# Exhibit 80



WASHINGTON DC OFFICE 1776 K Street NW, Suite 852 Washington, D.C. 20006

March 26, 2018

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

#### RE: Protecting Statutory Conscience Rights in Health Care (RIN 0945-ZA03)

The National Center for Lesbian Rights (NCLR) writes to urge that the above-referenced Proposed Rule be withdrawn in its entirety, as it would endanger patient health and encourage widespread discrimination in health care delivery.

NCLR is a non-profit, public interest law firm that litigates precedent-setting cases at the trial and appellate court levels, advocates for equitable public policies affecting the lesbian, gay, bisexual, and transgender (LGBT) community, provides free legal assistance to LGBT people and their advocates, and conducts community education on LGBT issues. NCLR has been advancing the civil and human rights of LGBT people and their families across the United States through litigation, legislation, policy, and public education since its founding in 1977. We also seek to empower individuals and communities to assert their own legal rights and to increase public support for LGBT equality through community and public education. NCLR recognizes the critical importance of access to affordable health care for all people, and is concerned about the increasing use of religious exemptions to undercut civil rights protections and access to services for our community.

Our overarching objections to this Proposed Rule are twofold. First, it strays far from the primary mission of the Department of Health & Human Services. Our nation's premier public health agency should always maintain a focus on protecting the health of all, rather than seeking to empower health care providers to withhold care, in contravention of the core principles of informed consent and adherence to accepted standard of care. Second, it exceeds the agency's authority and was promulgated in violation of the Administrative Procedure Act. We provide further detail below.

#### I. The Proposed Rule disregards HHS's core mission

The Proposed Rule disregards the health care needs of patients and the core mission of the Department of Health & Human Services (HHS). The purpose of our nation's health care delivery system is to deliver health care to the people of this country. As the nation's largest public health agency, and one that is charged with furthering the health of all Americans, HHS is primarily charged with assisting patients in accessing care and health care providers in

delivering high-quality, culturally-competent care to everyone. Access to care, rather than denials of care, should be the goal. This Proposed Rule, in addition to being on questionable legal ground, focuses exclusively on purported rights of health care providers to turn patients away, with virtually no mention of the impact on patient health and well-being or on how access to care will be ensured. The priorities reflected in the Rule represent a sharp departure from the missions of HHS and its Office for Civil Rights (OCR) and should be withdrawn.

#### A. HHS should be trying to broaden access, not encourage denials of care

The HHS web site states: "It is the mission of the U.S. Department of Health & Human Services (HHS) to enhance and protect the health and well-being of all Americans. We fulfill that mission by providing for effective health and human services and fostering advances in medicine, public health, and social services" (emphasis added). The Proposed Rule departs significantly from that vision as well as the Office for Civil Rights (OCR's) mission to address health disparities and discrimination that harm patients. Instead, the Proposed Rule appropriates language from civil rights statutes and regulations that were intended to improve access to health care and applies that language to situations for which it was not intended, proposing a regulatory scheme that would be affirmatively harmful to many patients seeking care.

HHS, through OCR, has an important role to play in ensuring equal opportunity to access health care and ending discriminatory practices that contribute to poor health outcomes and health disparities.<sup>3</sup> If finalized, however, the Proposed Rule will undermine HHS's mission of combating discrimination, protecting patient access to care, and eliminating health disparities. Through enforcement of civil rights laws, OCR has in the past worked to reduce discrimination in health care by ending discriminatory practices such as segregation in health care facilities based on race or disability, categorical insurance coverage denials of care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.<sup>4</sup>

<sup>2</sup> OCR's Mission and Vision, DEP'T OF HEALTH AND HUMAN SERVS. (2018), <a href="https://www.hhs.gov/ocr/about-us/leadership/mission-and-vision/index.html">https://www.hhs.gov/ocr/about-us/leadership/mission-and-vision/index.html</a> ("The mission of the Office for Civil Rights is to improve the health and well-being of people across the nation; to ensure that people have equal access to and the opportunity to participate in and receive services from HHS programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").

See https://www.hhs.gov/about/index.html.

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

<sup>&</sup>lt;sup>4</sup> See, e.g., Serving People with Disabilities in the Most Integrated Setting: Community Living and Olmstead, DEP'T OF HEALTH AND HUMAN SERVS. (2018), <a href="https://www.hhs.gov/civil-rights/for-individuals/special-topics/community-living-and-olmstead/index.html">https://www.hhs.gov/civil-rights/for-individuals/special-topics/community-living-and-olmstead/index.html</a>; Protecting the Civil Rights and Health Information Privacy

Despite this past progress, there is still much work to be done, and the Proposed Rule would divert limited resources away from ending discrimination. De facto segregation, for example, continues to contribute to poorer health outcomes for Black people. According to one study, over half of the racial disparity in survival for heart attack patients can be attributed to the lower performance of hospitals that serve predominantly people of color. 5 Black women are three to four times more likely than are white women to die during or after childbirth.6 And the disparity in maternal mortality is growing rather than decreasing, which in part may be due to the reality that women have long been the subject of discrimination in health care and the resultant health disparities. Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care (we discuss this further below).

There is an urgent need for OCR to address these disparities, yet the Proposed Rule seeks instead to prioritize the expansion of existing religious refusal laws beyond their statutory requirements to create new religious exemptions. The Proposed Rule will harm patient care and is antithetical to OCR's mission—to eliminate discriminatory practices that contribute to persistent health inequality.

#### B. The evidence does not support the existence of the problem the Proposed Rule purports to address

Rather than focusing on the overarching aim of ensuring that all people in this country have access to the health care they need, the Proposed Rule seeks to empower health care providers, whose very jobs are to deliver health care, to instead deny not only health care services but even information about services to which they might personally object. It would create additional barriers to care in a health care system already replete with obstacles, particularly for people with limited incomes or those who are LGBT.

Through prior rulemaking in this area, HHS has already created mechanisms by which any provider who believes they have been subject to discrimination in violation of any of the federal health care refusal statutes may file a complaint with OCR and seek redress. Complaints have been filed and resolved through this process. And HHS has the ability to decline to fund entities that engage in violations of these laws. Individual health care providers who wish to exercise a conscientious objection to participating in certain health care services have the ability to do so and HHS, through OCR, already has the tools it needs to protect those rights. Rather than seeking to engage in a sweeping new rulemaking effort that would inappropriately

Rights of People Living with HIV/AIDS, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civilrights/for-individuals/special-topics/hiv/index.html; National Origin Discrimination, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/index.html; Health Disparities, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/forindividuals/special-topics/health-disparities/index.html.

<sup>&</sup>lt;sup>5</sup> See Skinner et al., Mortality after Acute Myocardial Infarction in Hospitals that Disproportionately Treat African-Americans, NAT'L INSTIT. OF HEALTH 1 (2005),

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

<sup>&</sup>lt;sup>6</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-dving-after-giving-birth-shalon-irvingsstory-explains-why.

See id.

shift the balance too far in the direction of care denial, the agency should instead devote its resources to expanding access to health care for all.

#### 1. Discrimination against LGBT people in health care is pervasive

LGBT people, women, and other vulnerable groups already face significant barriers to getting the care they need. The Proposed Rule will compound the barriers to care that LGBT individuals face, particularly the effects of ongoing and pervasive discrimination, by inviting providers to refuse to provide services and information vital to LGBT health.

As a civil rights organization that has been advocating for the LGBT community for over four decades, we at NCLR see firsthand the negative effects of stigma and discrimination on LGBT people seeking care. Despite significant gains in societal acceptance and legal protections, we still face hostility and ill treatment simply for being who we are, and sometimes the consequences are fatal. For example, NLCR currently represents the parents of a transgender youth who died by suicide after being denied appropriate care and discharged prematurely by a hospital in southern California.<sup>9</sup>

LGBT people of all ages continue to face discrimination in health care on the basis of their sexual orientation and gender identity. The Department's Healthy People 2020 initiative recognizes that "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights." This surfaces in a wide variety of contexts, including physical and mental health care services. 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. They concluded that discrimination, as well as insensitivity or disrespect on the part of health care providers, were key barriers to health care access.

There is a growing body of research documenting how LGBT people encounter barriers in the health care system and suffer disproportionately from a variety of conditions due to health care

<sup>8</sup> See, e.g., Shabab Ahmed Mirza & Caitlin Rooney, Discrimination Prevents LGBTQ People from Accessing Health Care (2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discriminationprevents-lgbtq-people-accessing-health-care; Sandy E. James et al., The Report of the U.S. Transgender Survey 93–126 (2016), www.ustranssurvey.org/report; Institute of Medicine, The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding (2011), http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx; Lambda

http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx: Lambda Legal, When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV (2010), http://www.lambdalegal.org/publications/when-health-care-isnt-caring.

<sup>9</sup> See http://www.nclrights.org/cases-and-policy/cases-and-advocacy/case-prescott-v-rchsd/.

<sup>&</sup>lt;sup>10</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>&</sup>lt;sup>11</sup> HUMAN RIGHTS WATCH, All We want is Equality: Religious Exemptions and Discrimination against LGBT People in the United States, (Feb. 2018), <a href="https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people">https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people</a>.

<sup>&</sup>lt;sup>12</sup> Ning Hsich and Matt Ruther, HEALTH AFFAIRS, Despite Increased Insurance Coverage, Nonwhite Sexual Minorities Still Experience Disparities In Access To Care (Oct. 2017) 1786–1794.
<sup>13</sup> Id.

access issues compounded by stigma and discrimination. In 2010, Lambda Legal found that fifty-six percent of lesbian, gay, and bisexual survey respondents (out of 4,916 total respondents) experienced health-care discrimination in forms such as refusal of health care, excessive precautions used by health-care professionals, and physically rough or abusive behavior by health-care professionals. Seventy percent of transgender and gender nonconforming respondents experienced the same, and sixty-three percent of respondents living with HIV/AIDS had experienced health-care discrimination. In addition, low-income LGBT people and LGBT people of color experienced increased barriers to health care. Approximately seventeen percent of low-income lesbian, gay, and bisexual respondents and twenty-eight percent of low-income transgender respondents reported harsh language from health-care providers compared to under eleven percent of LGB respondents and twenty-one percent of transgender respondents, overall. 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.

