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Exhibit 119



NATIONAL CENTER FOR LESEIAN RIGHTS

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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The National Center for Lesbian Rights (NCLR) writes to urge that the above-referenced Proposed Rule be withdrawn in its entirety, as it would endanger patient health and encourage widespread discrimination in health care delivery.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 <u>of all Americans</u>. We fulfill that mission by providing for effective health and human services and fostering advances in medicine, public health, and social services" (emphasis added).¹ 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.² 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.³ 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.⁴

¹ See https://www.hhs.gov/about/index.html.

² OCR's Mission and Vision, DEP'T OF HEALTH AND HUMAN SERVS. (2018), <u>https://www.hhs.gov/ocr/about-us/leadership/mission-and-vision/index.html</u> ("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.").

³ 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.

⁴ See, e.g., Serving People with Disabilities in the Most Integrated Setting: Community Living and Olmstead, DEP'T OF HEALTH AND HUMAN SERVS. (2018). <u>https://www.hhs.gov/civil-rights/for-individuals/special-topics/community-living-and-olmstead/index.html</u>; *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,⁷ 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

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

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.

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

⁶ See Nina Martin, Black Mothers Keep Dying After Giving Birth. Shalon Irving's Story Explains Why, NPR (Dec. 2017), https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dving-after-giving-birth-shalon-irvings-story-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.⁸ 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.⁹

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."¹⁰ This surfaces in a wide variety of contexts, including physical and mental health care services.¹¹ 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.¹² They concluded that discrimination, as well as insensitivity or disrespect on the part of health care providers, were key barriers to health care access.¹³

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

⁸ See, e.g., Shabab Ahmed Mirza & Caitlin Rooney, Discrimination Prevents LGBTQ People from Accessing Health Care (2018), <u>https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discriminationprevents-lgbtq-people-accessing-health-care;</u> Sandy E. James et al., *The Report of the U.S. Transgender Survey* 93–126 (2016), <u>www.ustranssurvey.org/report;</u> 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 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. ⁹ See http://www.nclrights.org/cases-and-policy/cases-and-advocacy/case-prescott-v-rchsd/.

¹⁰ Healthy People 2020, Lesbian, Gay, Bisexual, and Transgender Health, U.S. DEPT. HEALTH & HUMAN SERV., <u>https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health</u>. (last accessed on Mar. 8, 2018).

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

¹² 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.
¹³ 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.¹⁴ 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

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).¹⁶

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;

¹⁴ 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/whcicreport_when-health-care-isntcaring.pdf.

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

¹⁶ 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-lgbtqpeople-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).¹⁷

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.¹⁸ 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.¹⁹ The lack of connection to positive, affirming resources also isolates LGBT youth, making them more susceptible to self-destructive behavior patterns.²⁰ Isolation continues into adulthood, when LGBT populations are more likely to experience depression and engage in high-risk behaviors.²¹

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.

¹⁷ Id.

 $^{^{18}}Id.$

¹⁹ 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.

²⁰ 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.

²¹ 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.²² 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,²³ with over 75 percent of chief executive officers of rural hospitals reporting physician shortages.²⁴ 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.²⁵

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.²⁶ Nonsectarian hospitals must often agree to comply with these Directives in order to merge with Catholic hospitals.²⁷

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.²⁸ 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.²⁹ 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.³⁰

²⁶ U.S. CONF. OF CATHOLIC BISHOPS, ETHICAL AND RELIGIOUS DIRECTIVES FOR CATHOLIC HEALTH SERVICES 25 (5th ed. 2009), available at <u>http://www.usccb.org/issues-and-action/human-life-and-dignity/health-</u>

care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf.

²² 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), <u>http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/</u>.

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

²⁴ 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/.

²⁵ 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.

²⁷ 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).

²⁸ 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/.

²⁹ 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), <u>https://www.aclu.org/files/assets/growth-ofcatholic-hospitals-2013.pdf</u>.

³⁰ 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), <u>https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf</u>.

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.³¹ 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.³² Health care providers have even sought exemptions from state antidiscrimination laws to avoid providing reproductive services to lesbian parents.³³ 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.³⁴ 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.³⁵ 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

<u>care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf</u>. (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.")

³⁴ 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-vnorth-coast-womens-care-medical-group. ³⁵ Id.

³¹ 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).

³² U.S. CONF. OF CATHOLIC BISHOPS, ETHICAL AND RELIGIOUS DIRECTIVES FOR CATHOLIC HEALTH SERVICES 25 (5th ed. 2009), available at <u>http://www.usccb.org/issues-and-action/human-life-and-dignity/health-</u>

³³ 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).

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,³⁶ 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:³⁷

- 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.

³⁶ This incident was reported to NCLR Legal Help Line attorneys; the name has been changed to protect the caller's privacy.

³⁷ 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. ³⁸ 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.³⁹ This right relies on two factors: access to relevant and medically-accurate information about treatment choices and alternatives, and provider guidance based on generally

³⁸ 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. CTVIL 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. CIVII. LIBERTIES UNION (2002), https://www.aclu.org/report/religiousrefusals-and-reproductive-rights-report.

