services (HHS) to withdraw the Proposed Rule: *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 83 Fed. Reg. 3,880 (Jan. 26, 2018), RIN 0945-ZA03 (“Proposed Rule” or “Rule”). This Proposed Rule would impede access to care and create barriers to patients’ exercise of their rights. Further, it undermines HHS’s mission to “enhance the health and well-being of all Americans, by providing for effective health and human services.”

As California’s Attorney General, I have a constitutional duty to protect Californians, by safeguarding their health and safety, and defending the State’s laws. Cal. Const., art. V, § 13. This Rule is an unlawful attempt by the Administration to proceed without congressional authority and is in conflict with the Constitution and multiple existing laws. If implemented, it will have significant negative impacts on States; their residents, including women, LGBTQ individuals, and other marginalized populations; and numerous entities in the State that receive federal healthcare funding. Thus, I urge that the Rule be withdrawn.

Among its many problems, the Proposed Rule threatens the removal of *all* federal healthcare funds from recipients, including the State, deemed not in compliance with the Rule. Jeopardizing this funding would have significant effects on California families as these funds support public healthcare programs and public health initiatives.

The Rule would also create rampant confusion about basic patient rights and federally entitled healthcare services, while discouraging providers from providing safe, legal care. The Rule not only permits any individual, entity, or provider to deny basic healthcare services—

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including emergency care—but also discharges a provider from the duties to cite evidence to support the denial of services, to notify a supervisor of the denial of services, and to provide notice or alternative options to patients that may want to seek services from another provider. There is little evidence that in drafting the Rule, HHS considered the impact to patients. 83 Fed. Reg. at 3,902; *Id.* at 3,902-3,918 (failing to mention, let alone quantify the impact of this Rule on patients). Moreover, the effects of the Proposed Rule would be widespread as it implicates “any program or activity with an *articulable connection* to a procedure, health service, health program, or research activity,” 83 Fed. Reg. at 3,923. The consequences of this overbroad Rule will disproportionately affect the most vulnerable populations, and in particular, could have a chilling effect on those seeking to exercise their constitutionally protected healthcare rights.

***a. The Proposed Rule Targets the State of California and its Interests in Protecting its Residents, Healthcare Industry, and Consumer Protections***

The Proposed Rule particularly aims to upend and target California’s concerted efforts to balance the rights of patients and providers. The Rule suggests that further federal guidance is needed because of an increase in lawsuits against state and local laws; however, HHS puts forth little actual evidence. In targeting California’s carefully crafted laws, the Rule tramples on the rights of patients and takes aim at California specifically.

First, the Rule references two pending federal lawsuits stemming from the California Department of Managed Health Care’s (DMHC) August 22, 2014 letters issued to health plans regarding abortion coverage. 83 Fed. Reg. at 3,889 (citing *Foothill Church v. Rouillard*, No. 2:15-cv-02165-KJM-EFB, 2016 WL 3688422 (E.D. Cal. July 11, 2016); *Skyline Wesleyan Church v. Cal. Dep’t of Managed Health Care*, No. 3:16-cv-00501 (S.D. Cal. 2016)). Then, noting that HHS’s Office of Civil Rights (OCR) previously closed three complaints against DMHC, the Rule states that OCR’s finding that the Weldon Amendment had not been violated by California law requiring that health plans include coverage for abortion “no longer reflects the current position of HHS, OCR, or the HHS office of the General Counsel.” 83 Fed. Reg. at 3,890. This reversal in the agency’s interpretation of the Weldon Amendment is apparently based on a misreading of the law, and is arbitrary and capricious. 5 U.S.C. § 706; *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974); *Jicarilla Apache Nation v. U.S. Dep’t of Interior*, 613 F.3d 1112, 1119 (D.C. Cir. 2010). Moreover, HHS cites no authority that permits it to reverse its position in this manner. Later, the Proposed Rule—apparently referencing California’s Reproductive Freedom, Accountability, Comprehensive Care, and Transparency (FACT) Act—announces that even requiring a clinic to post notices mentioning the existence of government programs that include abortion services would be considered a referral for abortion under the Weldon Amendment and Section 1303 of the Affordable Care Act.<sup>1</sup> 83 Fed. Reg. at 3,895. Such a broad definition of “refer for” is

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<sup>1</sup> Section 1303 prohibits the use of certain Federal funds to pay for abortion coverage by qualified health plans. 42 U.S.C. § 18023(b)(2)(A). However, Section 1303 permits an issuer to charge and collect \$1 per enrollee per month for coverage of abortion services so long as the

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unsupported by the plain language of these statutes, and is thus outside of HHS's delegated authority. *See infra* at 3-4.

HHS's attempt to redefine the law threatens California's sovereign and quasi-sovereign interests in regulating healthcare, criminal acts, and California-licensed entities and professionals. *See also New York v. United States*, 505 U.S. 144, 155-56 (1992); Cal. Bus. & Prof. Code §§ 101, 101.6, 125.6 (providing that a California licensee is subject to disciplinary action if he or she refuses to perform the licensed activity or aids or incites the refusal to perform the licensed activity by another licensee because of another person's sex, race, color, religion, ancestry, national origin, disability, medical condition, genetic information, marital status, sexual orientation, citizenship, primary language, or immigration status); 733 (a California licensee "shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient"); 2761; Cal. Penal Code § 13823.11(e) and (g)(4); Cal. Health & Saf. Code §§ 10123.196, 1367.25, 123420(d); Cal. Civ. Code § 51; *No. Coast Women's Care Med. Group, Inc. v. San Diego County Superior Court*, 44 Cal.4th 1145 (2008). "[T]he structure and limitations of federalism . . . allow the States great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) (internal quotation marks and citation omitted).

Furthermore, the estimated costs and benefits of the Rule do not justify it, but rather reveal it to be greatly wasteful of public funds. HHS admits that OCR has received only 44 complaints over the last 10 years of alleged instances of violations of conscience rights. 83 Fed. Reg. at 3,886. Yet, as HHS further admits, it will cost nearly \$1.4 billion over the first years to implement the Rule, and for the affected entities to comply with the new assurance and certification requirements. *Id.* at 3,902, 3,912-13. Meanwhile, HHS disclaims any ability to quantify the benefits. *Id.* at 3,902, 3,916-17.

In undercutting important patient protections and creating barriers to care, the Proposed Rule not only oversteps on policy grounds, but also has numerous legal deficiencies. Below I address many, but by no means all, of these deficiencies.

***b. The Proposed Rule Exceeds Congressional Authority***

As a threshold matter, the Proposed Rule exceeds the authority of the statutes it cites, and therefore violates the Administrative Procedure Act. 5 U.S.C. § 706. Nothing in the Church Amendments, the Coats-Snowe Amendment, the Weldon Amendment, or other statutes permits HHS to redefine the terms used in these underlying statutory schemes. Yet the Proposed Rule has characterized numerous terms, including "assist in the performance," "health care entity," and "referral or refer for," so broadly as to materially alter well-established statutory language.

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funds are deposited in a separate account, maintained separately, and used only for abortion services.

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For example, contrary to the implementing statutes, the Proposed Rule suggests that “assist in the performance” encompasses participating in “any” program or activity with an “articulable connection” to a procedure, health service, health program, or research activity, including “counseling, referral, training, and other arrangements for the procedure, health service, health program, or research activity.” 42 Fed. Reg. at 3,923. Only the Church Amendments refer to “assist in the performance” of an activity, and nothing in that statutory scheme envisions the broad definition in the Proposed Rule. 42 U.S.C. § 300a-7. That Congress specifically references “to counsel” in a separate Church Amendment provision, “training” in the Coats-Snowe Amendment, and “refer for” in the Weldon Amendment confirms that the Proposed Rule’s definition of “assist in the performance” should not include these additional activities. Reading and interpreting the statutes in these ways will allow for unlawful refusals of care.

Similarly, “health care entity” is defined in the Coats-Snowe Amendment, the Weldon Amendment, and the Affordable Care Act, yet the Proposed Rule goes beyond these definitions to include “health care personnel,” as distinct from a “health care professional,” such as a doctor or nurse. 42 Fed. Reg. at 3,924. Therefore, it appears that, under the Proposed Rule, even someone like a receptionist at a doctor’s office could refuse to provide services, including making an appointment for a patient, based on his or her moral objections. By expanding “health care entity” to cover personnel, “health care professional” is rendered superfluous, contrary to the rules of statutory interpretation. Additionally, the Proposed Rule’s definition of “health care entity” is overbroad, given that it includes “a plan sponsor, issuer, or third-party administrator, or any other kind of health care organization, facility, or plan.” 42 Fed. Reg. at 3,924. In short, the Rule’s redefinition of “health care entity” is arbitrary and capricious, as it runs counter to OCRs’ previous, well-reasoned interpretation of the term.