A recent survey conducted by the Center for American Progress found that among lesbian, gay, bisexual, and queer (LGBQ) respondents who had visited a doctor or health care provider in the year before the survey:

- 8 percent said that a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation;
- 6 percent said that a doctor or other health care provider refused to give them health care related to their actual or perceived sexual orientation;
- 7 percent said that a doctor or other health care provider refused to recognize their family, including a child or a same-sex spouse or partner;
- 9 percent said that a doctor or other health care provider used harsh or abusive language when treating them;
- 7 percent said that they experienced unwanted physical contact from a doctor or other health care provider (such as fondling, sexual assault, or rape).

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

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

<sup>&</sup>lt;sup>14</sup> Lambda Legal, When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination against LGBT People and People with HIV, 2010, https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report\_when-health-care-isntcaring.pdf.

<sup>&</sup>lt;sup>15</sup> NAT'L CTR. FOR TRANSGENDER EQUALITY, The Report of the 2015 U.S. Transgender Survey 5 (2016), available at <a href="https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf">https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf</a>.

<sup>&</sup>lt;sup>16</sup> Shabab Ahmed Mirza & Caitlin Rooney, Discrimination Prevents LGBTQ People from Accessing Health Care (2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

- 12 percent said a doctor or other health care provider refused to give them health care related to gender transition;
- 23 percent said a doctor or other health care provider intentionally used the wrong name;
- 21 percent said a doctor or other health care provider used harsh or abusive language when treating them;
- 29 percent said that they experienced unwanted physical contact from a doctor or other health care provider (such as fondling, sexual assault, or rape).<sup>17</sup>

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

Health-care disparities in general are often more pronounced in rural areas in the United States, and this is further compounded for LGBT individuals, often due to a lack of cultural competency. This hinders physical and mental health providers from meeting the health needs of rural communities. <sup>19</sup> The lack of connection to positive, affirming resources also isolates LGBT youth, making them more susceptible to self-destructive behavior patterns. <sup>20</sup> Isolation continues into adulthood, when LGBT populations are more likely to experience depression and engage in high-risk behaviors. <sup>21</sup>

NCLR has been holding convenings of LGBT people in rural communities for the past several years, and we hear consistently about difficulties in accessing adequate health care. The challenges our community faces in these rural settings include having few providers with LGBT competency, difficulty maintaining health insurance coverage due to employment challenges, transportation difficulties to get to what medical providers there are, food deserts, and specific health conditions that are often more prevalent among LGBT people because of having to live with discrimination and social isolation, including poor eating habits, smoking, and substance abuse.

<sup>&</sup>lt;sup>17</sup> *Id*.

 $<sup>^{18}</sup>Id.$ 

<sup>&</sup>lt;sup>19</sup> Cathleen E. Willging, Melina Salvador, and Miria Kano, "Pragmatic Help Seeking: How Sexual and Gender Minority Groups Access Mental Health Care in a Rural State," *Psychiatric Services* 57, no. 6 (June 2006): 871–4, http://doi.org/10.1176/ps.2006.57.6.871.

<sup>&</sup>lt;sup>20</sup> Colleen S. Poon and Elizabeth M. Saewyc, "Out Yonder: Sexual-Minority Adolescents in Rural Communities in British Columbia," *American Journal of Public Health* 99, no. 1 (January 2009): 118–24, http://doi.org/10.2105/AJPH.2007.122945.

<sup>&</sup>lt;sup>21</sup> Trish Williams et al., "Peer Victimization, Social Support, and Psychosocial Adjustment of Sexual Minority Adolescents," *Journal of Youth and Adolescence* 34, no. 5 (October 2005): 471–82, https://doi.org/10.1007/s10964-005-7264-x.

In rural areas, if care is denied for religious reasons, there may be no other sources of health and life-preserving medical care.<sup>22</sup> The ability to refuse care to patients would therefore leave many individuals in rural communities with no health care options. Medically underserved areas already exist in every state,<sup>23</sup> with over 75 percent of chief executive officers of rural hospitals reporting physician shortages.<sup>24</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>25</sup>

In addition to geographic challenges, the problems for patients presented by the expansion of refusal provisions in both federal and state law have been exacerbated by the growth in health care systems owned and operated by religious orders. Mergers between Catholic and nonsectarian hospitals have continued as hospital consolidation has intensified. Catholic hospitals and health systems must follow the church's Ethical and Religious Directives for Catholic Health Care Services ("Directives"), which prohibit a wide range of reproductive health services, such as contraception, sterilization, abortion care, and other needed health care. <sup>26</sup> Nonsectarian hospitals must often agree to comply with these Directives in order to merge with Catholic hospitals. <sup>27</sup>

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's care was delayed or they were transferred to other facilities at great risk to their health. <sup>28</sup> The reach of this type of religious refusal of care is growing with the proliferation of religiously affiliated entities that provide health care and related services. <sup>29</sup> New research shows that women of color in many states disproportionately receive their care at Catholic hospitals. In nineteen states, women of color are more likely than are white women to give birth in Catholic hospitals. <sup>30</sup>

<sup>&</sup>lt;sup>22</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), <a href="http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/">http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/</a>.

<sup>&</sup>lt;sup>23</sup> Health Res. & Serv. Admin, Quick Maps — Medically Underserved Areas/Populations, U.S. DEP'T OF HEALTH & HUM. SERV., <a href="https://datawarehouse.hrsa.gov/Tools/MapToolQuick.aspx?mapName=MUA">https://datawarehouse.hrsa.gov/Tools/MapToolQuick.aspx?mapName=MUA</a>, (last visited Mar. 21, 2018).

<sup>&</sup>lt;sup>24</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>&</sup>lt;sup>25</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.

<sup>&</sup>lt;sup>26</sup> U.S. CONF. OF CATHOLIC BISHOPS, ETHICAL AND RELIGIOUS DIRECTIVES FOR CATHOLIC HEALTH SERVICES 25 (5th ed. 2009), available at <a href="http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf">http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf</a>.

<sup>&</sup>lt;sup>27</sup> Elizabeth B. Deutsch, Expanding Conscience, Shrinking Care: The Crisis in Access to Reproductive Care and the Affordable Care Act's Nondiscrimination Mandate, 124 Yale L. J. 2470, 2488 (2015).

<sup>&</sup>lt;sup>28</sup> Lori R. Freedman, When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals, AM. J. PUB. HEALTH (2008), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.

<sup>&</sup>lt;sup>29</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), <a href="https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf">https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf</a>.

<sup>&</sup>lt;sup>30</sup> See Kira Shepherd, et al., Bearing Faith The Limits of Catholic Health Care for Women of Color, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 12 (2018), <a href="https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf">https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf</a>.

Refusals in the context of reproductive health care sometimes run in both directions – they prevent access to contraception and abortion, but also to assisted reproductive technologies (ART) to enable pregnancy. Not only does this infringe on individuals' right to information and care, for those with certain medical conditions it directly contravenes the standard of care. For individuals with cancer, for example, 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. Refusals to educate patients about or to provide ART, or to facilitate ART when requested, are contrary to the standard of care.

While religiously-based objections to contraception and abortion are well known and have posed access barriers for years, less evident is how these types of refusals can also affect the LGBT community. Not only are LGBT people affected by denials of reproductive health care, other types of medically necessary care, such a transition-related care, are also frequently refused.

Many religious health care providers are opposed to infertility treatments altogether or are opposed to providing it to certain groups of people such as members of the LGBT community. Health care providers have even sought exemptions from state antidiscrimination laws to avoid providing reproductive services to lesbian parents. For example, in one case, an infertility practice group subjected a woman to a year of invasive and costly treatments only to ultimately deny her the infertility treatment that she needed because she is a lesbian. When doctors at the practice group recognized that the woman needed in vitro fertilization to become pregnant, every doctor in the practice refused, claiming that their religious beliefs prevented them from performing the procedure for a lesbian. Because this was the only clinic covered by her health insurance plan, the woman had to pay out-of-pocket for the treatment at another clinic, which subjected her to serious financial harm.

The lack of clarity in the Proposed 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

8

<sup>&</sup>lt;sup>31</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; Joanne Frankel Kelvin, Fertility Preservation Before Cancer Treatment: Options, Strategies, and Resources, 20 CLINICAL J. ONCOLOGY NURSING 44-51 (Feb. 2016).

<sup>&</sup>lt;sup>32</sup> U.S. CONF. OF CATHOLIC BISHOPS, ETHICAL AND RELIGIOUS DIRECTIVES FOR CATHOLIC HEALTH SERVICES 25 (5th ed. 2009), available at <a href="http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf">http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf</a>. (Directive 41 of the Ethical and Religious Directives for Catholic Health Care states: "Homologous artificial fertilization is prohibited when it separates procreation from the marital act in its unitive significance.")

Douglas Nejaime et al., Conscience Wars: Complicity-Based Conscience Claims in Religion and Politics, 124
 Yale L.J. 2516, 2518 (2015). See, e.g., N. Coast Women's Care Med. Grp., Inc. v. San Diego Cnty. Superior
 Court, 189 P.3d 959 (Cal. 2008) (on the potential impact of healthcare refusal laws on same-sex couples).
 Benitez v. N. Coast Women's Care Med. Grp., Inc., 106 Cal. App. 4th 978 (2003); see also LAMBDA LEGAL,
 BENITEZ V. NORTH COAST MEDICAL GROUP (Jul. 1, 2001), http://www.lambdalegal.org/in-court/cases/benitez-v-north-coast-womens-care-medical-group.

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.

Religiously-based refusals can also result in the denial of other medically necessary care to LGBT people, particularly those who are transgender and in need of gender-affirming services. The following is one example that we learned about through a call to our Legal Help Line:

• Carl, <sup>36</sup> a transgender man, needed to undergo a hysterectomy and oophorectomy as part of his medically-supervised transition. Working with his healthcare providers, Carl obtained insurance coverage for the procedure. His surgeon, who had privileges at several hospitals in the area, scheduled the procedure at the hospital that was nearest to Carl and the surgeon. That hospital happened to be a religiously-affiliated facility. A few days before the procedure was scheduled to occur, Carl was informed that he could not have the procedure done at the hospital. According to the surgeon, the decision was made by the hospital's Ethics Committee. The reason Carl was given for the decision was that "the hospital does not perform that type of hysterectomy." Due to the short notice of the cancellation, the surgeon was unable to get the procedure moved to another hospital.