³⁹ 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."⁴⁰The 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."⁴¹ Pharmacists are also expected to respect the autonomy and dignity of each patient.⁴²

The Proposed Rule purports to improve communication between patients and providers,⁴³ 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. ⁴⁴ 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.⁴⁵

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

⁴¹ Code of ethics for nurses with interpretive statements, Provision 1.4 The right to self-determination, AM, NURSES ASS'N (2001), <u>https://www.truthaboutnursing.org/research/codes/code_of_ethics_for_nurses_US.html</u>.

⁴⁰ 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.

⁴² Code of Ethics for Pharmacists, AM, PHARMACISTS ASS'N (1994).

^{43 83} Fed. Reg. 3917.

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

⁴⁵ 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.⁴⁶ 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.⁴⁷ 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.⁴⁸ 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.⁴⁹ 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

http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_LDC1/DC_40_S1_final.pdf, The American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics guidelines state that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually suggested regardless of fetal age or potential for survival. AM. ACAD. OF PEDIATRICS & AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES FOR PERINATAL CARE 232 (7th cd, 2012).

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2881970/.

⁴⁶ 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

⁴⁷ 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

⁴⁸ Farr A. Curlin M.D., et al., Religion, Conscience, and Controverstal Clinical Practices, New Eng. J. MeD. 593–600 (2007) available at <u>http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2867473/</u>

⁴⁹ 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.⁵⁰

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.⁵¹ 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.⁵² 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.⁵³

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."⁵⁴ This desire arises from HHS's belief that the 25 cited statutes provide rights

 ⁵⁰ 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.
 ⁵¹ 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).

⁵² See 83 Fed. Reg. at 3928–30.

⁵³ *Id.* at 3930–31.

⁵⁴ 83 Fed. Reg. 3904.

"akin to other civil rights to be free from discrimination on the basis of race, national origin, disability, etc."⁵⁵ 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 1964,⁵⁶ 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."⁵⁷ Title VI soon became the model for other nondiscrimination laws.⁵⁸

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.⁵⁹ Congress explicitly granted HHS the authority to promulgate regulations to implement Section 1557.⁶⁰ Section 1553 of the ACA, which contains one of the refusal provisions cited by the Proposed Rule, does *not* contain such a grant.⁶¹ Rather, Section 1553 gives HHS the authority to "receive complaints of discrimination" based on its provisions.⁶² 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.⁶³ 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

⁵⁵ *Id.* at 3903.

⁵⁶ 42 U.S.C. 2000d et seq.

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

⁵⁸ 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.

⁵⁹ 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).

⁶⁰ 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.

⁶¹ See 42 U.S.C. § 18113.

⁶² Id.

⁶³ 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.⁶⁴ 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."⁶⁵ 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.⁶⁶

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."⁶⁷ 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

⁶⁴ 5 U.S.C. § 706(2)(A), (B), (C).

⁶⁵ 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)).

⁶⁶ Id. at 2125-26.

⁶⁷ 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."70 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.⁷¹ 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

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

⁴⁰ Executive Order 12866, at Sec. 4(b),(c).

⁷⁰ Id. at Sec. 6(b).

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

^{12 42} U.S.C. § 2000e-2 (1964).

⁷³ Title VII of the Civil Rights Act of 1964, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.ecoc.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.⁷⁴ 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.⁷⁵

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.⁷⁶ Under EMTALA every hospital is required to comply – even those that are religiously affiliated.⁷⁷ 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

⁷⁴ See id.

¹⁵ Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), available at https://www.eeoc.gov/eeoc/foia/letters/2008/tiflevii_religious_hhsprovider_reg.html.

⁷⁶ See 42 U.S.C. s 1295dd(a)-(c)

¹⁷¹ See, e.g., Shelton v. University of Medicine and Dentistry of New Jersey, 223 F.3d 220, 228 (3rd Cir. 2000); In In re Baby K, 16 F.3d 590, 597 (4th Cir. 1994); Nonsen v. Medical Staffing Network, Inc. 2006 WL 1529664 (W.D. Wis.); Grant v. Fairview Hosp., 2004 WL 326694, 93 Fair Empl. Prac. Cas. (BNA) 685 (D. Minn. 2006); Brownfield v. Daniel Freeman Marina Hosp., 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); Barris v. County of Los Angeles, 972 P.2d 966, 972 (Cal. 1999).

religious exemptions to existing legal requirements and, in fact, bars granting an exemption when it would detrimentally affect any third party.⁷⁸ It 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."⁷⁹ 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

⁷⁸ 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).

⁷⁹ Cutter, 544 U.S. at 720, 722; see also Thornton, 472 U.S. at 709-10.

^{80 42} USC 300a-7.

^{81 83} 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

87 83 Fed. Reg. 3894.

⁸² S9597, <u>https://www.gpo.gov/fdsys/pkg/GPO-CRECB-1973-pt8/pdf/GPO-CRECB-1973-pt8.pdf</u> (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 <u>religious affiliated hospitals</u>, doctors, or nurses to perform <u>surgical procedures</u> against which they may have religious or moral objection." S9601 (emphasis added).
⁸³ 83 Fed. Reg, 3895.