The Proposed Rule’s definition of “referral or refer for” is particularly broad, suggesting that “any method,” even posting of notices, would be considered a “referral.” 42 Fed. Reg. at 3,924. These new exceptions created by the Rule are not envisioned by any federal statute, and would permit healthcare professionals to elude the scope of state laws protecting a patient’s rights to healthcare services.

*c. The Proposed Rule is Contrary to Law*

The Rule also violates the U.S. Constitution in several respects, including conflicting with the Spending Clause, the Due Process Clause, the Establishment Clause, and Separation of Powers. Furthermore, the Rule conflicts with several federal statutes. 5 U.S.C. § 706.

The Proposed Rule violates the Spending Clause because it (a) coerces states and their entities to follow the Proposed Rule or lose billions of dollars in federal funds; (b) is vague and does not provide adequate notice of what specific action or conduct, if engaged in, will result in the withholding of federal funds; (c) constitutes post-acceptance conditions on federal funds; and (d) is not rationally related to the federal interest in the particular program that receives federal funds. *See NFIB v. Sebelius*, 567 U.S. 519, 582-83 (2012); *Pennhurst State Sch. and Hospital v.*

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*Halderman*, 451 U.S. 1, 17 (1981) (If Congress desires to condition the States' receipt of federal funds, it "must do so unambiguously . . . enabl[ing] the States to exercise their choice knowingly, cognizant of the consequences of their participation"); *South Dakota v. Dole*, 483 U.S. 203 (1987); *Massachusetts v. United States*, 435 U.S. 444, 461 (1978) (plurality op.) (conditioning federal grants illegitimate if unrelated "to the federal interest in particular national projects or programs"). The Rule is tantamount to "a gun to the head." *NFIB*, 567 U.S. at 581. If California opts out of complying with the Rule (or even "[i]f there appears to be a failure or threatened failure to comply"), it "would stand to lose not a relatively small percentage" of its existing federal healthcare funding, but all of it. *Id.*; 83 Fed. Reg. at 3,931.

It violates the Due Process Clause, as well, because it is unconstitutionally vague and permits OCR to immediately withhold billions of federal funding, if there "appears to be a failure" to comply, or just an apparent "threatened" failure to comply, and there is no review process. 83 Fed. Reg. at 3,931; *see Mathews v. Eldridge*, 424 U.S. 319, 349 (1976) ("The essence of due process is the requirement that a person in jeopardy of serious loss be given notice of the case against him and opportunity to meet it.") (internal alterations and quotations omitted); *Goldberg v. Kelly*, 397 U.S. 254 (1970). To satisfy due process, the law must (1) "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly," and (2) "provide explicit standards for those who apply them." *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). This Proposed Rule does not meet either of these requirements.

The Rule also constitutes an undue burden on a woman's decision to terminate her pregnancy before viability. *See Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016); *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833 (1992) (plurality op.). The net effect of this rule will result in women being denied access to crucial information and even necessary treatment, including lawful abortions.

The Proposed Rule violates the Establishment Clause by accommodating religious beliefs to such an extent that it places an undue burden on third parties—patients. *Estate of Thornton v. Caldor*, 472 U.S. 703, 710 (1985); *Cutter v. Wilkinson*, 544 U.S. 709, 722 (2005) ("[A]n accommodation must be measured so that it does not override other significant interests"); *Santa Fe Indep. Sch. Dist. v. Doe*, 530 U.S. 290 (2000); *Lee v. Weisman*, 505 U.S. 557 (1992). Furthermore, the Proposed Rule constitutes excessive government entanglement with religion. *Larkin v. Grendel's Den*, 459 U.S. 116, 122-27 (1982); *Williams v. California*, 764 F.3d 1002, 1015 (9th Cir. 2014); *see also Larson v. Valente*, 456 U.S. 228, 244 (1982); *Kiryas Joel Village Sch. Dist. v. Grument*, 512 U.S. 687, 703 (1994) ("[G]overnment should not prefer . . . religion to irreligion").

Last, the Proposed Rule violates the Separation of Powers. U.S. Const. art. I, § 8, cl. 1; *Dole*, 483 U.S. at 206; *Clinton v. City of New York*, 524 U.S. 417, 438 (1998). Although *Congress* may attach conditions to receipt of federal funds, the executive branch cannot "amend[] parts of duly enacted statutes" after they become law, including to place conditions on

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receipt of federal funds. *Clinton*, 524 U.S. at 439. HHS's attempt to broaden those statutes is thus a violation of the Separation of Powers.

In addition to these Constitutional violations, the Proposed Rule conflicts with several federal statutes and is written so broadly it could implicate others. First, the Proposed Rule clashes with several provisions of the Affordable Care Act, most notably section 1554, which prohibits the Secretary of HHS from creating barriers to healthcare, and section 1557, which prohibits discrimination in health programs or activities. 42 U.S.C. §§ 18114, 18116 (2015). Second, the Proposed Rule fails to reconcile its provisions with Title VII and the body of case law that has developed with regard to balancing religious freedoms and consumer rights. 42 U.S.C. § 2000e-2(e); *Sutton v. Providence St. Joseph Med. Ctr.*, 192 F.3d 826, 830 (9th Cir. 1999); *Peterson v. Hewlett Packard Co.*, 358 F.3d 599, 606-607 (9th Cir. 2004); *Opuku-Boateng v. State of California*, 95 F.3d 1461 (9th Cir. 1996). Third, the Proposed Rule contravenes Title X of the Public Health Services Act, 42 U.S.C. §§ 300-300a-6, which provides federal funding for family-planning services. Lastly, the Proposed Rule disregards the Emergency Medical Treatment & Labor Act (EMTALA), commonly known as the Patient Anti-Dumping Act, enacted by Congress in response to growing concern about the provision of adequate medical services to individuals, particularly the indigent and the uninsured, who sought care from hospital emergency rooms. 42 U.S.C. § 1395dd(a) (1986); *Jackson v. East Bay Hosp.*, 246 F.3d 1248, 1254 (9th Cir. 2001) (citation omitted).

To reiterate, the Proposed Rule fails to account for its potential impact on States and their citizens. The Rule will have damaging, irreparable repercussions for certain patient populations including women, LGBTQ individuals, and others. Even if OCR concludes, after an investigation, that a provider should have provided certain services that were denied for claimed religious or moral reasons, it will be too late for the patient who was wrongly deprived of that necessary care. As California knows from experience, OCR could take years to conduct an investigation; however, any correction at the end of that process would be inadequate for the patient whose healthcare has been compromised. This will be made worse by providers who are fearful of the federal government's enforcement of the Rule and threatened loss of funds, and who instead of treating a patient or providing a referral, will simply chose not to provide particular services, reducing access to care.

For the reasons set forth above, California strongly opposes the Proposed Rule and urges that it be withdrawn.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Xavier Becerra', is written over a faint, illegible background.

XAVIER BECERRA  
Attorney General of California

# Exhibit 87

**ATTORNEYS GENERAL OF NEW YORK, CONNECTICUT, DELAWARE, DISTRICT OF  
COLUMBIA, HAWAII, ILLINOIS, IOWA, MAINE, MARYLAND, MASSACHUSETTS,  
MINNESOTA, NEW JERSEY, NEW MEXICO, OREGON, PENNSYLVANIA, RHODE  
ISLAND, VERMONT, VIRGINIA, WASHINGTON**

March 27, 2018

**Via Federal eRulemaking Portal**

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

Re: Proposed Rule: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority [Department of Health and Human Services, Office for Civil Rights RIN 0945-ZA03]

The undersigned State Attorneys General submit these comments to urge the Department of Health and Human Services (“HHS”) to withdraw the proposed rule, “Protecting Statutory Conscience Rights in Health Care; Delegations of Authority” (the “Proposed Rule”).<sup>1</sup> HHS has proposed to codify a sweeping and overbroad right that would allow individuals and entire institutions to deny lawful and medically necessary care to patients for “religious, moral, ethical, or other reasons.” This Proposed Rule is unsupported by the federal health care conscience laws it purports to implement; conflicts with federal statutes regarding emergency health care, religious accommodations, and comprehensive family planning services; undermines the States’ health care policies and laws; would lead to status-based discrimination against patients; and would violate both the Spending Clause and the Establishment Clause of the United States Constitution. The Proposed Rule impermissibly seeks to coerce state compliance with its unlawful requirements by threatening to terminate billions of dollars in federal health care funding if at any point HHS determines that a state has failed—or even “threatened” to fail—to comply with the Proposed Rule’s extensive mandates.