The foregoing barriers and challenges are evident in the stories we are hearing from NCLR supporters who are alarmed by the prospect of this Rule, including the following comments that have been submitted already to HHS:<sup>37</sup>

- I and many of my community members struggle to afford healthcare as it is, even with full time jobs. I live in a rural area and even if you do have health insurance, access to healthcare is very difficult. I do not see how my sexual orientation, religion, or other parts of me that one might disagree with at a personal level has anything to do with my right to receive healthcare. This regulation, whatever its intentions, will give those who are discriminatory the ability to act on this in a way that can harm the community and disproportionately provide support based on personal differences. I fear this will only further drive people apart.
- As a retired nurse educator I find this proposed rule unethical, immoral, unconscionable & inhumane. All health professionals essentially take an oath to treat & or take care of any person regardless of their race/religion/age/sexual orientation/ethnic background. And women have a right to choose their own reproduction health care. I strongly oppose this rule which promotes discrimination & urge HHS to withdraw it.

<sup>&</sup>lt;sup>36</sup> This incident was reported to NCLR Legal Help Line attorneys; the name has been changed to protect the caller's privacy.

<sup>&</sup>lt;sup>37</sup> Some have been edited slightly for length and clarity.

- If this rule is allowed to exist, it will allow emergency room staff to turn away people maimed by car accidents, mass shootings and terrorist attacks. Do you really want to be waiting for life saving care as you are interviewed (interrogated) to determine that you are the "right" sort of person who aligns with a hospital staff member's religious beliefs? You could easily die as you try to prove that you are "worthy" of their care.
- I happen to be a health care provider and I see LGBT people in my practice regularly. I
  understand the disadvantages they face every day as they go to work, to school, and
  even at home in their families and communities. Access to health care is a critical
  problem for many people, and HHS should not be making the problem worse by
  inviting health care institutions and providers to turn people away based on religious or
  moral reasons.
- I am a US citizen, I am also Romani Hindu. I am an intersex female and lesbian. I greatly oppose any rules or laws that would allow any person to establish their personal religious views as a means to hold others as a lesser person. This archaic way of thinking does not create a peaceful and free nation. I live in America that is said to be a free nation. Yet I am not free simply because of who I am. I have a difficult time finding the heath care I need because of discrimination. I am a senior citizen of America and have been denied medical care. Giving any person the right to discriminate for any purpose does great harm to an entire country.
- I am an LBGTX woman, married and the mother of two adult children. I travel frequently for work and have paid into my company's health insurance system for over 40 years. While I'm fairly confident that wouldn't be refused treatment locally, the thought that I might be refused treatment during an emergency while I'm traveling because I am a gay woman is both appalling and frightening.
- I am a 75 year-old lesbian living in San Francisco. As an R.N. and an LCSW, I have worked in the healthcare field for my entire adult life. The proposed rule entitled "Protecting Statutory Conscience Rights in Health Care" would give permission to mistreat or not treat an entire group of citizens. This is outrageous! This would be against any oath that a healthcare provider has taken to provide healthcare to all without exception. An individual's personal opinions or biases have no place in the healthcare field. HHS should not promote discrimination of any kind. I am sure this proposed rule would prove to be unconstitutional if tested in our courts and it surely would be. This proposed rule should be withdrawn immediately! It's shocking that it's even been suggested.
- In many small communities there is a limited number of health care providers. Allowing this kind of bigotry and prejudice could be life-threatening to any number of people. I know of no religion that preaches withholding life-saving care from anyone. The whole idea of government sponsored bigotry is outrageous and about as un-American as you can get.
- In the last year alone, I had to be taken by ambulance to Emergency Rooms in Northern and Southern California due to a heart issue. I also had to go to an Emergency Room in

Rochester, NY. I dare to think what might have happened to me if the health care providers refused service because my same sex spouse was with me and they "objected" to our relationship.

- I fear we will return to the days where we could be refused health care because of who we love. In 2008, I had to carry legal papers with me to the emergency room so that my partner, before marriage was legal, could be informed about my illness and be involved in making decisions. We were lucky to have a nurse who was also lesbian and while she was on duty I had excellent care. One of my care givers was not happy that I had a female partner and excused himself from the room to send in another therapist a few hours later. We cannot go back, lives are at stake.
- I have personally known people who have come within inches of death from complications due to HIV/AIDS because of the neglect of a doctor based on that doctor's personal beliefs. Discrimination and personal beliefs should not factor in to medical treatment, ever.
- In our community there is a shortage of health care providers to begin with, and if you reduce the number of providers that LGBT people can use, people will die.
- My children (one of whom is still a minor) are part of the LGBTQ community, and your rule would allow physicians to deny them lifesaving medical treatment, should they fall ill or have a medical emergency, such as a car accident or appendicitis, because they are gay or trans. They could die in the waiting area of the ER while someone who would be willing to treat them is located, and brought to the hospital, or in transit to a hospital where someone would treat them. It would allow doctors providing preventative care like pap smears to turn away my trans son, so that he wouldn't be able to find out if he had ovarian cancer until it was too late. Or to deny them vaccines for preventable diseases, or even just the flu. It would allow pharmacists to deny my children a prescription for antibiotics, because they feel morally or religiously opposed to their "lifestyle choices." It could have allowed one of my best friends to die from the heart attack he had a few years ago, because he's married to another man - because he was taken to a Catholic hospital by the ambulance crew. If it happened again, and your rule is in place, that hospital, one of the largest and most comprehensive in coverage in our area, could start turning people away en mass, for simply not being Catholic. In a predominantly Mormon state, that means about half the population.

The fear expressed throughout these comments is palpable. LGBT people are all too familiar with discrimination and hostile treatment, including in health care settings, and inviting health care institutions and providers to turn away people and deny them care would exacerbate the widespread mistreatment experienced by many LGBT people in the health care system today.

#### 2. The Proposed Rule fits a troubling pattern at HHS

We are concerned that this overemphasis on the right to deny care rather than the right to receive it reflects a broader orientation on the part of the agency. In 2017, HHS adopted rules – with no prior public comment – vastly expanding existing religious exemptions from the

ACA's requirement of birth control coverage. This was followed by a Request for Information (RFI) regarding supposed barriers to participation in health care by religious entities, a puzzling choice given the proliferation of religiously affiliated health care systems in this country. The FY 2018 – 2022 HHS Strategic Plan also overemphasized accommodating religious beliefs and moral convictions of health care providers, while failing to mention key populations (like LGBT people) or include any measurable goals, as such a document is supposed to do. Taken together, these issuances from HHS signal an alarming approach to public health, one that elevates the personal religious beliefs of some health care providers far above patients' well-being.

#### C. The Proposed Rule fails completely to address its impact on patients

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

Existing refusals of care based on personal beliefs already undermine open communication between providers and patients, interfere with providers' ability to provide care according to medical standards, and ignore the reality that many providers want to provide comprehensive care. <sup>38</sup> The Proposed Rule would exacerbate these problems by emboldening health care entities and institutions to bind the hands of providers and attempt to limit the types of care they can provide. This has profound implications for the core medical ethical precept of informed consent, and for the ability of health care providers to follow accepted standards of care for their patients.

#### 1. 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. This right relies on two factors: access to relevant and medically-accurate information about treatment choices and alternatives, and provider guidance based on generally

<sup>38</sup> See, e.g., Kira Shepherd, et al., Bearing Faith The Limits of Catholic Health Care for Women of Color, Pub. RIGHTS PRIVATE CONSCIENCE PROJECT 1 (2018),

https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf, 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/, Julia Kaye, et al., Health Care Denied, AM. CIVIL LIBERTIES UNION 1 (2016),

https://www.aclu.org/sites/default/files/field\_document/healthcaredenied.pdf; Catherine Weiss, et al., Religious Refusals and Reproductive Rights, AM. CIVIL LIBERTIES UNION (2002), https://www.aclu.org/report/religious-refusals-and-reproductive-rights-report;.

<sup>&</sup>lt;sup>39</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).

accepted standards of practice. Both factors make trust between patients and health care professionals a critical component of quality care.

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." The American Nursing Association similarly maintains 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." Pharmacists are also expected to respect the autonomy and dignity of each patient.

The Proposed Rule purports to improve communication between patients and providers, <sup>43</sup> but in reality it will have the opposite effect, deterring open, honest conversations that are vital to ensuring that a patient is able to be in control of their medical circumstances. Informed consent is intended to address 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. <sup>44</sup> 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>45</sup>

In order to ensure that patient decisions are based on free will, informed consent is essential to the patient-provider relationship. The Proposed Rule threatens this principle by inviting

<sup>44</sup> BEAUCHAMP & CHILDRESS, supra note 39; Robert Zussman, Sociological perspectives on medical ethics and decision-making, 23 ANN. REV. Soc. 171-89 (1997).

<sup>&</sup>lt;sup>40</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>&</sup>lt;sup>41</sup> Code of ethics for nurses with interpretive statements, Provision 1.4 The right to self-determination, AM. Nurses Ass'n (2001), <a href="https://www.truthaboutnursing.org/research/codes/code">https://www.truthaboutnursing.org/research/codes/code</a> of ethics for nurses US.html.
<sup>42</sup> Code of Ethics for Pharmacists, AM. PHARMACISTS ASS'N (1994).

<sup>43 83</sup> Fed. Reg. 3917.

<sup>&</sup>lt;sup>45</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 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).

institutions and individual providers to withhold information about services to which they personally object, without regard for the patient's needs or wishes.

#### 2. Standards of care

The Proposed Rule also disregards standards of care established by the medical community by allowing providers to opt out of providing medical care. Medical practice guidelines and standards of care establish the boundaries of medical services that patients can expect to receive and that providers should be expected to deliver. Yet, the Proposed Rule seeks to allow providers and institutions to ignore standards of care, particularly surrounding reproductive and sexual health. Information, counseling, referral and provision of contraceptive and abortion services are not only important services in their own right, they are also part of the standard of care for a range of common medical conditions including heart disease, diabetes, epilepsy, lupus, obesity, and cancer. Allowing providers to flout established medical guidelines and deny medically accurate, evidence-based care to patients harms them and impairs their ability to make the health care decision that is right for them. It is alarming that a public health agency would actively encourage compromising patient health by facilitating departures from accepted standards of care.

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. While some of these physicians might refer their patients to another provider who could provide the necessary care, another 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. Meanwhile, the number of Catholic hospitals in the United States has increased by 22 percent since 2001, and they now control one in six hospital beds across the country. 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

\_

<sup>&</sup>lt;sup>46</sup> For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care. Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant. Am. DIABETES ASS'N, STANDARDS OF MEDICAL CARE IN DIABETES-2017, 40 DIABETES CARE § 114-15, S117 (2017), available at <a href="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</a>.