⁸⁴ 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).

^{85 83} Fed. Reg. 3893.

⁸⁶ 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.

or employment as well as an unspecified catch-all phrase "any activity reasonably regarded as discrimination."⁸⁸ 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.⁸⁹ 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."⁹⁰ 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.⁹¹ 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,"⁹² 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.

^{88 83} Fed. Reg. 3892.

⁸⁹ 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).

⁹⁰ Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751, slip op. at 46 (2014).

⁹¹ 83 Fed. Reg. 3890-91.

^{92 83} 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

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Exhibit 120



March 27, 2018

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

Re: NPRM on Religious Exemptions for Health Care Entities (RIN 0945-ZA03)

To Whom It May Concern:

The National Center for Transgender Equality (NCTE) submits the following comments to express our strong opposition to expanding exemptions for health care entities based on religious or moral objections.

Founded in 2003, NCTE is one of the nation's leading social justice organizations working for life-saving change for the over 1.5 million transgender Americans and their families. Over our years of advocacy, we have time and again seen the harmful impact that discrimination in health care settings has on transgender people and their loved ones, including discrimination based on religious or moral disapproval of who transgender people are and how they live their lives. Our experience has shown us that discrimination against transgender people in health care—whether it is being turned away from a doctor's office or emergency room, being denied access to basic care, or being mistreated and degraded simply because of one's transgender status—is widespread and creates significant barriers to care. The sweeping and excessive expansions to religious and moral exemptions sought by this rule go far beyond established law and threaten to severely exacerbate the barriers to care that transgender people and other vulnerable patient populations face.

We deeply respect and value freedom of religion, which is already protected by our Constitution, numerous federal statutes, and existing Department regulations. But refusing or obstructing access to medical care is a perversion of that cherished principle. In health care, patients must come first. By opening the door to health care refusals that go far beyond those permitted under federal law, this rule is harmful, unnecessary, and unsupported by federal law, and it would undermine the critical purposes of the Department's programs and the civil rights laws it is responsible for enforcing.

Simply put, the proposed rule is contrary to law and would harm patients. We urge the Department to reject this harmful and unnecessary rule.

I. Expanding religion-based exemptions can exacerbate the barriers to service access that transgender people and other vulnerable populations face.

For many Americans, including transgender Americans, discrimination in health care settings remains a grave and widespread problem and contributes to a wide range of health disparities. The proposed rule

1133 19th Street NW Suite 302 Washington, DC 20036 202-642-4542 www.TransEquality.org would exacerbate this urgent problem by encouraging actions that deny or obstruct access to timely medical care.

A. Transgender people face widespread discrimination in health care settings.

An estimated 0.6% of the U.S. adult population is transgender, representing 1.4 million adults over the age of 18, as well as hundreds of thousands of young Americans.¹ The medical and scientific community overwhelmingly recognizes that a person's innate experience of gender is an inherent aspect of the human experience for all people, including transgender people.² For example, the American Psychological Association states that having "deeply felt, inherent" gender identity that is different from the gender one was thought to be at birth is part of "healthy and normative" range of variation in human development found across cultures and across history.³ The Department has previously recognized that "variations in gender identity and expression are part of the normal spectrum of human diversity."⁴

Many, though not all, transgender people experience a medical condition known as gender dysphoria. Gender dysphoria is a serious medical condition that is codified in the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM 5), which defines it as clinically significant distress or impairment related to an incongruence between one's experienced gender and the gender one was thought to be at birth.⁵ Like anyone, transgender people need preventive care to stay healthy and acute care when they become sick or injured. Some may also need medical care to treat gender dysphoria. Under the treatment protocol widely accepted by the medical community, medically necessary treatment for gender dysphoria may require steps to help an individual transition from living as one gender to another.⁶ This treatment, sometimes referred to as "transition-related care," may include

¹ Andrew R. Flores et al., *How Many Adults Identify as Transgender in the United States*? (2016),

http://williamsinstitute.law.ucla.edu/wp-content/uploads/How-Many-Adults-Identify-as-Transgender-in-the-United-States.pdf. See also Jody L. Herman et al. Age of Individuals who Identify as Transgender in the United States (2017), https://williamsinstitute.law.ucla.edu/wp-content/uploads/TransAgeReport.pdf (estimating that 0.7% of people in the United States between the ages of 13 and 17, or 150,000 adolescents, are transgender).

⁵ Am. Psychiatric Ass'n, Diagnostic and Statistical Manual of Mental Disorders 452 (5th ed. 2013).