If adopted, the Proposed Rule would effectuate a substantial change in the delivery of health care, and it would do so at the expense of not only employers and states, but also of patients whose access to medically necessary care would be seriously threatened by the Proposed Rule. At a time when many Americans are struggling to obtain affordable health care, the Proposed Rule would reduce access to health care by allowing a vast new set of individuals and institutions to opt out of providing that care. It would also unnecessarily decrease the information patients receive about their health care options, undermining their ability to choose the best options for their own health care. It would impose particularly onerous burdens on marginalized patients who already

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<sup>1</sup> 83 Fed. Reg. 3880 (Jan. 26, 2018).

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confront discrimination in obtaining health care. It would do so needlessly because existing federal and state laws already provide a time-tested, established framework that balances respect for religious freedom with the rights and needs of patients, employers, and states.

The Proposed Rule prioritizes providers over patients. If implemented, the Proposed Rule will enable health care workers to refuse to provide life-saving care without notice to their employers—and to the detriment of patients—and impose massive burdens on both private and public institutions. As officials of States entrusted with the power to protect the health, safety, and welfare of the public, we urge that the Proposed Rule be withdrawn.

## **I. Background**

The Proposed Rule purports to implement a litany of federal statutes concerning conscience objections in health care.<sup>2</sup> Several of these statutes concern behavior by state governments. Generally speaking, the statutes concerning state behavior relate to the procedures of: abortion and sterilization; assisted suicide, euthanasia, and mercy killing; and counseling and referral.<sup>3</sup>

### *(A) Three Long-standing Statutes Concern Objections to Abortion and Sterilization.*

The Church Amendments, originally passed in the 1970s and now codified at 42 U.S.C. § 300a-7, provide in relevant part that:

1. the receipt of any grant, contract, loan, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act does not obligate any individual “to perform or assist in the performance of any sterilization procedure or abortion” if doing so would be contrary to the individual’s religious beliefs or moral convictions;
2. entities that receive a grant, contract, loan, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act cannot discriminate against physicians or health personnel because they assisted in a sterilization procedure or abortion, because they refused to participate in a sterilization procedure or abortion on the grounds of religious beliefs or moral

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<sup>2</sup> 83 Fed. Reg. at 3881-86.

<sup>3</sup> Additional statutes that may apply to states that are not discussed in this section include: 29 U.S.C. § 669(a)(5)-1 (concerning occupational illness examinations and tests); 42 U.S.C. §§ 290bb-36(f), 5106i (concerning medical service or treatment, including suicide assessment, early intervention, and treatment services, for youth whose parents or guardians object based on religious beliefs or, in certain cases, moral objections); 42 U.S.C. §§ 1320a-1, 1320c-11, 1395i-5, 1395x(e), 1395x(y)(1), 1396a(a), 1397j-1(b), 5106ia(2)-1 (concerning certain exemptions from law and standards for religious nonmedical health care institutions and “an elder’s right to practice his or her religion through reliance on prayer alone for healing” in certain cases); and 42 U.S.C. § 1396s(c)(2)(B)(ii) (concerning pediatric vaccination).

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- convictions, or because of their religious beliefs or moral convictions regarding sterilization or abortion;
3. entities that receive a grant or contract for biomedical or behavioral research cannot discriminate against physicians or health personnel because they assisted in any lawful health service or research activity, because they refused to do so on the grounds of religious beliefs or moral convictions, or because of their religious beliefs or moral convictions regarding the service or activity;
  4. HHS's funding of a health service program or research activity does not obligate any individual to "perform or assist in the performance of" any part of that health service program or research activity if contrary to the individual's religious beliefs or convictions; and
  5. entities that receive a grant, contract, loan, loan guarantee, or interest subsidy under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 cannot discriminate against applicants for training or study based on "the applicant's reluctance, or willingness, to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations contrary to or consistent with the applicant's religious beliefs or moral convictions."

The Coats-Snowe Amendment, passed in 1996 and codified at 42 U.S.C. § 238n, prohibits state governments that receive federal funds, among others, from discriminating against:

1. any health care entity that refuses to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions;
2. any health care entity that refuses to make arrangements for any of the activities specified in paragraph (1); or
3. any health care entity that attends (or attended) a post-graduate physician training program, or any other program of training in the health professions, that does not (or did not) perform induced abortions or require, provide or refer for training in the performance of induced abortions, or make arrangements for the provision of such training.

The Weldon Amendment, an appropriations rider first passed in 2004 and that has been attached to the Labor, Health and Human Services, Education, and Related Agencies Appropriations Act every year since, states in relevant part that none of the funds appropriated in the Act may be made available to any state government if it discriminates against any "institutional or individual health care entity" because it "does not provide, pay for, provide coverage of, or refer for abortions."<sup>4</sup>

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<sup>4</sup> The citation for the 2017 appropriations bill's Weldon Amendment is Consolidated Appropriations Act of 2017, Public Law 115-31, 131 Stat. 135, 562.

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*(B) Two Statutes Concern Objections to Assisted Suicide, Euthanasia, and Mercy Killing.*

Section 1553 of the Affordable Care Act, codified at 42 U.S.C. § 18113, proscribes state governments that receive federal funding under the Affordable Care Act from discriminating against an “individual or institutional health care entity on the basis that the entity does not provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing.”<sup>5</sup>

A statutory provision applying to state-administered Medicaid programs, 42 U.S.C. § 14406, clarifies that the advanced directives requirements applicable to those programs, codified at 42 U.S.C. § 1396a(w), do not require a provider, organization, or employee of a provider or organization “to inform or counsel any individual regarding any right to obtain an item or service furnished for the purpose of causing, or the purpose of assisting in causing, the death of the individual, such as by assisted suicide, euthanasia, or mercy killing or to apply to or to affect any requirement with respect to a portion of an advance directive that directs the purposeful causing of, or the purposeful assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing.”

*(C) A Medicaid Managed Care Organization Statute Concerns Objections to Counseling or Referral.*

A statutory provision related to state-administered Medicaid programs, 42 U.S.C. § 1396u-2(b)(3)(B), explains that a Medicaid managed care organization is not required “to provide, reimburse for, or provide coverage of, a counseling or referral service if the organization objects to the provision of such service on moral or religious grounds” and “makes available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization adopts a change in policy regarding such a counseling or referral service.”

**II. The Proposed Rule Exceeds HHS’s Authority under the Referenced Statutes by Adopting Excessively Broad Definitions of Statutory Text.**

The Proposed Rule states that “the statutory provisions and the regulatory provisions contained in [the Proposed Rule] are to be interpreted and implemented broadly to effectuate their protective purposes.”<sup>6</sup> In HHS’s attempt to broaden what it views as the referenced statutes’ purposes, however, it has ventured far beyond the text of those statutes and the bounds of the statutory authority Congress delegated to it. HHS has done this by proposing excessively broad definitions of statutory terms, at least one of which is already more narrowly defined by the statutes themselves.

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<sup>5</sup> 42 U.S.C. § 18113(a).

<sup>6</sup> 83 Fed. Reg. at 3923.

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*(A) The Proposed Rule’s Definition of “Assist in the Performance” Is Excessively Broad.*

The Proposed Rule aims to enforce “[f]ederal health care conscience and associated anti-discrimination laws,” which allow certain individuals and entities to “refuse to perform, assist in the performance of, or undergo” health care services or research “to which they may object for religious, moral, ethical, or other reasons.”<sup>7</sup> In implementing this aim, the Proposed Rule adopts a definition of “**assist in the performance**” that is untethered from and unsupported by the statutory text. HHS proposes that this common-sense phrase actually “means to participate in any program or activity with an *articulable connection* to a procedure, health service, health program, or research activity, so long as the individual involved is a part of the workforce of a Department-funded entity. This includes but is not limited to counseling, referral, training, and other arrangements for the procedure, health service, health program, or research activity.”<sup>8</sup>

The Proposed Rule’s overly broad definition of “assist in the performance”—which requires only an “articulable connection” to a procedure, health service, health program, or research activity—is intended to capture acts with only a remote connection to a given medical procedure. Indeed, it expressly includes “counseling, referral, training, and other arrangements for the procedure, health service, health program, or research activity.” This strained definition is much broader than that contemplated by Congress, as evidenced by the text of the statutes the Proposed Rule purports to implement. Indeed, the statutory text when read as a whole demonstrates that Congress made clear textual distinctions when discussing the performance of a medical procedure and other services, such as counseling. This Proposed Rule blurs that Congressionally-adopted distinction. For example, the first four subsections of the Church Amendments refer to the performance or assistance in the performance of a particular activity or activities.<sup>9</sup> The fifth and last, however, applies to “reluctance, or willingness, to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations...”<sup>10</sup> When Congress intended to include activities such as counseling in its mandates, it did so. Likewise, the Coats-Snowe Amendment extends to those who refuse “to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions,” among others, indicating that Congress again knew how to—and did—include training and referrals in its mandates when it desired to do so.<sup>11</sup> The Weldon Amendment is yet another example of how Congress’s drafting decisions reflect its intent, as the Amendment reaches entities that do not “provide, pay for, provide coverage of, or refer for abortions.”<sup>12</sup> Congress mentions “referral” separate and apart from “assistance in the

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<sup>7</sup> 83 Fed. Reg. at 3923.