The American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics guidelines state that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually suggested regardless of fetal age or potential for survival. Am. ACAD. OF PEDIATRICS & Am. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES FOR PERINATAL CARE 232 (7th ed. 2012).

<sup>&</sup>lt;sup>47</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 <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2881970/">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2881970/</a>.

<sup>&</sup>lt;sup>48</sup> Farr A. Curlin M.D., et al., Religion, Conscience, and Controversial Clinical Practices, New Eng. J. Med. 593–600 (2007) available at <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2867473/">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2867473/</a>.

<sup>&</sup>lt;sup>49</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.

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>50</sup>

As outlined below, there are significant questions regarding the authority of HHS to enforce the statutes cited in the Proposed Rule in the manner suggested. But even if the types of care denials this rule encourages are ultimately found to contravene federal law, we have grave concerns that the very promulgation of this Rule in its current form will encourage some health care providers and institutions to improperly restrict access to care for LGBT people, those seeking reproductive health care, and others, with harmful consequences. The ability to seek legal redress at a later date is cold comfort to a patient denied essential, even life-saving, care.

#### II. HHS has failed to establish its authority to issue the Proposed Rule

It is incumbent upon HHS to set forth with specificity the source of its purported authority to engage in this rulemaking, through which it seeks to reinterpret the scope of over two dozen federal statutes by, among other things, redefining key terms and adopting a wider array of enforcement tools. Absent such a detailed showing, the Proposed Rule should be withdrawn because, in addition to representing misguided and dangerous public health policy, it goes well beyond the authority of HHS and is therefore unlawful.

#### A. HHS has exceeded its rulemaking authority

The Proposed Rule exceeds HHS's authority under the various federal refusal statutes it references and seeks to enforce. An agency may not promulgate regulations that purport to have the force of law without delegated authority from Congress.<sup>51</sup> Yet none of the 25 statutory provisions cited by the Proposed Rule delegates authority to HHS to engage in rulemaking as contemplated in the Proposed Rule. Specifically, nothing within the 25 statutes cited by the Proposed Rule gives HHS the authority to require healthcare entities to provide assurances or certifications, to post the extensive notice included as Appendix A of the Proposed Rule, or to keep and make records available for review.<sup>52</sup> Nor does it give HHS the authority to conduct periodic compliance reviews or to subject healthcare entities to the full investigative process described in Section 88.7 of the Proposed Rule.<sup>53</sup>

The Department draws this purported authority not from the cited statutes but from its desire to implement a regulatory scheme "comparable to the regulatory schemes implementing other civil rights laws." This desire arises from HHS's belief that the 25 cited statutes provide rights

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.
 Gonzales v. Oregon, 546 U.S. 243, 274-75 (2006); United States v. Mead, 533 U.S. 218, 229-30 (2001); Motion Picture Ass'n of Am., Inc. v. FCC, 309 F.3d 796, 801 (D.C. Cir. 2002); Amalgamated Transit Union v. Skinner, 894 F.2d 1362, 1371 (D.C. Cir. 1990)Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs., 43 F. Supp. 3d 28, 39-40 (D.D.C. 2014).

<sup>&</sup>lt;sup>52</sup> See 83 Fed. Reg. at 3928–30.

<sup>&</sup>lt;sup>53</sup> *Id.* at 3930–31.

<sup>&</sup>lt;sup>54</sup> 83 Fed. Reg. 3904.

"akin to other civil rights to be free from discrimination on the basis of race, national origin, disability, etc." Both the plain text and legislative history of these "other civil rights laws" distinguish them from the 25 statutes cited by the Proposed Rule, however. Each of the "other civil rights laws" cited by the Proposed Rule expressly authorizes HHS to promulgate regulations for their uniform implementation.

Title VI of the Civil Rights Act of 1964,<sup>56</sup> for example, which prohibits discrimination on the basis of race, color, or national origin in federal funding, states that "[e]ach Federal department and agency which is empowered to extend Federal financial assistance to any program or activity . . . is authorized and directed to effectuate the provisions of [Title VI] with respect to such program or activity by issuing rules, regulations, or orders of general applicability."<sup>57</sup> Title VI soon became the model for other nondiscrimination laws.<sup>58</sup>

Most recently, in Section 1557 of the Patient Protection and Affordable Care Act of 2009 (ACA), Congress clarified that the protections of Title VI, Title IX, the Age Discrimination Act, and Section 504 of the Rehabilitation Act of 1973 apply to all health programs or activities that receive federal financial assistance. Congress explicitly granted HHS the authority to promulgate regulations to implement Section 1557. Section 1553 of the ACA, which contains one of the refusal provisions cited by the Proposed Rule, does *not* contain such a grant. Rather, Section 1553 gives HHS the authority to "receive complaints of discrimination" based on its provisions. When Congress has explicitly granted an agency rulemaking authority in one section of a statute, the lack of such a grant in another section of the statute clearly indicates that Congress did not intend the agency to exercise rulemaking authority over that section. The ACA conforms to the pattern Congress has followed for the past half-century: When it intends to grant HHS the kind of rulemaking authority claimed by the Proposed Rule, it does so expressly. The lack of such an explicit grant in any of the 25 cited statutes is

<sup>&</sup>lt;sup>55</sup> *Id.* at 3903.

<sup>&</sup>lt;sup>56</sup> 42 U.S.C. 2000d et seq.

<sup>&</sup>lt;sup>57</sup> Pub. L. No. 88-352, Title VI, § 602, 78 Stat. 252 (1964) (codified at 42 U.S.C. § 2000d-1).

<sup>&</sup>lt;sup>58</sup> Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act (ADA) of 1990, both of which prohibit disability discrimination, explicitly refer to Title VI's enforcement provisions. *See* 29 U.S.C. § 794a(a)(2) (Section 504); 42 U.S.C. § 12133 (ADA). The Age Discrimination Act of 1975 not only permitted but required the Department to promulgate regulations to carry out its nondiscrimination provisions. 42 U.S.C. § 6103(a)(1). Title IX of the Education Amendments Act of 1972, which prohibits sex discrimination in education, contained delegation language that exactly mirrors that of Title VI. 20 U.S.C. § 1682.

<sup>&</sup>lt;sup>59</sup> See Pub. L. 111-148, Title I, § 1557 (2010) (codified at 42 U.S.C. § 18116(a)). Congress did not include conscience protections in Section 1557, strongly implying that it does not see them as being "akin to," 83 Fed. Reg. at 3904, or "on an equal basis" with "other civil rights laws," *id.* at 3896. See *Gen. Dynamics Land Sys., Inc. v. Cline*, 540 U.S. 581, 600 (2004) (noting that relationship with other federal statutes can be useful in statutory interpretation).

<sup>&</sup>lt;sup>60</sup> 42 U.S.C. § 18116(c). The Department did so on May 18, 2016. *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31376 (May 18, 2016) (to be codified at 45 C.F.R. part 92). The final rule contains no mention of conscience protections.

<sup>61</sup> See 42 U.S.C. § 18113.

<sup>&</sup>lt;sup>62</sup> *Id*.

<sup>&</sup>lt;sup>63</sup> See Amalgamated Transit Union, 894 F.2d at 1371 ("[O]n the few occasions when Congress intended to give UMTA broad rulemaking authority . . . it did so expressly.").

therefore clear evidence that HHS does not have congressional authority to promulgate the Proposed Rule.

#### B. The Proposed Rule violates the Administrative Procedure Act

Even if HHS could promulgate a rule such as this based on its general authority to engage in rulemaking, that authority is not without limits. Under the Administrative Procedure Act (APA), "agency action, findings, and conclusions found to be... arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "contrary to a constitutional right," or "in excess of statutory jurisdiction, authority, or limitations" shall be held unlawful and set aside. An agency must provide "adequate reasons" for its rulemaking, in part by "examin[ing] the relevant data and articulat[ing] a satisfactory explanation for its action including a rational connection between the fact found and the choice made. In addition, an agency can only change an existing policy if it provides a "reasoned explanation" for disregarding or overriding the basis for the prior policy.

#### 1. The Proposed Rule is arbitrary and capricious

In promulgating this Proposed Rule, HHS acted in an arbitrary and capricious manner in violation of the APA, and as a result the rule should be withdrawn in its entirety. The Proposed Rule is arbitrary and capricious on a number of grounds.

HHS fails to provide "adequate reasons" or a "satisfactory explanation" for this rulemaking based on the underlying facts and data. As stated in the Proposed Rule itself, between 2008 and November 2016, the Office of Civil Rights received ten complaints alleging violations of federal religious refusal laws; OCR received an additional 34 such complaints between November 2016 and January 2018. By comparison, during a similar time period from fall 2016 to fall 2017, OCR received *over 30,000 complaints* alleging either civil rights or HIPAA violations. These numbers demonstrate that rulemaking to enhance enforcement authority over religious refusal laws is not warranted.

HHS also fails to adequately assess the costs imposed by this Proposed Rule, both by underestimating quantifiable costs, and by neglecting to address the costs that would result from delayed or denied care. Under Executive Order 12866, when engaging in rulemaking, "each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify the costs." Under Executive Order 13563, an agency must "tailor its regulations to impose the least burden on society" and choose "approaches that maximize net benefits (including

<sup>&</sup>lt;sup>64</sup> 5 U.S.C. § 706(2)(A), (B), (C).

<sup>&</sup>lt;sup>65</sup> Encino Motorcars, LLC v. Navarro, 136 S.Ct. 2117, 2125 (June 20, 2016) (citing Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co., 463 U.S. 29, 103 (1983)).

<sup>&</sup>lt;sup>67</sup> Executive Order 12866 on Regulatory Planning and Review (September 30, 1993).

potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity)."68

HHS has failed to take the appropriate steps to ensure that the Proposed Rule is consistent with applicable law and does not conflict with the policies or actions of other agencies. Under Executive Order 12866, in order to ensure that agencies does not promulgate regulations that are "inconsistent, incompatible, or duplicative with its other regulations of those of other Federal agencies," each agency must include any significant regulatory actions in the Unified Regulatory Agenda. 69 HHS failed to include any reference to this significant regulation in its regulatory plans, and therefore failed to put impacted entities, including other federal agencies, on notice of possible rulemaking in this area. In addition, prior to publication in the Federal Register, the Proposed Rule must be submitted to the Office of Information and Regulatory Affairs (OIRA), within the Office of Management and Budget (OMB), to provide "meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order [12866] and do not conflict with the policies or actions of another agency." According to OIRA's website, HHS submitted the Proposed Rule to OIRA for review on January 12, 2018, one week prior to the Proposed Rule being published in the Federal Register. Standard review time for OIRA is often between 45 and 90 days; one week was plainly insufficient time for OIRA to review the rule, including evaluating the paperwork burdens associated with implementing it. In addition, it is extremely unlikely that within that one week timeframe, OIRA could or would have conducted the interagency review necessary to ensure that this Proposed Rule does not conflict with other federal statutes or regulations.