² See, e.g., Am. Psychological Ass'n, Guidelines for Psychological Practice with Transgender and Gender Nonconforming People, 70 AMERICAN PSYCHOLOGIST 832, 834-35 (2015), https://www.apa.org/practice/guidelines/transgender.pdf; Brief of American Academy of Pediatrics, American Psychiatric Association, American College of Physicians, and 17 Additional Medical and Mental Health Organizations in Support of Respondent, G. G. v. Gloucester County Sch. Bd., No. 16-274 8–9 (Sup. Ct. filed March 2, 2017) (affirming that "[e]veryone—whether they are transgender or cisgender—develops awareness of their gender identity along a 'pathway'" with typical stages and that transgender identity is a normal variation of this development); Human Rights Campaign, Am. Acad. of Pediatrics, & Am. College of Osteopathic Pediatricians, Supporting & Caring for Transgender Children (2016), https://assets2.hrc.org/files/documents/SupportingCaringforTransChildren.pdf; World Prof. Ass'n for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People 16 (7th ed. 2011), https://www.wpath.org/publications/soc.

³ Am. Psychological Ass'n, Guidelines for Psychological Practice with Transgender and Gender Nonconforming People, *e*, 70(9):832, 834-35 (2015).

⁴ Substance Abuse & Mental Health Servs., *Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth* 1 (2015), https://store.samhsa.gov/shin/content/SMA15-4928/SMA15-4928.pdf.

⁶ See generally World Prof. Ass'n for Transgender Health, supra note 2; Wylie C. Hembree et al., Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, 102 THE JOURNAL OF CLINICAL ENDOCRINOLOGY & METABOLISM 3869 (2017). See also Am. Medical Ass'n, AMA Policies on GLBT Issues, Patient-Centered Policy H-185.950, Removing Financial Barriers to Care for Transgender Patients (2008),

http://www.imatyfa.org/assets/ama122.pdf (recognizing WPATH Standards as "internationally accepted"); Am. Psychiatric Ass'n, Position Statement on Discrimination Against Transgender and Gender Variant Individuals (2012),

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counseling, hormone therapy, and/or a variety of possible surgical treatments, depending on the individualized needs of each patient.⁷ It is the overwhelming consensus among major medical organizations—including the American Medical Association,⁸ the American College of Physicians,⁹ the American Psychological Association,¹⁰ the American Psychiatric Association,¹¹ the American Academy of Family Physicians,¹² the Endocrine Society,¹³ the American College of Obstetricians and Gynecologists,¹⁴ and the World Professional Association for Transgender Health¹⁵—that transition-related treatments are medically necessary, effective, and safe when clinically indicated to alleviate gender dysphoria. For example, the American Psychiatric Association "[a]dvocates for removal of barriers to care…for gender transition treatment," emphasizing that "[s]ignificant and long-standing medical and psychiatric literature exists that demonstrates clear benefits of medical and surgical interventions to gender variant individuals seeking transition" and "[a]ccess to medical care (both medical and surgical) positively impacts the mental health of transgender and gender variant individuals."¹⁶ Numerous studies and meta-analyses have demonstrated the significant benefits of transition-related care in the treatment of gender dysphoria.¹⁷ Indeed, transition-related treatments are the only treatments that have been demonstrated to be effective in treating gender dysphoria.¹⁸

⁷ See World Prof. Ass'n for Transgender Health, supra note 2 at 16.

¹⁰ Am. Psychological Ass'n, supra note 6.

https://www.aafp.org/dam/AAFP/documents/about_us/special_constituencies/2012RCAR_Advocacy.pdf. ¹³ Hembree et al., *supra* note 6.

¹⁴ Am. College of Obstetricians & Gynecologists, Committee Opinion No. 512: Health Care for Transgender Individuals, 118 OBSTETRICS & GYNECOLOGY 1454 (2011), <u>https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-for-Transgender-Individuals</u>.

¹⁵ World Prof. Ass'n for Transgender Health, *supra* note 2.

¹⁶ Am. Psychiatric Ass'n, *supra* note 6.

¹⁷ See, e.g., Ashli A. Owen-Smith, et al., Association Between Gender Confirmation Treatments and Perceived Gender Congruence, Body Image Satisfaction, and Mental Health in a Cohort of Transgender Individuals. J SEXUAL MEDICINE (Jan. 17 2018); Gemma L. Witcomb et al., Levels of Depression in Transgender People and its Predictors: Results of a Large Matched Control Study with Transgender People Accessing Clinical Services, J. AFFECTIVE DISORDERS (Feb. 2018) Cecilia Dhejne et al., Mental Health and Gender Dysphoria: A Review of the Literature, 28 INI'L REV. PSYCHIATRY 44 (2016): William Byne et al., Report of the American Psychiatric Association Task Force on Treatment of Gender Identity Disorder, 41 ARCHIVES OF SEXUAL BEHAVIOR 759 (2012); Marco Colizzi, Rosalia Costa, & Orlando Todarello, Transsexual Patients' Psychiatric Comorbidity and Positive Effect of Cross-Sex Hormonal Treatment on Mental Health: Results from a Longitudinal Study, 39 PSYCHONEUROENDOCRINOLOGY 65 (2014); Audrey Gorin-Lazard et al., Hormonal Therapy is Associated with Better Self-Esteem, Mood, and Quality of Life in Transsexuals, 201 J. NERVOUS & MENTAL DISORDERS 996 (2013); M. Hussan Murad et al., Hormonal Therapy and Sex Reassignment: A Systematic Review and Meta-Analysis of Quality of Life and Psychosocial Outcomes, 72 CLINICAL ENDOCRINOLOGY 214 (2010); Griet De Cuypere et al., Sexual and Physical Health After Sex Reassignment Surgery, 34 ARCHIVES OF SEXUAL BEHAVIOR 679 (2005); Giuloio Garaffa, Nim A. Christopher, & David J. Ralph, Total Phallic Reconstruction in Female-to-Male Transsexuals, 57 EUROPEAN UROLOGY 715 (2010); Caroline Klein & Boris B. Gorzalka. Sexual Functioning in Transsexuals Following Hormone Therapy and Genital Surgery: A Review, 6 J. SEXUAL MEDICINE 2922 (2009).