<sup>8</sup> *Id.* (emphasis added).

<sup>9</sup> 42 U.S.C. §§ 300a-7(b)-(d).

<sup>10</sup> 42 U.S.C. § 300a-7(e).

<sup>11</sup> 42 U.S.C. § 238n(a)(1); *see also* 42 U.S.C. § 238n.

<sup>12</sup> Consolidated Appropriations Act of 2017, Pub. L. 115-31, 131 Stat. 135, 562.

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performance” in at least five other statutory provisions that the Proposed Rule claims to implement and to which HHS seeks to apply this definition.<sup>13</sup> Such an application to these statutes would make the statutory text superfluous and flout the authority delegated to HHS by Congress.

*(B) The Proposed Rule’s Definition of “Health Care Entity” Is Excessively Broad.*

The Proposed Rule would apply the protections of the referenced statutes not only to individual health care professionals, but also to other “health care entities” on the basis of their “religious, moral, ethical, or other” objections.<sup>14</sup> The Proposed Rule’s definition of “**health care entity**” extends far broader than the statutory text it professes to interpret, including “health care personnel” beyond health care professionals like doctors and nurses, laboratories, and health plan sponsors, issuers, and third-party administrators. The Coats-Snowe Amendment, the Weldon Amendment, and the Affordable Care Act each define “health care entity,” and none of the statutory definitions is as broad as the one contemplated by the Proposed Rule.<sup>15</sup>

None of the statutory definitions, for example, include “health care personnel” as a category distinct from “an individual physician or other health care professional.” Including “health care personnel” in conjunction with the broad definition of “assist in the performance” could force an employer to plan its employee schedules around not only doctors and nurses who may be asked to perform or assist in the performance of a procedure, but also around a receptionist who may otherwise have to schedule an appointment for that procedure. This would not only impose significant burdens on employers, but it would also write out of the statutory texts altogether those specific activities and procedures to which the statutes apply. The definition of “health care professional,” on the other hand, is already appropriately defined under at least two of the statutes referenced by the Proposed Rule.<sup>16</sup>

Moreover, none of the statutory definitions include “a laboratory” or “a plan sponsor, issuer, or third-party administrator.” The addition of laboratories is unrelated to the procedures targeted by any of the referenced statutes, and their inclusion could lead to the refusal of all manner of routine testing, including pregnancy testing, because of an “articulable connection” to an objected-to procedure. Most importantly, the addition of plan sponsors (typically employers), plan issuers (such as insurance companies), and third-party administrators (which perform claims processing and administrative tasks as opposed to actual health care services), enlarges the number of entities affected by the Proposed Rule in ways that are unnecessary, not contemplated by the

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<sup>13</sup> 22 U.S.C. § 7631(d)(1)(B) (President’s Emergency Program for AIDS Relief); 42 U.S.C. § 1395w-22(j)(3)(B) (Medicare+Choice); 42 U.S.C. § 1396u-2(b)(3)(B) (Medicaid managed care organization); 42 U.S.C. § 18023(b)(4) (Affordable Care Act); 42 U.S.C. § 18023(c)(2)(A)(i)-(iii) (Affordable Care Act); Consolidated Appropriations Act of 2017, Pub. L. 115-31, 131 Stat. 135, 539 (Medicare Advantage).

<sup>14</sup> 83 Fed. Reg. at 3923.

<sup>15</sup> 42 U.S.C. § 238n(c)(2) (Coats-Snowe); 42 U.S.C. § 18113(b) (Affordable Care Act); Consolidated Appropriations Act of 2017, Pub. L. 115-31, 131 Stat. 135, 562 (Weldon Amendment).

<sup>16</sup> 42 U.S.C. § 1395w-22(j)(3)(D) (Medicare+Choice) (including physicians, specialists, physician assistants, nurses, and social workers, among others); 42 U.S.C. § 1396u-2(b)(3)(C) (Medicaid managed care organization) (same).

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statutes, and not sensible. These new categories of “health care entit[ies],” particularly when combined with the excessively broad definition of “assist in the performance,” could lead to objections by human resources analysts, customer service representatives, data entry clerks, and numerous others who believe that analyzing benefits, answering a benefits-related question, or entering a pre-authorization for an objected-to procedure, for example, is assisting in the performance of that procedure. It is difficult to estimate the immense scope of administrative difficulty that this definition could cause at facilities nationwide, and the Proposed Rule offers no reasonable explanation for these new categories of “health care entit[ies].” In fact, there is no judicious interpretation of “health care entity” that includes every employer who offers a health care plan because 49% of Americans have employer-provided health insurance.<sup>17</sup> This definition applied to the Weldon Amendment could also prohibit a state government from requiring an employer to provide insurance coverage for lawful abortions.

*(C) The Proposed Rule’s Definition of “Referral or Refer For” Is Excessively Broad.*

Finally, several of the federal health care conscience statutes prohibit discrimination against health care providers who elect not to provide “referrals” or “refer for” objected-to procedures. The Proposed Rule defines “**referral or refer for**” in an unjustified and unreasonable manner, allowing a health care provider to refuse to provide “any information” by “any method” that could provide “any assistance” to an individual when obtaining an objected-to procedure is a “possible outcome” of the information.<sup>18</sup> Based on this definition, a health care professional would not be required to refer a woman to Planned Parenthood for prenatal care—even if it were the only option she could afford—because abortion is a “possible outcome of the referral.” Likewise, a health care professional would not be required to refer a woman for the treatment of an extensive ovarian or other reproductive system cancer because sterilization is a “possible outcome of the referral.” The Proposed Rule’s expansive definition would serve to drastically decrease access to information about health care services and access to those services themselves and to undermine the States’ interest in ensuring access to health care to their citizens.

**III. The Proposed Rule is Contrary to Federal Law—Resulting in Harm to Patients.**

*(A) The Proposed Rule Conflicts with the Emergency Medical Treatment and Labor Act (EMTALA).*

While the Proposed Rule asserts the primacy of provider conscience, it contains no protections to ensure that patients have adequate access to necessary health care in emergencies. In fact, the Proposed Rule does not reference the treatment of patients in emergency situations at all. This places the Proposed Rule in direct conflict with the Emergency Medical Treatment and

<sup>17</sup> *Health Insurance Coverage of the Total Population (2016)*, Kaiser Family Foundation, <https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> (last visited Mar. 12, 2018).

<sup>18</sup> 83 Fed. Reg. at 3924.

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Labor Act (“EMTALA”),<sup>19</sup> a federal law requiring hospitals to provide for emergency care. The absence of an explicit recognition of the EMTALA requirements in the Proposed Rule could jeopardize patient lives. EMTALA defines the term “emergency medical condition” to include:

a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy....<sup>20</sup>

Yet, under the Proposed Rule, a woman suffering an ectopic pregnancy, for example, could be turned away from her nearest provider and forced to locate a doctor willing and available to provide her with an appropriate treatment before it is too late. The Proposed Rule’s impact on access to emergency care would likely be particularly dangerous in the rural areas of the States where an alternative provider may be difficult—or even impossible—to find in the necessary timeframe.

This reduction in access to emergency care is not supported by the statutes upon which the Proposed Rule purports to be based. Indeed, Representative Weldon stated shortly after his Amendment’s passage that the law was not intended to reach emergency abortions and that EMTALA requires critical-care health facilities to provide appropriate treatment to women in need of emergency abortions, the Weldon Amendment notwithstanding. Representative Weldon explained:

The Hyde-Weldon amendment is simple. It prevents Federal funding when courts and other government agencies force or require physicians, clinics and hospitals and health insurers to participate in *elective* abortions. ...It simply prohibits coercion *in nonlife-threatening situations*. ...It ensures that in situations where a mother’s life is in danger a health care provider must act to protect the mother’s life. In fact, Congress passed the Federal Emergency Medical Treatment and Active Labor Act (EMTALA) forbidding critical-care health facilities to abandon patients in medical emergencies, and requires them to provide treatment to stabilize the medical condition of such patients—particularly pregnant women.<sup>21</sup>

Moreover, at least one of the statutes referenced in the Proposed Rule is clear that it shall not be “construed to relieve any health care provider from providing emergency services as required by State or Federal law, including section 1395dd of this title (popularly known as “EMTALA”).”<sup>22</sup>

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<sup>19</sup> 42 U.S.C. § 1395dd.

<sup>20</sup> 42 U.S.C. § 1395dd(c)(1)(A).

<sup>21</sup> 151 Cong. Rec. H176-77 (Jan. 25, 2005) (statement of Rep. Weldon) (emphases added).