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

The Proposed Rule also conflicts with several key federal statutes, as well as the U.S. Constitution. It makes no mention of Title VII, 72 the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII. 73 With respect to religion, Title VII requires reasonable accommodation of

<sup>68</sup> Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Sec. 1 (b).

<sup>69</sup> Executive Order 12866, at Sec. 4(b),(c).

<sup>70</sup> Id. at Sec. 6(b).

<sup>71 &</sup>quot;Removing Barriers for Religious and Faith-Based Organizations To Participate in HHS Programs and Receive Public Funding," 82 Fed. Reg. 49300 (Oct. 25, 2017).

<sup>72 42</sup> U.S.C. § 2000e-2 (1964).

<sup>&</sup>lt;sup>73</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.

employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer. The For decades, Title VII has established the legal framework for religious accommodations in the workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on patients, coworkers, public safety, and other legal obligations. The Proposed Rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both. Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard. To

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

The Proposed Rule also conflicts with the Emergency Medical Treatment and Active Labor Act ("EMTALA"), which requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person to another facility. Under EMTALA every hospital is required to comply – even those that are religiously affiliated. Heaving 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 – such as those experiencing an ectopic pregnancy or miscarriage - not receiving necessary care. The Proposed Rule fails to explain how entities will be able to comply with the new regulatory requirements in a manner consistent with the statutory requirements of EMTALA, making the Proposed Rule unworkable.

Finally, the Establishment Clause of the First Amendment requires the government to adequately account for just these sorts of consequences when considering whether to grant

<sup>74</sup> See id.

<sup>&</sup>lt;sup>75</sup> Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), available at <a href="https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii\_religious\_hhsprovider\_reg.html">https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii\_religious\_hhsprovider\_reg.html</a>.

<sup>76</sup> See 42 U.S.C. s 1295dd(a)-(c)

<sup>&</sup>lt;sup>77</sup> 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 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).

religious exemptions to existing legal requirements and, in fact, bars granting an exemption when it would detrimentally affect any third party. The requires an agency 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." The proposed exemptions clearly impose burdens on and harm others and thus, violate the clear mandate of the Establishment Clause.

In promulgating a regulation that is inconsistent with federal statutes and regulations, as well as the Constitution, HHS engaged in arbitrary and capricious rulemaking, and its conduct was further compounded by a failure by OIRA to engage in appropriate oversight and review. For these reasons, the Proposed Rule should be withdrawn.

## 2. The Proposed Rule is not in accordance with law and exceeds statutory authority

The Proposed Rule is also not in accordance with law because much of its language exceeds the plain parameters and intent of the underlying statutes it purports to enforce. It defines common phrases and words used throughout existing refusals of care laws and civil rights laws in ways that stretch their intended meaning beyond recognition. Therefore, the Proposed Rule violates the APA and should be withdrawn.

For example, the Church Amendments prohibit federal funding recipients from discriminating against those who refuse to perform, or "assist in the performance" of, sterilizations or abortions on the basis of religious or moral objections, as well as those who choose to provide abortion or sterilization. 80 The statute does not contain a definition for the phrase "assist in the performance." Instead the Proposed Rule creates a definition, but one that is not in accordance with the Church Amendments themselves. The proposed definition includes participation "in any activity with an articulable connection to a procedure, health service or health service program, or research activity" and greatly expands the types of services that can be refused to include merely "making arrangements for the procedure" no matter how tangential. 81 This means individuals not "assisting in the performance" of a procedure within the ordinary meaning of the term, such as the hospital room scheduler, the technician charged with cleaning surgical instruments, and other hospital employees, could now assert a new right to refuse. As Senator Church stated from the floor of the Senate during debate on the Church Amendments: "The amendment is meant to give protection to the physicians, to the nurses, to the hospitals themselves, if they are religious affiliated institutions. There is no intention here to permit a frivolous objection from someone unconnected with the procedure to be the basis for a refusal

<sup>&</sup>lt;sup>78</sup> U.S. Const. amend. I; *Cutter v. Wilkinson.* 554 U.S. 709, 720, 722 (2005) (to comply with the Establishment Clause, courts "must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries" and must ensure that the accommodation is "measured so that it does not override other significant interests") (citing *Estate of Thornton v. Caldor*, 472 U.S. 703, 710 (1985)); *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 n.8 (1989); *see also Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).

<sup>&</sup>lt;sup>79</sup> Cutter, 544 U.S. at 720, 722; see also Thornton, 472 U.S. at 709-10.

<sup>80 42</sup> USC 300a-7.

<sup>81 83</sup> Fed. Reg. 3892.

to perform what would otherwise be a legal operation."82 This overly broad definition opens the door for religious and moral refusals from precisely the type of individuals that the amendment's sponsor himself sought to exclude. This arbitrary and capricious broadening of the amendment's scope goes far beyond what was envisioned when the Church Amendments were enacted.

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 applicable standards of care.

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.83 Any information distributed by any method, including online or print, regarding any service, procedure, or activity could be refused by an individual or entity if the information given would lead to a service, activity, or procedure to which the provider objects.

Under the Coats and Weldon Amendments, "health care entity" is defined to encompass a limited and specific range of individuals and entities involved in the delivery of health care. 84 The Proposed Rule attempts to combine separate definitions of "health care entity" found in different statutes and applicable in different circumstances into one broad term. 85 Such an attempt to expand the meaning of a statutory term Congress already took the time to define not only fosters confusion, but contravenes congressional intent. By expressly defining the term "health care entity" Congress implicitly rejected the inclusion of the other terms HHS now attempts to insert.86

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."87 Under this definition, virtually any member of the health care workforce could ostensibly refuse to serve a patient in any way.

The Weldon Amendment is expanded under the Proposed Rule by defining "discrimination" against a health care entity broadly to include a number of activities, including denying a grant

85 83 Fed. Reg. 3893.

<sup>82</sup> S9597, https://www.gpo.gov/fdsvs/pkg/GPO-CRECB-1973-pt8/pdf/GPO-CRECB-1973-pt8.pdf (emphasis added). Senator Church went on to reiterate that "[t]his amendment makes it clear that Congress does not intend to compel the courts to construe the law as coercing religious affiliated hospitals, doctors, or nurses to perform <u>surgical procedures</u> against which they may have religious or moral objection." S9601 (emphasis added). 83 Fed. Reg. 3895.

<sup>84</sup> The Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009); Public Health Service Act, 42 U.S.C. § 238n (2018).

<sup>86</sup> The doctrine of expressio unius est exclusio alterius (the expression of one thing implies the exclusion of others) as applied to statutory interpretation creates a presumption that when a statute designates certain persons, things, or manners of operation, all omissions should be understood as exclusions. 87 83 Fed. Reg. 3894.

or employment as well as an unspecified catch-all phrase "any activity reasonably regarded as discrimination." Such a vague and inappropriate definition provides no functional guidance to entities on how to comply with the applicable requirements, thereby fostering confusion and undermining non-discrimination laws. Because of the potential harm to individuals if religious refusals were allowed, courts have long rejected arguments that religiously affiliated organizations can opt out of anti-discrimination requirements. Instead, courts have held that the government has a compelling interest in ending discrimination and that anti-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." In seeking to craft a regulatory scheme mirroring "other civil rights laws," HHS is in fact hampering enforcement of the very civil rights laws it claims to be emulating.

Moreover, 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 – the denial may be for any reason at all. <sup>91</sup> The preamble uses language such as "those who choose not to provide" or "would rather not" as justification for a refusal. This unbounded license to deny care is made more dangerous by the fact that 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. 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.

The Proposed Rule also purports to equip OCR with a range of enforcement tools that it in fact lacks the authority to employ, including referring matters to the Department of Justice "for additional enforcement," something not contemplated within any of the statutes referenced in the Proposed Rule. These measures, combined with the impermissibly broad definitions and other inappropriately expansive interpretations of the underlying statutes, would have a chilling effect on the provision of a range of medically necessary health care services.

<sup>88 83</sup> Fed. Reg. 3892.

<sup>&</sup>lt;sup>89</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).

<sup>&</sup>lt;sup>90</sup> Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751, slip op. at 46 (2014).

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

<sup>92 83</sup> Fed. Reg. 3898.

#### Conclusion

The Proposed Rule departs from the core mission of HHS, would undermine patient care, and is contrary to law. We therefore urge that it be withdrawn.

If you have any questions regarding these comments, please contact Julianna S. Gonen, PhD, JD, NCLR Policy Director, at jgonen@nclrights.org or 202-734-3547.

National Center for Lesbian Rights

# Exhibit 81

## City and County of San Francisco Mark Farrell

Mayor

#### San Francisco Department of Public Health

Barbara A. Garcia, MPA Director of Health

Secretary Alex Azar
The U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Department of Health and Human Services Proposed Rule, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," Docket ID No. HHS-OCR-2018-0002 (RIN 0945-ZA03)

Dear Secretary Azar,

Thank you for the opportunity to submit comments on "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," Department of Health and Human Services (HHS) proposed rule RIN0945-ZA03, Docket ID No. HHS-OCR-2018-0002. The San Francisco Department of Public Health (SFDPH) strongly opposes this proposed rule and requests that it be withdrawn. In support of our position, we offer the information below based on our experience as a safety net provider of direct health services to thousands of insured and uninsured residents of San Francisco, including those most socially and medically vulnerable.

SFDPH, through the San Francisco Health Network (SFHN), provides San Francisco's only complete care system and includes primary care, dental care, emergency and trauma treatment, medical and surgical specialties, diagnostic testing, skilled nursing and rehabilitation, behavioral health services and jail health services. The mission of SFDPH is to protect and promote the health of all San Franciscans. SFDPH is dedicated to reducing health disparities and providing inclusive care to all patients. SFDPH provides this care though its top-rated programs, fifteen primary care community clinics, and hospitals, including Zuckerberg San Francisco General Hospital and Trauma Center (ZSFG). For example, Zuckerberg San Francisco General alone delivers over one thousand babies a year, has been at the forefront of HIV/AIDS care from the beginning of the AIDS crisis, and provides gender-confirmation surgeries to transgender patients.