¹⁸ See, e.g., Substance Abuse & Mental Health Servs., *supra* note 3.

http://www.dhcs.ca.gov/services/MH/Documents/2013_04_AC_06d_APA_ps2012_Transgen_Disc.pdf (citing WPATH Standards); Am. Psychological Ass'n, Policy on Transgender, Gender Identity & Gender Expression Non-Discrimination (2008), http://www.apa.org/about/policy/transgender.aspx (same).

⁸ Am. Medical Ass'n, *supra* note 6.

⁹ Am. College of Physicians, Lesbian, Gay, Bisexual and Transgender Health Disparities: A Policy Position Paper from the American College of Physicians, 163 ANNALS OF INTERNAL MEDICINE 135, 140 (2015).

¹¹ Am. Psychiatric Ass'n, supra note 6.

¹² Am. Acad. of Family Physicians, Resolution No. 1004: Transgender Care (2012),

Despite the medical consensus regarding the necessity of transition-related care, many transgender people have struggled to get access to medically necessary care—including care recommended to treat gender dysphoria, as well as medical care for unrelated conditions. Numerous studies have documented the widespread and pervasive discrimination experienced by transgender people and their families in the health care system. For example, the 2015 U.S. Transgender Survey, a national study of nearly 28,000 transgender adults in the United States, found that:

- Just in the year prior to taking the survey, one-third (33%) of respondents who saw *any health care provider* during that year were turned away because of being transgender, denied treatment, physically or sexually assaulted in a health care setting, or faced another form of mistreatment or discrimination due to being transgender.¹⁹
- In the year prior to taking the survey, nearly one-quarter (22%) of respondents who visited a *drug* or alcohol treatment program where staff thought or knew they were transgender were denied equal treatment or service, verbally harassed, or physically assaulted there due to being transgender.²⁰
- In the year prior to taking the survey, 14% of respondents who visited a *mursing home or extended care facility* where staff thought or knew they were transgender were denied equal treatment or service, verbally harassed, or physically assaulted there due to being transgender.²¹
- In the year prior to taking the survey, one-quarter (25%) of respondents *experienced a problem* with their health insurance related to being transgender. This included being denied coverage for treatments for gender dysphoria as well as being denied coverage for a range of unrelated conditions simply because they are transgender.²²
- In the year prior to taking the survey, 23% of respondents *avoided seeking medical care* when they needed it because of fear of being mistreated, and 33% avoided seeking necessary health care because they could not afford it.²³

The 2015 U.S. Transgender Survey also revealed patterns of marked health disparities affecting respondents. Respondents were approximately five times more likely than the general population to have been diagnosed with HIV, with elevated rates among people of color and in particular among Black transgender women, who were over 60 times more likely to be living with HIV than the general population.²⁴ Standard questions based on the K-6 Kessler Psychological Distress Scale revealed that transgender respondents were approximately eight times more likely than the general population to have experienced serious psychological distress in the month prior to taking the survey.²⁵ Further, respondents were nearly twelve times more likely to have attempted suicide in the previous year than the general population.²⁶ Rates of suicide attempts and psychological distress were particularly high among respondents who had faced barriers to accessing medical care and anti-transgender discrimination in health care and other settings.

¹⁹ Sandy E. James et al., *The Report of the 2015 U.S. Transgender Survey* 96–97 (2016), <u>www.ustranssurvey.org/report.</u> ²⁰ *Id.* at 216.

²¹ *Id.* at 219.

²² Id. at 95.

²³ Id. at 98.

²⁴ Id. at 122.

²⁵ Id. at 105.

Similarly, a nationally representative 2017 study found that transgender respondents faced high rates of discrimination in health care settings.²⁷ Out of those who had visited a doctor or health care provider in the previous year:

- Nearly one-third (29%) reported that a health care provider refused to see them because of their actual or perceived gender identity.
- One in eight (12%) said that a health care provider refused to provide them with care related to gender dysphoria.
- More than one in five (21%) said that a health care provider used harsh or abusive language when treating them.
- Nearly one-third (29%) experienced unwanted physical contact or sexual assault by a health care
 provider.