<sup>22</sup> 42 U.S.C. § 18023(d).

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Any proper rule implementing this statute, as well as the others referenced, must explicitly ensure that patients receive emergency medical treatment.

*(B) The Proposed Rule Conflicts with the Affordable Care Act.*

The Affordable Care Act prohibits the Secretary of Health and Human Services from promulgating any regulation that:

1. creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
2. impedes timely access to health care services;
3. interferes with communications regarding a full range of treatment options between the patient and the provider;
4. restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
5. violates the principles of informed consent and the ethical standards of health care professionals; or
6. limits the availability of health care treatment for the full duration of a patient's medical needs.<sup>23</sup>

The Proposed Rule violates nearly every one of these proscriptions. First, by not clarifying that emergency medical care is mandatory under federal law, the Proposed Rule creates unreasonable barriers to timely access to appropriate medical care. Second, by disavowing principles of informed consent in its broad definitions of “assist in the performance” and “referral or refer for,” the Proposed Rule interferes with “communications regarding a full range of treatment options between the patient and the provider,” “restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions,” and “violates the principles of informed consent and the ethical standards of health care professionals.”<sup>24</sup> The Proposed Rule's violation of these federal protections is unlawful. It is also unnecessary given that the States already have systems in place to protect religious freedom while ensuring access to health care and compliance with federal law.<sup>25</sup>

*(C) The Proposed Rule Does Not Properly Account for the Costs It Seeks to Impose on Patients.*

The Proposed Rule also fails to comply with the requirement that federal agencies accurately assess the costs and benefits of their proposed regulations whenever possible.<sup>26</sup> HHS

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<sup>23</sup> 42 U.S.C. § 18114.

<sup>24</sup> *Id.*

<sup>25</sup> *See infra* Section V.

<sup>26</sup> The Proposed Rule states that “The Department has examined the impacts of the proposed rule as required under Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 13771 on Reducing Regulation

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estimates that the first year of this rule would cost the economy, mostly in the already highly-regulated health care industry, \$312.3 million, and years two through five would cost the economy \$125.5 million annually. This estimate fails to include or account for, in any measure, the potentially substantial monetary costs of the health consequences resulting from the denials of care that would inevitably follow the Proposed Rule's unlawful expansion of the referenced statutes. At least some of these costs would likely be borne by states. For example, for each pregnant teen who is not referred to affordable prenatal care for fear that abortion is a "possible outcome of the referral," the subsequent health care for that teen and her child (if carried to term) could cost a state Medicaid program \$2,369 to \$3,242, depending on when the care was ultimately initiated.<sup>27</sup>

Moreover, as "Non-quantified Costs" of the Proposed Rule, HHS lists only vaguely and briefly: "Any ancillary costs resulting from a protection of conscience rights,"<sup>28</sup> while ignoring the impact on patient care. It does not list the loss of health or human dignity caused when a health care professional denies care to someone facing an emergency medical issue or with some other medical need. It does not list the emotional and other harm inherent in going forward with a medical procedure and later discovering that a better option was available—an option that a health care professional decided not to disclose at the time of treatment. It does not list the loss of the Constitutional right to abortion that will occur when women are denied information about termination of pregnancy before the procedure can no longer be lawfully performed.<sup>29</sup>

#### **IV. The Proposed Rule is Contrary to Federal Law and Unconstitutional—Resulting in Harm to Employers.**

##### *(A) The Proposed Rule Conflicts with Title VII of the Civil Rights Act of 1964.*

The Proposed Rule defines "discriminate or discrimination" without explaining how it interacts with existing laws protecting employees from discrimination on the basis of religion. For example, Title VII of the Civil Rights Act of 1964 ("Title VII") prohibits discrimination in employment on the basis of religious beliefs.<sup>30</sup> Its protection also extends to "moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional

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and Controlling Regulatory Costs (January 30, 2017), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96-354, 5 U.S.C. 601-612), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104-04), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), the Assessment of Federal Regulation and Policies on Families (Pub. L. 105-277, section 654, 5 U.S.C. 601 (note)), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520)." 83 Fed. Reg. at 3901-02.

<sup>27</sup> William J. Hueston, et al., *How Much Money Can Early Prenatal Care for Teen Pregnancies Save?: A Cost-Benefit Analysis*, 21 J. Am. Bd. Family Med. 184 (2008). Women who are denied abortions based on existing legal restrictions are also more likely to receive public assistance than women who obtain abortions—both shortly after the denial and for years afterward. See Diana Greene Foster, et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 108 Am. J. Pub. Health 407 (2018).

<sup>28</sup> Table 1—Accounting Table of Benefits and Costs of All Proposed Changes, 83 Fed. Reg. at 3902.

<sup>29</sup> See *An Overview of Abortion Laws*, Guttmacher Inst. (last updated Mar. 20, 2018), <https://www.guttmacher.org/state-policy/explore/overview-abortion-laws> (last visited Mar. 26 2018).

<sup>30</sup> 42 U.S.C. § 2000e-2(a).

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religious views.”<sup>31</sup> Title VII, unlike the Proposed Rule, states that employers are not obligated to accommodate employees’ religious beliefs to the extent that such an accommodation would cause “undue hardship” on the employer.<sup>32</sup> This carefully constructed balancing test, which is conducted on a case by case basis, recognizes that employers should not be forced to sacrifice their principal obligations—to their business, their patients, and their other employees—in order to accommodate the religious beliefs of one employee. Moreover, at least one of the statutes referenced in the Proposed Rule is clear that it shall not “alter the rights and obligations of employees and employers under [T]itle VII of the Civil Rights Act of 1964.”<sup>33</sup> Any proper rule implementing this statute, as well as the others referenced, must ensure that employers are not faced with undue hardships in accommodating employee beliefs.

By contrast, the Proposed Rule ignores the “undue hardship” test and instead contains a blanket prohibition on “discrimination.” This blanket prohibition could be interpreted to prevent the transfer of an employee to another area of a health care entity or a different shift even if the employee’s beliefs prevent the employee from performing the essential functions of the initial position. When applied without any reference to employer or patient needs, this broad definition of discrimination could be interpreted to require a health care entity to hire someone who cannot deliver health care services that are critical to the health care entity’s mission or risk sanction. For example, even a small women’s health clinic could be in violation of the Proposed Rule for refusing to hire a doctor who would not perform, or a receptionist who would not schedule, a tubal ligation. Congress did not intend to so constrain health care providers as to force them to abandon patient care—or their missions and businesses altogether.<sup>34</sup>

*(B) The Proposed Rule Conflicts with Title X of the Public Health Service Act of 1970.*

Family planning projects funded through Title X are required to counsel pregnant patients about all health care options, including abortion, and provide referrals for those options if requested.<sup>35</sup> The Proposed Rule ignores Title X and, in fact, conflicts with its requirements. Specifically, the Proposed Rule defines discrimination to include the utilization of:

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<sup>31</sup> 29 C.F.R. § 1605.1.

<sup>32</sup> 42 U.S.C. § 2000e(j). The New York State Human Rights Law also requires the accommodation of religious beliefs “unless, after engaging in a bona fide effort, the employer demonstrates that it is unable to reasonably accommodate the employee’s or prospective employee’s sincerely held religious observance or practice without undue hardship on the conduct of the employer’s business.” N.Y. Human Rights L. § 296(10).

<sup>33</sup> 42 U.S.C. § 18023(c)(3).

<sup>34</sup> See 151 Cong. Rec. H176-77 (Jan. 25, 2005) (statement of Rep. Weldon) (“The amendment does not apply to willing abortion providers. Hyde-Weldon allows any health care entity to participate in abortions in any way they choose.”).

<sup>35</sup> See Title X, Public Health Service Act of 1970 § 1001, 42 U.S.C. § 300; Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135, 521 (2017) (“all pregnancy counseling shall be nondirective”); 42 C.F.R. § 59.5(a)(5) (requiring that a family planning project offer pregnant women the opportunity to be provided information and counseling regarding prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination). *Id.* (dictating that a family planning project, “[i]f requested to provide such information and counseling, provide

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any criterion, method of administration, or site selection, including the enactment, application, or enforcement of laws, regulations, policies, or procedures directly or through contractual or other arrangements, that tends to subject individuals or entities protected under this part to any adverse effect described in this definition....<sup>36</sup>

An “adverse effect” as referenced in this definition includes the denial of grants or contracts or any other benefits or privileges.<sup>37</sup> Thus, a state could be unable to select Title X sub-recipients on the basis of their willingness to counsel about and refer for abortions. Application of the definition of “discriminate or discrimination” without any reference to states’ Title X obligations leaves states with a Hobbesian choice: they can either withhold federal family planning dollars from organizations unwilling to provide “non-directive” pregnancy counseling about (and potential referral to) all of the health care options—in direct contravention of the Proposed Rule—or provide such funding—in direct contravention of Title X. Like the Weldon Amendment, Congress passes the non-directive pregnancy counseling requirement applicable to Title X in appropriations measures each year and did so as recently as last year.<sup>38</sup> Congress surely did not intend in 2017 that the non-directive pregnancy counseling requirement be nullified by a new agency interpretation of statutes predating this Congressional action.