Zuckerberg San Francisco General cares for approximately one in eight San Franciscans a year, regardless of their ability to pay. As the City's safety net hospital, Zuckerberg San Francisco General provides the highest-quality services, including to many patients covered through Medi-Cal (California's Medicare program). It provides life-saving emergency care as the only level one trauma center in San Francisco, serving a region of more than 1.5 million people. With the busiest emergency room in San Francisco, Zuckerberg San Francisco General receives one-third of all ambulances in the City, and treats nearly four

The mission of the San Francisco Department of Public Health is to protect and promote the health of all San Franciscans.

We shall ~ Assess and research the health of the community ~ Develop and enforce health policy ~ Prevent disease and injury ~

~ Educate the public and train health care providers ~ Provide quality, comprehensive, culturally-proficient health services ~ Ensure equal access to all ~

barbara.garcia@sfdph.org + (415) 554-2526 + 101 Grove Street, Room 308, San Francisco, CA 94102

thousand patients with traumatic injuries, annually. Many of Zuckerberg San Francisco General's programs focus on providing life-saving care in emergency situations.

As a safety net provider, SFDPH is extremely concerned by the proposed rule. HHS recently created the Division of Conscience and Religious Freedom with the purpose of protecting health care workers who refuse to treat patients on the basis of religious and moral objections. This new division and the proposed rule threaten the health of our patients, and are likely to have a particular negative impact on low-income people, women, and the LGBTQ community.

The proposed rule compromises patient care, undermines the oaths sworn to by medical and healthcare professionals, is unnecessary, and is practically unworkable.

First, the proposed rule provides no benefits and imposes only burdens on patients. It fails to take into account the very real costs it imposes on patients' rights to access care, and to do so without being subjected to discrimination. Prioritizing religious freedom over the provision of care allows discrimination and threatens the lives of patients, including women and the LGBTQ community. The proposed rule would undermine San Francisco's long-standing efforts to advance women's health and reproductive rights, prevent domestic violence, address sexual assault and human trafficking, and promote the health and well-being of women and the LGBTQ community through access to health promotion and health care services. The proposed rule threatens patients' constitutional right to access reproductive healthcare services, including abortions. This proposed rule would also exacerbate already enormous deficiencies in health care access among transgender and gender non-conforming individuals. Nearly a quarter of transgender people already report avoiding seeking medical care for fear of being mistreated.<sup>1</sup> This rule could further dissuade transgender people from seeking even the most routine services. The breadth of the rule is such that it is impossible to fully predict how the rule could impact patients—even access to basic care that on its face has no discernable connection to religious observance, such as dental care, could be threatened. Further, it would disproportionately place low-income San Franciscans at risk and threaten San Francisco's ability to provide necessary healthcare services to its residents most in need. The proposed rule completely fails to take into account the very real costs it imposes on patients' rights to access care, and to do so without being subjected to discrimination.

Second, the proposed rule elevates a right of conscience above all other ethical considerations. The proposed rule is in direct violation of the Hippocratic Oath, in which doctors swear to do no harm and to treat the ill to the best of their ability. Its definition of "refer" is so broad that it could potentially prevent SFDPH from ensuring that if one health care provider were unwilling to give certain care, another provider would be able to provide it without delay. When a patient seeks care from one of SFHN's clinics or hospitals, both the patient and SFDPH need to know that the patient is receiving all medically-necessary care.

Third, existing laws and regulations ensure that patients receive the essential health services they need, while adequately protecting the rights of conscience of healthcare workers. Patients have the right to access high-quality, inclusive and comprehensive care without encountering discrimination, and current

<sup>&</sup>lt;sup>1</sup> Sandy E. James et al., The Report of the U.S. Transgender Survey 98 (2016), www.ustranssurvey.org/report.

law ensures that access while also allowing accommodations for healthcare workers' religious beliefs. SFDPH is not aware of any employee request for a religious accommodation that it has been unable to provide under existing laws and regulations. Current law is perfectly adequate, and there is no need for the proposed rule.

Lastly, the proposed rule is unworkable in many other respects. In addition to ignoring the needs of patients, the proposed rule fails to account for how a health care organization could legally administer it. The proposed rule ignores competing obligations imposed on SFHN by other statutes such as the Emergency Medical Treatment and Active Labor Act and California's Unruh Civil Rights Act. It also ignores SFDPH's contractual obligations to its employees; the proposed rule could create problems with the fair administration of labor contracts between employees asserting conscience rights and those who do not.

The rule also appears to create administrative obstacles to providing employees with religious accommodations. The current draft lacks a requirement that workers seeking to assert a right of conscience inform their organization of their request, and therefore could deny the organization an opportunity to provide the worker with an accommodation. Moreover, the proposed definition of "discrimination" is so broad that even if a worker did request an accommodation, the very act of providing one could be considered discriminatory. If an employee failed to request an accommodation in advance of being presented with a patient who has an immediate need for care, the proposed rule creates a very real risk that the patient could be denied legally required or medically necessary care. Patient care is SFDPH's first and primary priority, but it is worth noting that in addition to harming a patient, such a situation could also potentially expose SFDPH to liability for violations of other laws and for malpractice.

For these reasons, we respectfully request HHS withdraw the Proposed Rule from consideration.

Sincerely,

20

Barbara A. Garcia

Director of Health

San Francisco Department of Public Health

# Exhibit 82

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."

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 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

<sup>&</sup>lt;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").

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. Women of color experience health care disparities such as high rates of cervical cancer and are disproportionately impacted by HIV.

<sup>&</sup>lt;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>&</sup>lt;sup>3</sup> 83 Fed. Reg. 3917.

<sup>&</sup>lt;sup>4</sup> *Id*.

<sup>&</sup>lt;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>&</sup>lt;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

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, 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>

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

<sup>&</sup>lt;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

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

#### b. The proposed rule will negatively impact rural communities

The ability to refuse care to patients will leave many individuals in rural communities with no health care options. Medically underserved areas already exist in every state, <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>&</sup>lt;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. 

13 Id at 12

<sup>&</sup>lt;sup>14</sup> Id at 9.

<sup>&</sup>lt;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* <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/</a>.

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

<sup>&</sup>lt;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>&</sup>lt;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.

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>&</sup>lt;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>&</sup>lt;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>&</sup>lt;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://aiph.aphapublications.org/doi/full/10.2105/AJPH.94.10.1695.

<sup>&</sup>lt;sup>23</sup> Lisa I. lezzoni 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>&</sup>lt;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 <a href="http://onlinelibrary.wiley.com/doi/10.1002/hep.23802/full">http://onlinelibrary.wiley.com/doi/10.1002/hep.23802/full</a>.

<sup>&</sup>lt;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>&</sup>lt;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.

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." 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. 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. 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.

#### i. <u>Discrimination against the transgender community</u>

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

<sup>&</sup>lt;sup>28</sup> Human Rights Watch, *All We want is Equality: Religious Exemptions and Discrimination against LGBT People in the United States*, (Feb. 2018), <a href="https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people">https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people</a>.

<sup>29</sup> Ning Hsieh and Matt Ruther, Health Affairs, *Despite Increased Insurance Coverage, Nonwhite* 

<sup>&</sup>lt;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); Doddsv. 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. III. 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. III.

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."

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>&</sup>lt;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>&</sup>lt;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-lgbtg-people-accessing-health-care/?link\_id=2&can\_id=d90c309ac9b5a0fa50d294d0b1cdf0b2&source=email\_rx-for-discrimination&email\_referrer=&email\_subject=rx-for-discrimination.

35 Nat'l CTR. FOR TRANSGENDER EQUALITY, The Report of the 2015 U.S. Transgender Survey 5 (2016),

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

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

<sup>&</sup>lt;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>&</sup>lt;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>&</sup>lt;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

<sup>.</sup>http://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report\_when-health-care-isnt-caring.pdf.

- 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. The World Professional

<sup>&</sup>lt;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>&</sup>lt;sup>42</sup> *Id*.

<sup>&</sup>lt;sup>43</sup> *Id*.

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

<sup>&</sup>lt;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>&</sup>lt;sup>47</sup> Mirza, supra note 34.

<sup>&</sup>lt;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/delivening-care/creating-lgbtq-friendly-practice#Meet a Standard of Practice (last visited Jan. 26, 2018, 12:56 PM).

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>&</sup>lt;sup>49</sup> Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, World Prof. Ass'n for Transgender Health (2011),

 $https://s3.amazonaws.com/amo\_hub\_content/Association 140/files/Standards \% 20 of \% 20 Care \% 20 V7\% 20 \% 20 Care \% 20 (2) (1).pdf.$ 

<sup>&</sup>lt;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>&</sup>lt;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>&</sup>lt;sup>53</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>&</sup>lt;sup>54</sup> More than 1 in 4 transgender women are HIV positive. Kates, *supra* note 37, at 6.

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 to 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>&</sup>lt;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://nwlc.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.

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. 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>&</sup>lt;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>&</sup>lt;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

decisions are based on free will, informed consent must be upheld in the patientprovider 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."61The American Nursing Association similarly requires that patient autonomy and self-determination are core ethical tenets of nursing. "Patients have the moral and legal right to determine what will be done with their own persons; to be given accurate, complete and understandable information in a manner that facilitates an informed judgment: to be assisted with weighing the benefits, burdens and available options in their treatment."62 Similarly, pharmacists are called to respect the autonomy and dignity of each patient.63

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

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

to choose between sterilization and medical care or welfare benefits and Mexican women forcibly sterilized). See also Buck v. Bell, 274 U.S. 200, 207 (1927) (upholding state statute permitting compulsory sterilization of "feeble-minded" persons); Vanessa Volz, A Matter of Choice: Women With Disabilities, Sterilization, and Reproductive Autonomy in the Twenty-First Century, 27 WOMEN RTS. L. REP. 203 (2006) (discussing sterilization reform statutes that permit sterilization with judicial authorization). 61 The AMA Code of Medical Ethics' Opinions on Informing Patients: Opinion 9.09 – Informed Consent,

<sup>14</sup> 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.