For many transgender people, especially those living outside of metropolitan areas, simply finding a different provider is not a viable option. Many transgender respondents to the 2017 study reported that it would be very difficult or impossible for them to find alternative providers to get the care they need if they were turned away by a health care provider. For example, nearly one-third (31%) of transgender respondents said it would be "very difficult" or "not possible" to find the same type of service at a different hospital and 30% said it would be "very difficult" or "not possible" to find the same type of service at a different community health center or clinic.²⁸

Health disparities facing transgender people have been recognized in a major 2011 report of the National Academy of Medicine (then the Institute of Medicine),²⁹ and by the Department's Healthy People 2020 initiative.³⁰ These disparities do not reflect inherent pathology; as the American Psychiatric Association has stated, "[b]eing transgender or gender variant implies no impairment in judgment, stability, reliability, or general social or vocational capabilities; however, these individuals often experience discrimination due to a lack of civil rights protections for their gender identity or expression."³¹ Discrimination and barriers to care exacerbate the marked health disparities affecting transgender individuals,³² including by increasing transgender people's risk factors for poor physical and mental

²⁷ Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessinghealth-care.

²⁸ Id.

²⁹ Inst. of Medicine, The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding (2011), <u>http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx</u>.

³⁰ Dep't of Health & Human Servs., Healthy People 2020: LGBT Health Topic Area (2015),

http://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health ("LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights.") ³¹ Am. Psychiatric Ass'n, *supra* note 6.

³² See, e.g., Ilan H. Meyer et al., Demographic Characteristics and Health Status of Transgender Adults in Select US Regions: Behavioral Risk Factor Surveillance System, 2014, 107 AM. J. PUB. HEALTH 582 (2017); Joint Comm'n, Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for the LGBT Community: A Field Guide (2011), <u>http://www.jointcommission.org/assets/1/18/LGBTFieldGuide.pdf</u>.

health³³ and driving high rates of HIV.³⁴ Numerous studies have found that when transgender people are supported in their environment, including by accessing the health care they need without discrimination, the health disparities they experience decrease substantially.³⁵

As leading medical organizations such as American Medical Association³⁶ and the American Psychological Association³⁷ have emphasized, robust laws protecting patients from discrimination are essential in addressing these disparities and reducing the barriers to care facing millions of Americans, including transgender Americans, while expanding religious exemptions can dangerously exacerbate those barriers to care. In response to the Department's recent Request for Information regarding "Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding," numerous medical organizations expressed concerns with expanding religious exemptions in health care, including the American Psychiatric Association,³⁸ the American Psychological Association,³⁹ the American Medical Association,⁴⁰ the American Academy of Pediatrics,⁴¹ and the American Academy of Nursing.⁴²

B. Other vulnerable populations, including women, lesbian, gay, and bisexual people, communities of color, people with disabilities, and people with limited English proficiency, struggle to access adequate care.

³⁷ Am. Psychological Ass'n, Comment Letter on Request for Information on Patient Protection and Affordable Care Act: Reducing Regulatory Burdens and Improving Health Care Choices to Empower Patients (July 12, 2017), <u>https://www.regulations.gov/document?D=CMS-2017-0078-2528</u>.

³⁸ Am. Psychiatric Ass'n, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 22, 2017), <u>https://www.regulations.gov/document?D=HHS-OS-2017-0002-10700</u>.

³³ Ctrs. for Disease Control & Prevention, *Lesbian, Gay, Bisexual, and Transgender Health* (2014), http://www.ede.gov/lgbthealth/about.htm.

³⁴ Ctrs. for Disease Control & Prevention, *HIV and Transgender Communities* (2016), https://www.cdc.gov/hiv/pdf/policies/cdc-hiv-transgender-brief.pdf.

³⁵ See, e.g., Lily Durwood, Katie A. McLaughlin, & Kristina R. Olson, Mental Health and Self-Worth in Socially Transitioned Transgender Youth, 56 J. AM. ACAD. CHILD ADOLESC. PSYCHIATRY 116 (2017); Kristina R. Olson et al., Mental Health of Transgender Children Who Are Supported in Their Identities, 137 PEDIATRICS (2016); Annelou L. C. de Vries et al., Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment, 134 PEDIATRICS (2014).

³⁶ Am. Medical Ass'n, *Letter to Director Roger Severino* (Sept. 1, 2017), <u>https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2017-09-01_Letter-to-Severino-re-Section-1557-Identity-Protection.pdf.</u>

³⁹ Am. Psychological Ass'n, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 21, 2017), <u>https://www.regulations.gov/document?D=HHS-OS-2017-0002-8429</u>.

⁴⁰ Am. Medical Ass'n, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 17, 2017),

https://www.regulations.gov/document?D=HHS-OS-2017-0002-7327https://www.regulations.gov/document?D=HHS-OS-2017-0002-7327.

⁴¹ Am. Acad. of Pediatrics, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 21, 2017), <u>https://www.regulations.gov/document?D=HHS-OS-2017-0002-12098</u>.

⁴² Am. Academy of Nursing, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 24, 2017), <u>https://www.regulations.gov/document?D=HHS-OS-2017-0002-11760</u>.