*(C) The Proposed Rule Violates the Establishment Clause.*

The Proposed Rule’s failure to consider the needs of patients or employers, including those governed by Title X, in its mandates implies that health care professionals have an unprecedented absolute right to religious accommodation, which is incompatible with the United States Constitution. Indeed, the Proposed Rule does not include any provision for balancing or accounting for a patient’s right to care or an employer’s commitment to deliver that care. Laws that compel employers to “conform their business practices to the particular religious practices of . . . employees” violate the Establishment Clause.<sup>39</sup> In *Estate of Thornton v. Caldor*, the Supreme Court invalidated a law providing employees with the absolute right not to work on their chosen Sabbath in part because the law unfairly and significantly burdened the employers and fellow employees who did not share the employee’s Sabbath. “The First Amendment . . . gives no one the right to insist that in pursuit of their own interests others must conform their conduct to his own religious necessities.”<sup>40</sup> The Court found the law “unyielding[ly] weight[ed]” the interests of Sabbatarians “over all other interests” and was invalid under the Establishment Clause.<sup>41</sup> To the extent that the Proposed Rule requires businesses to accommodate their employees’ religious

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neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.”).

<sup>36</sup> 83 Fed. Reg. at 3923-24.

<sup>37</sup> *Id.*

<sup>38</sup> Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135, 521 (2017).

<sup>39</sup> *Estate of Thornton v. Caldor*, 472 U.S. 703, 709 (1995).

<sup>40</sup> *Id.* at 710 (quoting *Otten v. Baltimore & Ohio R.R. Co.*, 205 F.2d 58, 61 (1953)).

<sup>41</sup> *Id.*

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beliefs at all costs, it is directly analogous to the law successfully challenged in *Caldor* and thus contravenes the First Amendment.

**V. The Proposed Rule Undermines State Policies Regarding Health Care and Would Require States to Violate Their Own Laws.**

HHS states that while the Proposed Rule “is expected to affect State and local governments, the anticipated effect is not substantial.”<sup>42</sup> The States disagree. In order to ensure access to care for their citizens, the States have enacted laws to guarantee emergency and medically necessary care as well as informed consent. State laws also protect the religious freedom of employees while respecting the business necessities of their employers. These important, sometimes competing needs have been carefully balanced in various ways in each of the States. The Proposed Rule upsets these delicate and long-standing balances and ignores the needs of patients and employers.

First, as noted above, the Proposed Rule does not so much as mention the provision of emergency health care, which can require abortions or other procedures to which a health care professional may object. In addition to conflicting with federal law requiring emergency medical care,<sup>43</sup> the Proposed Rule is at odds with state law that requires the provision of emergency medical care.<sup>44</sup> In many states, mandatory emergency care includes the provision of emergency contraception to survivors of sexual assault.<sup>45</sup> In addition to mandating emergency care, several state regulations also prohibit health care professionals from abandoning a patient in medical need without first arranging for the patient’s care.<sup>46</sup> The Proposed Rule ignores the requirement of emergency or medically necessary care under federal or state law,<sup>47</sup> seemingly leaving the provision of this care solely to chance.

Second, the Proposed Rule does not allow for state laws that already facilitate the accommodation of religious or moral objections, balancing conscience protection with patients’ rights to access care. For example, several states have laws allowing an individual to refuse to

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<sup>42</sup> 83 Fed. Reg. at 3918.

<sup>43</sup> See *supra* Section III.

<sup>44</sup> *E.g.*, N.Y. Pub. Health Law § 2805-b.

<sup>45</sup> See, *e.g.*, MGL c. 111, s. 70E (requiring the provision of information about emergency contraception and emergency contraception to survivors of sexual assault); N.J.S.A. 26:2H-12.6c (same); N.Y. Pub. Health Law § 2805-p (same); Wash. Rev. Code § 70.41.350 (same). See also 410 ILCS 70/2.2(b) (similar).

<sup>46</sup> Conn. Gen. Stat. § 19a-580a (“An attending physician or health care provider who is unwilling to comply with the wishes of the patient . . . , shall, as promptly as practicable, take all reasonable steps to transfer care of the patient to a physician or health care provider who is willing to comply with the wishes of the patient . . . .”); 8 NYCRR § 29.2 (noting unprofessional conduct includes “abandoning or neglecting a patient or client under and in need of immediate professional care, without making arrangements for the continuation of such care . . . .”); Wash. Admin. Code § 246-840-700; Wash. Admin. Code § 246-817-380; Wash. Admin. Code § 246-808-330. See also N.J.S.A. 45:14-67.1 (requiring a pharmacy to fill lawful prescriptions without undue delays despite employee objections); Wash. Admin. Code § 246-869-010 (same).

<sup>47</sup> States are required to define medically necessary care for their Medicaid plans. 42 C.F.R. § 438.210(a)(5). The Proposed Rule, however, would undermine the ability of states to use these federally-mandated definitions of medically necessary care to select Medicaid providers.

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assist in a non-emergency abortion as long as the individual notifies the employer in advance.<sup>48</sup> This type of state law facilitates accommodations such as “staffing or scheduling practices that respect an exercise of conscience rights under Federal law.”<sup>49</sup> The Proposed Rule, however, states that “OCR will regard as presumptively discriminatory any law, regulation, policy, or other such exercise of authority that has as its purpose, or explicit or otherwise clear application, the targeting of religious or conscience-motivated conduct.” Thus, HHS would regard these laws, which are targeted at religious or conscience-motivated conduct—but only to accommodate it—as presumptively discriminatory. Given that all federal health care funding could be terminated for any “threatened failure to comply” with the Proposed Rule, states are faced with either having no such laws (or even policies for their own hospital systems), which would threaten efficient health care administration and the provision of care, or losing all federal funding to provide that care.

Third, the Proposed Rule does not acknowledge or recognize the import of patient informed consent, which is protected by the Affordable Care Act and state law. The Proposed Rule does not require that a patient be informed that a health care provider is refusing to counsel them about, or refer them to, certain health care services. States such as New York and Massachusetts mandate informed consent for patients to ensure that patients can make their own informed medical decisions.<sup>50</sup> In other states, the failure to inform patients of possible alternative treatments increases the risk of malpractice liability for the health care providers involved in the patients’ care and the health care facility at which the care is performed.<sup>51</sup> The complexity of identifying which members of a large health care team have objections to providing full informed consent—and about which topics—not only risks delay in necessary care, but increases the risk of liability for health care providers and facilities. The President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, which consisted of leading experts in research, law, medicine, and medical ethics, issued a seminal 1982 report on the ethical and legal implications of informed consent that concluded that patients must be provided with “all relevant information regarding their condition and alternative treatments.”<sup>52</sup> Other federal laws recognize the importance of informed consent, including two of the statutes that the Proposed Rule professes to implement. These statutes require plans that refuse “to provide, reimburse for, or provide coverage of a counseling or referral service” on the basis of a moral or religious objection to “make[] available information on its policies regarding such service to prospective enrollees before

<sup>48</sup> See, e.g., Conn. Regs. § 19–13–D54(f); 720 ILCS 510/13; MGL c. 112 s. 12I; N.Y. Civ. Rights L. § 79-1. See also Wash. Rev. Code § 48.43.065 (protecting right of provider, carrier, or facility to refrain from participating in provision or payment for specific service they find objectionable, but requiring advanced notice); Wash. Rev. Code § 70.47.160 (same); Wash. Admin. Code § 284–43–5020 (requiring carriers to file plan ensuring timely access to services).

<sup>49</sup> 83 Fed. Reg. at 3913.

<sup>50</sup> MGL c. 111, s. 70E; N.Y. Pub. Health L. § 2805-d. See also 720 ILCS 510/13 (“If any request for an abortion is denied [because of a conscience objection], the patient shall be promptly notified.”)

<sup>51</sup> See, e.g., Wash. Rev. Code § 7.70.050.

<sup>52</sup> President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Making Health Care Decisions: A Report on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship*, Washington, DC: U.S. Government Printing Office, 1982, <https://repository.library.georgetown.edu/handle/10822/559354>.