Code of Ethics for Pharmacists, Am. Pharmacists Ass'n (1994).

<sup>&</sup>lt;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/statepolicy/explore/emergency-contraception.

<sup>65</sup> Brownfield v. Daniel Freeman Marina Hospital, 256 Cal. Rptr. 240 (Ct. App. 1989).

In addition, the proposed rule does not provide any protections for health care professionals who want to provide, counsel, or refer for health care services that are implicated in this rule, for example, reproductive health or gender affirming care. Due to the rule's aggressive enforcement mechanisms and its vague and confusing language, providers may fear to give care or information. The inability of providers to give comprehensive, medically accurate information and options that will help patients make the best health decisions violates medical principles such as, beneficence, nonmaleficence, respect for autonomy, and justice. In particular, the principle of beneficence "requires that treatment and care do more good than harm; that the benefits outweigh the risks, and that the greater good for the patient is upheld."66 In addition, the proposed rule undermines principles of quality care. Health care should be safe, effective, patient-centered, timely, efficient, and equitable <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>&</sup>lt;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>&</sup>lt;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 <a href="http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf">http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf</a>.

<sup>68</sup> Id.

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).71 Buprenorphine, methadone, and naltrexone are the three FDA-approved drugs for treating patients with opioid use disorder. MAT is so valuable to treatment of addiction that the World Health Organization considers buprenorphine and methadone "Essential Medications." Buprenorphine and methadone are, in fact, opioids. However, while they operate on the same receptors in the brain as other opioids, they do not produce the euphoric effect of other opioids but simply keep the user from experiencing withdrawal symptoms. They also keep patients from seeking opioids on the black market, where risk of death from accidental overdose increases. Patients on MAT are less likely to engage in dangerous or risky behaviors because their physical cravings are met by the medication, increasing their safety and the safety of their communities. 73 Naloxone is another medication key to saving the lives of people experiencing an opioid overdose. This medication reverses the effects of an opioid and can completely stop an overdose in its tracks.<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>&</sup>lt;sup>69</sup> Holly Hedegaard M.D., et al. *Drug Overdose Deaths in the United States, 1999-2016*, NAT'L CTR. FOR HEALTH STATISTICS1-8 (2017).

 $<sup>^{70}</sup>$  Vital Signs, CTRs. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vitalsigns/opioid-overdoses/.

<sup>&</sup>lt;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.

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

borne illnesses such as HIV, Hepatitis C, and bacterial endocarditis was shut down in October 2017 by the Lawrence County, Indiana County Commission due to their moral objection to drug use, despite overwhelming evidence that these programs are effective at reducing harm and do not increase drug use. 76 One commissioner even quoted the Bible as he voted to shut it down. Use of naloxone to reverse overdose has been decried as "enabling these people" to go on to overdose again.<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." 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." The scientific consensus is that SUD is a chronic disease, and yet many recoil from the idea of treating SUD with medication like any other illness such as diabetes or heart disease. 80 The White House's own opioid commission found that "negative attitudes regarding MAT appeared to be related to negative judgments about drug users in general and heroin users in particular."81

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

<sup>&</sup>lt;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-lawrencecounty-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-exacta-higher-price-communities-ponder-who-should-be-saved/2017/07/15/1ea91890-67f3-11e7-8eb5cbccc2e7bfbf\_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.wvgazettemail.com/news/health/trump-officials-seek-opioid-solutions-in-wv/article\_52c417d8-16a5-59d5-8928-13ab073bc02b.html.

<sup>&</sup>lt;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 82 Christine Vestal, In Opioid Epidemic, Prejudice Persists Against Methadone, Stateline, Nov. 11, 2016, http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/11/11/in-opioid-epidemicprejudice-persists-against-methadone 83 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),

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

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

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

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

86 For example, Black women are three times more likely to be diagnosed with lupus than white women. Latinas and Asian, Native American, and Alaskan Native women also are likely to be diagnosed with lupus. Office on Women's Health, Lupus and women, U.S. DEP'T HEALTH & HUM. SERV. (May 25, 2017), https://www.womenshealth.gov/lupus/lupus-and-women. Black and Latina women are more likely to experience higher rates of diabetes than their white peers. Office of Minority Health, Diabetes and African Americans, U.S. DEP'T OF HEALTH & HUM. SERV. (Jul. 13, 2016),

https://minorityhealth.hhs.gov/omh/browse.aspx?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.

https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/plenary-addres-to-nationalgovernors-association.html. <sup>85</sup> Azar, *supra* note 84.

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/.

care from physicians who do not believe they have any obligations to refer their patients to other providers. 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. 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.

### 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. Precommendations 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.

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. Dow-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. The Institute of Medicine has

<sup>&</sup>lt;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 <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2867473/">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2867473/</a>.

<sup>&</sup>lt;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.

<sup>&</sup>lt;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 .odf

<sup>&</sup>lt;u>.pdf</u> <sup>92</sup> *Id.* at S114.

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

<sup>&</sup>lt;sup>94</sup> Lawrence B. Finer & Stanley K. Henshaw, Disparities in rates of unintended pregnancy in the United

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. Gonsistent 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.

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

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

 <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).
 96 Sexually Transmitted Disease Surveillance 2016, CTR. FOR DISEASE CONTROL & PREVENTION (Sept. 2017), https://www.cdc.gov/std/stats16/CDC\_2016\_STDS\_Report-for508WebSep21\_2017\_1644.pdf.
 97 American Academy of Pediatrics Committee on Adolescence, Condom Use by Adolescents, 132
 PEDIATRICS (Nov. 2013), http://pediatrics.aappublications.org/content/132/5/973; American Academy of Pediatrics, American College of Obstetricians and Gynecologists, March of Dimes Birth Defects
 Foundation. Guidelines for perinatal care. 6th ed. Elk Grove Village, IL; Washington, DC: American Academy of Pediatrics; American College of Obstetricians and Gynecologists; 2007; American College of Obstetricians and Gynecologists. Barrier methods of contraception. Brochure (available at http://www.acog.org/publications/patient\_education/bp022.cfm). Washington, DC: American College of Obstetricians and Gynecologists; 2008 July; World Health Organization, UNAIDS, UNFPA, Position statement on condoms and HIV prevention, UNICEF (2009),

https://www.unicef.org/aids/files/2009\_position\_paper\_condoms\_en.pdf.

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

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

### 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. Twenty three percent of the hospitals limited EC to victims of sexual assault.

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

<sup>&</sup>lt;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-incardiology/ten-points-to-remember/2017/01/24/14/40/management-of-pregnancy-in-patients-with-complex-chd.

<sup>&</sup>lt;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>&</sup>lt;sup>103</sup> For example, the American College of Obstetricians and Gynecologists specifically recommends that if a woman taking lodine 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 Obstetricians & Gynecology 387-96 (2002).

<sup>&</sup>lt;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
<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.

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. Refusals to educate patients about or to provide ART occur for two reasons: refusal based on religious beliefs about ART itself and refusals to provide ART to LGBTQ individuals because of their LGBTQ identity. In both situations, refusals to educate patients about ART and fertility preservation, and to facilitate ART when requested, are against the standard of care.

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

### f. HIV Health

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

<sup>&</sup>lt;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>&</sup>lt;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; Joanne Frankel Kelvin, Fertility Preservation Before Cancer Treatment: Options, Strategies, and Resources, 20 CLINICAL J. ONCOLOGY NURSING 44-51 (Feb. 2016).

<sup>&</sup>lt;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.

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

### VI. The proposed rule violates the Establishment Clause

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

The Supreme Court acknowledged the limitations imposed by the Establishment Clause in *Burwell v. Hobby Lobby Stores, Inc.*, declaring the effect on employees of an accommodation provided to employers under the Religious Freedom Restoration Act (RFRA) "would be precisely zero." Justice Kennedy emphasized that an accommodation must not "unduly restrict other persons, such as employees, in protecting their own interests." 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." 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>&</sup>lt;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>&</sup>lt;sup>112</sup> Hobby Lobby, 134 S. Ct. 2751, 2760 (2014).

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

<sup>&</sup>lt;sup>114</sup> 83 Fed. Reg. 3894.

#### 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. 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. 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 muddles 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. Instead, courts have held that the government has a compelling interest in ending discrimination

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

<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).

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

<sup>&</sup>lt;sup>119</sup> 83 Fed. Reg. 3892.

<sup>&</sup>lt;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-73ececea23c4/.

<sup>&</sup>lt;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.

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

<sup>&</sup>lt;sup>124</sup> *Id*. at 3895.

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

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

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

#### Conclusion

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.

<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).
127 83 Fed. Reg. 3893.

<sup>&</sup>lt;sup>128</sup> *Id*.

<sup>&</sup>lt;sup>129</sup> *Id*.

### Exhibit 83

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."

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 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

<sup>&</sup>lt;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").

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.

### 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. Women of color experience health

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 83</sup> Fed. Reg. 3917.

<sup>4</sup> Id.

<sup>&</sup>lt;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.

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." 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. In a recent study published in *Health Affairs*, researchers examined the

<sup>&</sup>lt;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>&</sup>lt;sup>8</sup> HUMAN RIGHTS WATCH, All We want is Equality: Religious Exemptions and Discrimination against LGBT People in the United States, (Feb. 2018), <a href="https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people">https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people</a>.

intersection of gender identity, sexual orientation, race, and economic factors in health care access. 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. 10

#### 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. 11 Numerous federal courts have found that federal sex discrimination statutes reach these forms of gender-based discrimination. 12 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." 13

<sup>&</sup>lt;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>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); Doddsv. U.S. Dep't of Educ., 845 F.3d 217 (6th Cir. 2016) (Title IX and Equal Protection Clause); Bames 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. III. 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. III. 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>&</sup>lt;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>&</sup>lt;sup>13</sup> Macy v. Holder, E.E.O.C. App. No. 0120120821, 2012 WL 1435995, \*12 (Apr. 20, 2012).

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. 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. 15

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.

<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.

<sup>&</sup>lt;sup>15</sup> NAT'L CTR. FOR TRANSGENDER EQUALITY, The Report of the 2015 U.S. Transgender Survey 5 (2016), available at <a href="https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf">https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf</a> [hereinafter 2015 U.S. Transgender Survey].

<sup>&</sup>lt;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 <a href="https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/">https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/</a>.

In the weeks leading up to the deadline for these comments, Callen-Lorde administered a short online 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. TGBTQ 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>&</sup>lt;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.