Similarly, a wide range of vulnerable communities face routine discrimination and barriers to care. While the Department's primary focus should be on eliminating these barriers to care, its proposed rule does the opposite and threatens to exacerbate them.

For example, despite the substantial progress made after the enactment of the Affordable Care Act, health care discrimination against women remains rampart.⁴³ Many health plans continue to exclude treatments that are primarily required by women, such as coverage of pregnancy-related conditions.⁴⁴ In many parts of the country, access to reproductive health services is sparse, and some hospitals refuse to treat patients experiencing miscarriages, ectopic pregnancies, and other conditions affecting reproductive health, even when the condition is emergent or the patient has nowhere else to go.⁴⁵ Even among providers who do offer reproductive health services, many refuse to provide them to women who are unmarried or who do not conform to sex stereotypes, or subject women to harassment and mistreatment.⁴⁶ Women are also more likely than men to receive substandard care for conditions such as heart disease or chronic pain,⁴⁷ which further limits women's options when seeking a provider who will meet their needs.

Gender disparities in health care disproportionately affect women of color. Women of color are particularly likely to experience discrimination and harassment in health care.⁴⁸ Research has found that women of color face significant barriers to reproductive care: for example many respondents were neglected by medical staff, received inadequate or misleading information about the range of treatment options they had for labor and delivery, or were stigmatized and shamed by medical providers based on racial stereotypes.⁴⁹ In many states, women of color are more likely than white women to receive their care at Catholic hospitals, whose ethical directives regarding reproductive care often prevent patients from receiving treatment consistent with medical standards of care.⁵⁰ Inadequate access to reproductive care is one of the main drivers in persistent racial disparities in maternal mortality—with Black women being three to four times more likely to die in childbirth than white women⁵¹—as well as higher rates of

 ⁴⁴ See, e.g., Nat'l Women's Law Ctr., NWLC Section 1557 Complaint: Sex Discrimination Complaints Against Five Institutions, <u>http://www.nwlc.org/resource/nwlc-section-1557-complaint-sex-discrimination-complaints-against-five-institutions</u> (Section 1557 complaints filed against five institutions that exclude pregnancy coverage).
 ⁴⁵ See, e.g., Nat'l Women's Law Ctr., *Health Care Refusals Harm Patients: The Threat to Reproductive Health Care* (2014), <u>https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2015/08/refusals harm_patients_repro_factsheet_5-</u>

⁴⁶ *Id.* ⁴⁷ *See, e.g.*, Judith H.

⁴⁷ See, e.g., Judith H. Lichtman et al., Symptom Recognition and Healthcare Experiences of Young Women with Acute Myocardial Infarction, 10 J. AM. HEART ASS N 1 (2015); Jennifer A. Kent, Vinisha Patel, & Natalie A. Varela, Gender Disparities in Health Care, 79 MOUNT SINAI J. MED. 555 (2012); Diane E. Hoffmann & Anita J. Tarzian, The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain, 29 J. LAW, MED. & ETHICS, 13 (2001); Inst. of Med., Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research 75–77 (2011).
⁴⁸ Nat'l Public Radio, Robert Wood Johnson Foundation, & Harvard T. H. Chan School of Public Health, Discrimination in

America: Experiences and Views of American Women (2017), https://cdn1.sph.harvard.edu/wpcontent/uploads/sites/21/2017/12/NPR-RWJF-HSPH-Discrimination-Women-Final-Report.pdf.

⁵⁰ Kira Shepherd & Katherine Franke, *Bearing Faith: The Limits of Catholic Health Care for Women of Color* (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

⁵¹ Ctr. for Reproductive Rights et al., *supra* note 49.

⁴³ See, e.g., Nat'l Women's Law Ctr., *Turning to Fairness* (2012), <u>https://nwlc.org/wp-content/uploads/2015/08/nwlc_2012_turningtofairness_report.pdf</u>.

<u>30-14.pdf</u>.

⁴⁹ Ctr. for Reproductive Rights, Nat'l Latina Inst. for Reproductive Health, & SisterSong Women of Color Reproductive Justice Collective, *Reproductive Injustice: Racial and Gender Discrimination in U.S. Health Care* 20-22 (2014), https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/CERD_Shadow_US_6.30.14_Web.pdf.

cervical cancer and HIV among women of color.⁵² People of color of all genders often face prohibitive barriers to care: for example, people of color are significantly more likely to be uninsured,⁵³ and people of color in rural America are also more likely to live in an area with a shortage of health professionals, leaving many with no alternatives if they are refused care.

People with disabilities also continue to face discriminatory barriers to care, including physical barriers in health care settings, mistreatment by health care providers, and the unavailability or inaccessibility of health care providers who are competent in meeting their health care needs. These barriers are often especially heighted for people with disabilities who live or spend much of their time in providercontrolled settings, including Medicaid-funded Home and Community-Based Services, where they receive supports and services for daily living, including assistance with dressing, grooming, bathing, transportation to social and health-related appointments, and participating in recreational activities. These services can be intensely intimate and implicate a person's right to pursue and maintain romantic relationships, build a family, and make basic decisions about one's life. In such settings, expansive religious exemptions that encourage aides to interfere with someone's health care can be extremely harmful for the health of a person with a disability and their ability to exercise their right to basic selfdetermination.