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or during enrollment and to enrollees within 90 days after the date that the organization or plan adopts a change in policy regarding such a counseling or referral service.”<sup>53</sup> Both laws also provide that they shall not “be construed to affect disclosure requirements under State law.”<sup>54</sup> The Proposed Rule seeks not only to write the disclosure requirement out of these two statutes but also to take power from the states that Congress has expressly reserved to them. An agency action that seeks to preempt state laws without the proper Congressionally delegated authority is unlawful.<sup>55</sup>

## **VI. The Proposed Rule’s Funding Termination Scheme Exceeds HHS’s Statutory Authority and Is Unconstitutional.**

### *(A) The Proposed Rule Exceeds HHS’s Statutory Authority by Threatening to Terminate All Federal Health Care Funding to Recipients for Any “Failure or Threatened Failure” to Comply.*

The Proposed Rule seeks to impose new and unnecessary conditions on billions of federal health care dollars that states rely on to ensure access to care for patients. The Proposed Rule emphasizes its intention to terminate a “variety of financing streams” for *any* failure—or *threatened* failure—to comply with any of the statutes referenced, and it does so without so much as defining the term “threatened failure.”<sup>56</sup> HHS does provide a non-exclusive list of “examples” of financing streams that it proposes should be dependent on the states’ ability to avoid a vague and non-defined “threatened failure” to comply with the Proposed Rule. This list expressly includes reimbursement for health-related activities provided by programs including: Medicaid and the Children’s Health Insurance Program; public health and prevention programs; HIV/AIDS and STD prevention and education; substance abuse screening; biomedical and behavioral research at state institutions of higher education; services for older Americans; medical assistance to refugees; and adult protection services to combat elder justice abuse.<sup>57</sup>

HHS states that “Congress has exercised the broad authority afforded to it under the Spending Clause to attach conditions on Federal funds for respect of conscience...”<sup>58</sup> Indeed, the relevant statutes condition funding from specific sources to specific requirements and prohibitions. For example, the first two of the five requirements of the Church Amendments condition only grants, contracts, loans, or loan guarantees under the Public Health Service Act, the Community

<sup>53</sup> 42 U.S.C. § 1395w-22(j)(3)(B) (Medicare+Choice); 42 U.S.C. § 1396u-2(b)(3)(B) (Medicaid managed care organization).

<sup>54</sup> 42 U.S.C. § 1395w-22(j)(3)(C) (Medicare+Choice); 42 U.S.C. § 1396u-2(b)(3)(B) (Medicaid managed care organization).

<sup>55</sup> See *Texas v. United States*, 95 F. Supp. 3d 965, 980-81 (N.D. Tex. 2015) (enjoining a U.S. Department of Labor rule implementing the Family and Medical Leave Act on the ground that compliance with the rule would require the plaintiff states to violate their own state laws and that the rule exceeded the agency’s congressionally delegated authority).

<sup>56</sup> 83 Fed. Reg. at 3905, 3931.

<sup>57</sup> 83 Fed. Reg. at 3905.

<sup>58</sup> 83 Fed. Reg. at 3889.

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Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act.<sup>59</sup> The third Church Amendment requirement conditions only grants or contracts “for biomedical or behavioral research,” the fourth applies to HHS’s funding of a particular health service program or research activity, and the fifth conditions funds similar to those conditioned by the first two.<sup>60</sup> Many of the referenced statutes have a similar framework.<sup>61</sup> The Proposed Rule ignores the sources of funds Congress has conditioned upon obedience to each statute, instead threatening to terminate *all* federal health care funding to recipients for *any* failure—or *threatened* failure—to comply with any of the statutes referenced.<sup>62</sup> These sanctions far exceed HHS’s statutory authority,<sup>63</sup> and if acted upon, would unjustifiably terminate sources of funding that states rely on to provide critical, and sometimes life-saving, health services to their citizens.

Moreover, the Proposed Rule’s funding termination provisions require no administrative process before HHS terminates all federal health care funding for a state or other entity. Under the Proposed Rule, HHS can terminate all federal health care funding solely upon its determination that “there appears to be a failure or threatened failure to comply” with either the referenced statutes or the Proposed Rule itself.<sup>64</sup> It can do so even if only a state’s sub-recipient—not the state itself—is accused of wrongdoing.<sup>65</sup> It can also do so while a state or other entity is attempting to resolve the matter informally.<sup>66</sup>

*(B) The Proposed Rule Violates the Spending Clause.*

As noted in Section VI(A), *supra*, there is no statutory authority for HHS’s assertion of a vast new power to terminate broad swaths of federal health care funding that are unrelated to the program funds that Congress has expressly conditioned. If, however, Congress did delegate to HHS the authority to terminate *all* federal health care funding to the states on the basis of a failure or threatened failure to comply with any of the referenced statutes, such an action would violate the Spending Clause.

Congress may use the Spending Clause power to condition grants of federal funds upon the states taking certain actions that Congress could not otherwise require them to take, but this

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<sup>59</sup> 42 U.S.C. §§ 300a-7(b)-(c)(1).

<sup>60</sup> 42 U.S.C. §§ 300a-7(c)(2)-(e).

<sup>61</sup> *E.g.*, 22 U.S.C. § 7631(d) (President’s Emergency Program for AIDS Relief); 42 U.S.C. §§ 1395w-22(j)(3)(A)-(B) (Medicare+Choice); 42 U.S.C. §§ 1396u-2(b)(3)(A)-(B) (Medicaid managed care organization); 42 U.S.C. § 18113 (Affordable Care Act).

<sup>62</sup> 83 Fed. Reg. at 3931.

<sup>63</sup> *See County of Santa Clara v. Trump*, 250 F. Supp.3d 497, 530-532 (N.D. Cal. 2017) (enjoining executive order regarding sanctuary cities in part because order violated separation of powers by attempting to exercise Congress’s spending power in its enforcement).

<sup>64</sup> *Id.*

<sup>65</sup> 83 Fed. Reg. at 3929.

<sup>66</sup> 83 Fed. Reg. at 3931.

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power is not without limit.<sup>67</sup> Importantly, if Congress seeks to condition the states' receipt of federal funds, it "must do so unambiguously."<sup>68</sup> Conditions on federal grants can also be barred if they are unrelated "to the federal interest in particular national projects or programs."<sup>69</sup> Additionally, "the financial inducement offered by Congress" cannot be "so coercive as to pass the point at which pressure turns into compulsion."<sup>70</sup> The Proposed Rule would violate each of these limits on Congress's exercise of the Spending Clause power.

In the first instance, the vague notion of a "threatened failure to comply" offends the requirement that Congress must unambiguously state the prohibited conduct that will trigger the loss of funding under its Spending Clause power.<sup>71</sup> Additionally, because the Proposed Rule conflicts with other federal laws, the states risk all of their federal health care funding by merely complying with (other) federal law—leaving them no unambiguously compliant course of action. For example, if a pregnancy counselor at a public health department that receives Title X funds objects to providing counseling about or referral to abortion services, the facility will have to decide whether to 1) transfer that employee in violation of the Proposed Rule or 2) allow that employee not to counsel about or refer to these services in violation of Title X. Should it choose the first option, it could lose all of its federal health care funding; should it choose the second option, it could lose all of its federal Title X funding.

Next, the funding that HHS proposes it should be allowed to terminate, on the basis of a "threatened failure to comply" with the Proposed Rule, includes programs, like the Children's Health Insurance Plan, that are entirely unrelated to the federal interest in protecting conscience objections to a narrow category of procedures, such as abortion and sterilization.<sup>72</sup>

Last, the Supreme Court has already held that Congress's imposition of new, unrelated conditions on an amount *less* than the amount of funding at stake under the Proposed Rule was so coercive as to be likened to a "gun to the head."<sup>73</sup> In *National Federation of Independent Business v. Sebelius*, the Supreme Court reasoned that a Congressional threat to a state's Medicaid funding was unconstitutional because it was so coercive as to deprive states of any meaningful choice whether to accept the condition attached to receipt of federal funds.<sup>74</sup> The Proposed Rule would eliminate not only states' Medicaid funding, but a host of other federal health care funding as well.

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<sup>67</sup> See *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 578 (2012).

<sup>68</sup> *Id.* at 576.

<sup>69</sup> *South Dakota v. Dole*, 483 U.S. 203, 207 (1987) (internal citation omitted).

<sup>70</sup> *Sebelius*, 567 U.S. at 580 (internal citation and quotation marks omitted).

<sup>71</sup> *Dole*, 483 U.S. at 207.

<sup>72</sup> 83 Fed. Reg. at 3905.

<sup>73</sup> *Sebelius*, 567 U.S. at 581.

<sup>74</sup> *Id.* at 579-585.