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. Almost ten percent of LGB respondents reported that they had been denied necessary health care expressly because of their sexual orientation. 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

<sup>&</sup>lt;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

<sup>.</sup>http://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report\_when-health-care-isnt-caring.pdf.

<sup>20</sup> Id.

<sup>&</sup>lt;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>&</sup>lt;sup>24</sup> CTRS FOR DISEASE CONTROL & PREVENTION, CDC Fact Sheet: HIV Among Gay and Bisexual Men 1(Feb. 2017), <a href="https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/cdc-msm-508.pdf">https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/cdc-msm-508.pdf</a>.

<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.

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. The World Professional Association for Transgender Health guidelines provide that gender-affirming interventions, when sought by transgender individuals, are medically necessary and part of the standard of care. The American College of Obstetricians and Gynecologists warns that failure to provide gender-affirming treatment can lead to serious health consequences for transgender individuals. 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>28</sup> HUMAN RIGHTS WATCH, supra note 28.

<sup>&</sup>lt;sup>27</sup> Mirza, supra note 34.

<sup>&</sup>lt;sup>26</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.

<sup>&</sup>lt;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>&</sup>lt;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.

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

<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>&</sup>lt;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>&</sup>lt;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

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." 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." Similarly, pharmacists are called to respect the autonomy and dignity of each patient.

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." 42

NURSES ASS'N (2001),

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).

38 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.

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>&</sup>lt;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).

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 fall 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 2016.46 The latest

<sup>&</sup>lt;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>&</sup>lt;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 <a href="http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf">http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf</a>.
<sup>45</sup> Id.

<sup>&</sup>lt;sup>46</sup> Holly Hedegaard M.D., et al. *Drug Overdose Deaths in the United States, 1999-2016*, NAT'L CTR. FOR HEALTH STATISTICS1-8 (2017).

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. $^{47}$ 

The clear, evidence-based treatment standard for opioid use disorder (OUD) is medication-assisted treatment (MAT). AB 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." 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. 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. 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

<sup>&</sup>lt;sup>47</sup> Vital Signs, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vitalsigns/opioidoverdoses/.

<sup>&</sup>lt;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.

World Health Organization, 19th WHO Model List of Essential Medicines (April 2015), http://www.who.int/medicines/publications/essentialmedicines/EML2015\_8-May-15.pdf
 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>&</sup>lt;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>&</sup>lt;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-treatmentmethadone-buprenorphine-naltrexone.

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." 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." 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. 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."

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

<sup>&</sup>lt;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-lawrencecounty-needle-exchange.

<sup>&</sup>lt;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-exacta-higher-price-communities-ponder-who-should-be-saved/2017/07/15/1ea91890-67f3-11e7-8eb5cbccc2e7bfbf\_story.html?utm\_term=.4184c42f806c.

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

<sup>&</sup>lt;sup>56</sup> Eric Eyre, Trump officials seek opioid solutions in WV, CHARLESTON GAZETTE-MAIL, May 9, 2017, https://www.wvgazettemail.com/news/health/trump-officials-seek-opioid-solutions-in-wv/article\_52c417d8-16a5-59d5-8928-13ab073bc02b.html.

<sup>&</sup>lt;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>&</sup>lt;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
<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 42</sup> C.F.R. §8.610.

<sup>&</sup>lt;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), <a href="http://www.bmj.com/content/357/bmj.i1550">http://www.bmj.com/content/357/bmj.i1550</a>.; Alex Azar, Secretary, U.S. Dep't of Health & Hum. Serv., Plenary Address to National Governors Association, (Feb. 24, 2018), <a href="https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/plenary-addres-to-national-governors-association.html">https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/plenary-addres-to-national-governors-association.html</a>.

"impossible" to quell the opioid epidemic without increasing the number of providers offering the evidence-based standard of care. 62 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. 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>

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

<sup>&</sup>lt;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 on Women's Health, *Lupus and women*, U.S. DEP'T HEALTH & HUM. SERV. (May 25, 2017), <a href="https://www.womenshealth.gov/lupus/lupus-and-women">https://www.womenshealth.gov/lupus/lupus-and-women</a>. 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),

<sup>&</sup>lt;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>&</sup>lt;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 <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2867473/">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2867473/</a>.

#### 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. 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.

#### 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

<sup>&</sup>lt;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.
<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). 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.

<sup>&</sup>lt;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.

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." 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. 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. 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 muddles 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. 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

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

<sup>&</sup>lt;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), <a href="https://www.eeoc.gov/laws/statutes/titlevii.cfm">https://www.eeoc.gov/laws/statutes/titlevii.cfm</a>.
<sup>71</sup> Id.

<sup>&</sup>lt;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).

basis of race, because such prohibitions further a "compelling interest in providing an equal opportunity to participate in the workforce without regard to race," and are narrowly tailored to meet that "critical goal." The uncertainty regarding how the proposed rule will interact with non-discrimination laws is extremely concerning.

#### 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 212-271-7200 ext.7134

Kimberleigh Joy Smith, MPA Senior Director for Community Health Planning and Policy ksmith@callen-lorde.org 212-271-7184

<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,

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

<sup>&</sup>lt;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>&</sup>lt;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), <a href="https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/">https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/</a>; Uttley, L., et al, Miscarriage of Medicine, MergerWatch and the ACLU (2013), <a href="https://www.aclu.org/report/miscarriage-medicine.">https://www.aclu.org/report/miscarriage-medicine.</a>
<

<sup>&</sup>lt;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 <a href="https://www.lambdalegal.org/news/ca\_20090929\_settlement-reached">https://www.lambdalegal.org/news/ca\_20090929\_settlement-reached</a>.
<sup>5</sup> Erdely, Sabrina, Doctors' beliefs can hinder patient care, SELF magazine, June 22, 2007, accessed at <a href="http://www.nbcnews.com/id/19190916/print/1/displaymode/1098/">https://www.nbcnews.com/id/19190916/print/1/displaymode/1098/</a>



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."

### 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>&</sup>lt;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>&</sup>lt;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-Apri; 21(2): 104-9, accessed at <a href="https://www.ncbi.nlm.nih.gov/pubmed/21353977">https://www.ncbi.nlm.nih.gov/pubmed/21353977</a>

<sup>§</sup> Stein, Rob, Religious hospitals' restrictions sparking conflicts, scrutiny, The Washington Post, January 3, 2011, accessed at <a href="https://www.washingtonpost.com/health-environment-science/religious-hospitals-restrictions-sparking-conflicts-scrutiny/2011/01/03/ABVVxmD">https://www.washingtonpost.com/health-environment-science/religious-hospitals-restrictions-sparking-conflicts-scrutiny/2011/01/03/ABVVxmD</a> story.html?utm term=.cc34abcbb928

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

<sup>&</sup>lt;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 (3rd Cir. 2000); In re Baby K, 16 F.3d 590, 597 (4th Cir. 1994); Nonsen v. Medical Staffing Network, Inc. 2006 WL 1529664 (W.D. Wis.); Grant v. Fairview Hosp., 2004 WL 326694, 93 Fair Empl. Prac. Cas. (BNA) 685 (D. Minn. 2006); Brownfield v. Daniel Freeman Marina Hosp., 208 Cal. App. 3d 405



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

<sup>&</sup>lt;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; also Guiahi, Maryam, Jeanelle Sheeder, and Stephanie Teal, Are women aware of religious restrictions on reproductive health at Catholic hospitals? A survey of women's expectations and preferences for family planning care, Contraception and Stulberg, D., et all, accessed here: http://www.contraceptionjournal.org/article/S0010-7824(14)00358-8/fulltext; Do women know when their hospital is Catholic and how this affects their care? Restrictions in Catholic Hospitals (PARRCH) national survey, Contraception, Volume 96, Issue 4, 268-269,accessed here: <a href="http://www.contraceptionjournal.org/article/S0010-7824(17)30235-4/fulltext">http://www.contraceptionjournal.org/article/S0010-7824(17)30235-4/fulltext</a>; 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.

 $<sup>^{16}</sup>$  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. 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. In rural areas there may be no other sources of health and life preserving medical care. 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>&</sup>lt;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>&</sup>lt;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.

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

<sup>&</sup>lt;sup>20</sup> See The Patient Should Come First: Refusals to Provide Reproductive Health Care, NAT'L WOMEN'S L. CTR. (2017), <a href="https://nwlc-ciw49tixgw5]bab.stackpathdns.com/wp-content/uploads/2017/05/Refusals-FS.pdf">https://nwlc-ciw49tixgw5]bab.stackpathdns.com/wp-content/uploads/2017/05/Refusals-FS.pdf</a>; Sandhya Somashekhar, A Pregnant Woman Wanted her Tubes Tied. Her Catholic Hospital Said No., WASH. POST (Sept. 13, 2015), <a href="https://www.washingtonpost.com/national/a-pregnant-woman-wanted-her-tubes-tied-her-catholic-hospital-said-no/2015/09/13/bd2038ca-57ef-11e5-8bb1-b488d231bba2\_story.html?utm\_term=.8c022b364b75.</a>
<sup>21</sup> See Kira Shepherd, et al., <a href="https://www.usahingtonpost.com/national/a-pregnant-woman-wanted-her-tubes-tied-her-catholic-hospital-said-no/2015/09/13/bd2038ca-57ef-11e5-8bb1-b488d231bba2\_story.html?utm\_term=.8c022b364b75.</p>

<sup>&</sup>lt;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), <a href="http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage">http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage</a>.

<sup>&</sup>lt;sup>23</sup> Athena Tapales et al., *The Sexual and Reproductive Health of Foreign-Born Women in the United States*, CONTRACEPTION 8, 16 (2018), <a href="http://www.contraceptionjournal.org/article/80010-7824(18)30065-9/pdf">http://www.contraceptionjournal.org/article/80010-7824(18)30065-9/pdf</a>; 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), <a href="http://www.nuestrotexas.org/pdf">http://www.nuestrotexas.org/pdf</a>/NT-spread.pdf.

<sup>&</sup>lt;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), <a href="https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/">http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/</a>. <sup>25</sup> See Kira Shepherd, et al., <a href="mailto:supra">supra</a> note 19, at 12.

<sup>&</sup>lt;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. Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care. 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. 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 pule 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>&</sup>lt;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), <a href="https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf">https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf</a>.

<sup>&</sup>lt;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-irvings-story-explains-why.

<sup>&</sup>lt;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.

30 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.

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