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**VII. The Proposed Rule Will Increase Discrimination, Limit Health Care Providers, and Harm Patients.**

The States maintain a quintessential interest in the civil rights and health of their residents, an interest alternately described as quasi-sovereign and within those police powers reserved to them.<sup>75</sup> The States have considered the Proposed Rule in light of their twin duties to protect civil rights and the public health, and believe that it harms both patients and health care providers. Despite HHS's stated interest in "a society free from discrimination,"<sup>76</sup> the Proposed Rule substantially increases the risk of discrimination against patients on the basis of, *inter alia*, sex, sexual orientation, or gender identity. The Proposed Rule also risks having a chilling effect upon health care providers in a manner that will likely harm patients and vulnerable populations. Both of these anticipated harms arise from the unnecessary and unsupported breadth and scope of the Proposed Rule.

*(A) The Proposed Rule Will Increase Status-Based Discrimination Against Patients.*

The statutes referenced in the Proposed Rule in no way permit entities or health care personnel to deny care to a patient based on his or her status, *e.g.*, a patient's status as lesbian, gay, bisexual, or transgender. Rather, those statutes set forth narrowly tailored exemptions to the provision of specific procedures, irrespective of a patient's status.<sup>77</sup> Against this backdrop of narrow statutory protections allowing health care workers to opt out of certain procedures and services, HHS seeks to expand the scope of the referenced statutes, its regulatory footprint, and its own power. As set forth in Section II, *supra*, the Proposed Rule defines the terms "assist in the performance" and "health care entity" in ways that broaden the scope of the referenced statutes, vastly expand the number of individuals potentially eligible to assert a "religious, moral, ethical, or other" objection, and dramatically increase the types of services to which they may object. This expanded universe of individuals who can refuse to provide patient care or perform activities with an "articulable connection" to patient care, combined with the enormous sanctions faced by states and other entities if they do not allow for these exemptions, raises the specter of heightening status-based discrimination against existing patient populations.

The States have serious concerns, for example, that an expanded universe of potential conscience objectors may seek to use the statutory tether of a "sterilization procedure" to deny care to transgender patients. Transgender people regularly experience discrimination within the health care industry, resulting in substantial health disparities with the non-transgender

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<sup>75</sup> See, *e.g.*, *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 488 (1987) (acknowledging state police power and interest in public health); *Snapp v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 609 (1982) (acknowledging state interest in eradicating the "political, social, and moral damage" resulting from "invidious discrimination"); *Mackey v. Montrym*, 443 U.S. 1, 17 (1979) (acknowledging state interest in public health and safety).

<sup>76</sup> 83 Fed. Reg. at 3903.

<sup>77</sup> See, *e.g.*, 42 U.S.C. § 300a-7(b)(1) (Church Amendment) (referring to "performance of any sterilization *procedure* or *abortion*" (emphasis added)).

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population.<sup>78</sup> This discrimination includes both denials of care related to gender transition as well as denials of care for routine medical issues—*e.g.*, physicals, treatment for the flu, or care for diabetes—completely unrelated to their transgender status.<sup>79</sup> In some instances, this discrimination has occurred in emergency medical settings in which prompt and effective care for patients is urgent and its absence could be life-threatening.<sup>80</sup> Similarly, the States also have concerns that an expanded universe of conscience objectors could seek to use the Proposed Rule to deny medical care to male patients who seek pre- or post-exposure prophylactic medications to prevent HIV infection based upon those men’s actual or perceived sexual orientation.<sup>81</sup> Any regulatory expansion of statutory conscience exceptions that results in status-based discrimination would fundamentally undermine patient health and the interest of the States in preserving that health within their borders.

*(B) The Proposed Rule Will Have a Chilling Effect Upon Health Care Providers, Further Harming Patients.*

The Proposed Rule would also inhibit the provision of health care in a manner that harms public health and likely falls more heavily on the shoulders of vulnerable populations. Not only does the Proposed Rule vastly expand the scope of individuals who may lodge conscience-based objections to the provision of medical procedures and other services with an “articulable connection” to those procedures,<sup>82</sup> it also exceeds its statutory authority in intending to cut off all federal health care funding for any failure or threatened failure to comply with the Proposed Rule.<sup>83</sup> This regulatory combination is an especially dangerous one that is likely to have a chilling effect upon health care providers. Health care providers faced with a potentially limitless universe of conscience objections from any employee, including members of the janitorial or secretarial staff, have strong incentives to cease offering procedures like abortion or gender transition-related

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<sup>78</sup> See, *e.g.*, Grant, Jaime M., et al., *Injustice at Every Turn: A Report of the National Transgender Discrimination Survey*, (Nat’l Ctr. Transgender Equal./Nat’l Gay & Lesbian Task Force, Washington, D.C.), 2011 (“2011 Report”), at 6; James, Sandy E., et al., *The Report of the 2015 U.S. Transgender Survey*, (Nat’l Ctr. Transgender Equal., Washington D.C.), 2016 (“2016 Report”), at 103-07.

<sup>79</sup> See 2011 Report, at 6 (noting that 19% of survey respondents reported being refused medical care due to their transgender or gender non-conforming status); 2016 Report, at 96-97 (noting that 15% of survey respondents reported a health care provider asking unnecessary or invasive questions about their transgender status unrelated to the reason for their visit; 8% of respondents reported a provider’s denial of transition-related care; and 3% of respondents reported a denial of care unrelated to gender transition).

<sup>80</sup> See, *e.g.*, *Rumble v. Fairview Health Servs.*, 2015 U.S. Dist. LEXIS 31591 (D. Minn. Mar. 16, 2015) (detailing emergency room physician’s actions toward transgender man in suit brought under Affordable Care Act and Minnesota Human Rights Law).

<sup>81</sup> See, *e.g.*, Donald G. McNeil, Jr., *He Took a Drug to Prevent AIDS. Then He Couldn’t Get Disability Insurance*, N.Y. Times (Feb. 12, 2018), available at: <https://www.nytimes.com/2018/02/12/health/trivada-hiv-insurance.html> (last visited Mar. 26, 2018).

<sup>82</sup> See *supra* Section II.

<sup>83</sup> See *supra* Section VI(A).

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therapies or surgeries in order to avoid any possibility of the loss of all federal health care funding, including Medicaid funding, which could literally close a health care provider's doors.

Such a net reduction in the medical care offered by health care providers would harm the public health in each of the States. Additionally, because the Proposed Rule generally targets health care services supported by federal funds, its impact would be felt most by low-income patients who are far less likely to have alternative health care services available after a provider ceases to provide certain medical care or procedures. Further, patients reliant upon federal funding for the provision of health care are disproportionately non-white: 21% black and 25% Hispanic, as compared to those communities' respective proportions of 13.3% and 17.8% in the United States population. Consequently, any chilling effect the Proposed Rule has upon health care providers' decisions to offer abortion or other procedures will be borne disproportionately by minority populations.<sup>84</sup>

### VIII. Conclusion

If adopted, the Proposed Rule will harm patients by increasing discrimination and decreasing the provision of health care and information about health care. It will harm the Constitutional rights of the States and their residents. It will needlessly and carelessly upset the balance that has long been struck in federal and state law to protect the religious freedom of providers, the business needs of employers, and the health care needs of patients. Accordingly, we urge HHS to withdraw the Proposed Rule.

Respectfully submitted,



ERIC T. SCHNEIDERMAN  
New York Attorney General



Matthew P. Denn  
Delaware Attorney General



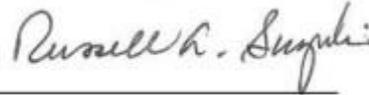
George Jepsen  
Connecticut Attorney General

<sup>84</sup> Compare *Medicaid Enrollment by Race/Ethnicity*, Kaiser Family Foundation, <https://www.kff.org/medicaid/state-indicator/medicaid-enrollment-by-raceethnicity/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> (last visited Mar. 23, 2018), and *Quick Facts: United States*, United States Census Bureau, <https://www.census.gov/quickfacts/fact/table/US/PST045216> (last visited Mar. 23, 2018).

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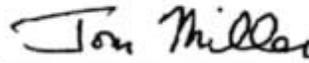
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Attorney General for the District of Columbia



Russell A. Suzuki  
Acting Attorney General, State of Hawaii



Lisa Madigan  
Illinois Attorney General



Tom Miller  
Iowa Attorney General



Janet T. Mills  
Maine Attorney General



Brian E. Frosh  
Maryland Attorney General



Maura Healey  
Massachusetts Attorney General



Lori Swanson  
Minnesota Attorney General



Gurbir S. Grewal  
New Jersey Attorney General



Hector Balderas  
New Mexico Attorney General



Ellen F. Rosenblum  
Oregon Attorney General



Josh Shapiro  
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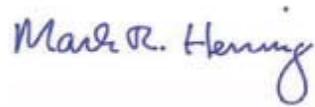


Peter F. Kilmartin  
Rhode Island Attorney General



Thomas J. Donovan Jr.  
Vermont Attorney General

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Mark R. Herring  
Virginia Attorney General



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Bob Ferguson  
Washington Attorney General