Lesbian, gay, and bisexual people (LGB) experience frequent discrimination when accessing healthrelated services. For example, a recent study found that 8% of LGB respondents reported that a doctor or other health care provider refused to see them because of their sexual orientation, and 7% experienced unwanted physical contact by a health care provider.⁵⁴ Many LGB people, especially those in rural areas, report that finding an alternative provider if they are refused treatment or harassed would be very difficult or even impossible.⁵⁵ Additionally, many LGB people struggle to access reproductive and sexual health services, including fertility services and HIV prevention treatments such as pre-exposure prophylaxis (PrEP). Inadequate access to care contributes to significant health disparities affecting the LGB

⁵² See, e.g., Ctrs. for Disease Control & Prevention, Cervical Cancer Rates by Rates and Ethnicity (Jun. 19, 2017), https://www.cdc.gov/cancer/cervical/statistics/race.htm; HIV Among Women (March 9, 2018),

https://www.cdc.gov/hiv/group/gender/women/index.html (noting that at the end of 2015, 59% of women living with diagnosed HIV were Black, 19% were Latina, and 17% were white, and that Black women were more likely to contract HIV through sexual contact than white women).

⁵³ Kaiser Family Found., Uninsured Rates for the Nonelderly by Race/Ethnicity (2016), <u>https://www.kff.org/uninsured/state-indicator/rate-by-</u>

raceethnicity/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

⁵⁴ Mirza & Rooney, see supra note 27. See also Lambda Legal, When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV (2010),

https://www.lambdalegal.org/sites/default/files/publications/downloads/wheie-report_when-health-care-isnt-caring.pdf; Ning Hsieh & Matt Ruther, Despite Increased Insurance Coverage, Nonwhite Sexual Minorities Still Experience Disparities in Access to Care, 36 HEALTH AFFAIRS 1786 (Oct. 2017),

https://www.hcalthaffairs.org/doi/abs/10.1377/hlthaff.2017.0455?journalCodc=hlthaff; Human Rights Watch, All We Want is Equality: Religious Exemptions and Discrimination against LGBT People in the United States (2018),

https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people. ⁵⁵ Mirza & Rooney, see *supra* note 27 (finding that 18% of LGBT people overall and 41% of LGBT people living outside of metropolitan areas report that it would be "very difficult" or "impossible" to find equivalent treatment at another hospital if they were to be turned away).

population,⁵⁶ including higher prevalence of disabilities and chronic conditions,⁵⁷ certain cancers,⁵⁸ cardiovascular disease,⁵⁹ and depression, anxiety, and other mental health conditions.⁶⁰ Barriers to accessing care also contribute to high rates of HIV infection among gay and bisexual men, who account for 56% of all people living with HIV in the United States and 70% of new HIV infections.⁶¹

C. Transgender people and other vulnerable communities already face barriers to care based on the personal beliefs of health care workers or administrators.

The personal beliefs of health care providers, administrators, and others in the health care industry have too often been used to deny individuals access to health care and other critical services—a problem that can be significantly worsened by expanding existing exemptions. For example, religious or moral disapproval has been invoked to refuse to provide infertility and reproductive care,⁶² treat patients with HIV,⁶³ treat a newborn because of her parents' same-sex relationship,⁶⁴ and provide emergency services and other care for people who are suffering miscarriages.⁶⁵ Religious objections have also been invoked to deny transgender people access to medical care—both care related and unrelated to gender transition— or subject transgender people to degrading or abusive treatment in medical settings. Consider the following examples:

east-1.amazonaws.com//files/assets/resources/IIRC-Bil lealthBrief.pdf. ⁶¹ Ctrs. for Disease Control & Prevention, CDC Fact Sheet: HIV Among Gay and Bisexual Men (2017),

https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/cdc-msm-508.pdf.

⁶² Casey Ross, Catholic Hospitals are Multiplying, Boosting Their Impact on Reproductive Health, SCIENTIFIC AMERICAN (Sept. 14, 2017), <u>https://www.scientificamerican.com/article/catholic-hospitals-are-multiplying-boosting-their-impact-on-reproductive-health-care</u>; Nat'l Women's Law Ctr., *supra* note 45, *see also North Coast Women's Care Medical Grp., Inc. v. San Diego County Superior Court*, 189 P.3d 959, 959 (Cal. 2008).

https://www.huffingtonpost.com/entry/catholic-hospitals-miscarriage-management_us_5759bf67e4b0e39a28aceea6.

⁵⁶ See generally Dep't of Health & Human Servs., supra note 30.

⁵⁷ David J. Lick, Laura E. Durso, & Kerri L. Johnson, *Minority Stress and Physical Health Among Sexual Minorities*, 8 PERSPECTIVES ON PSYCHOLOGICAL SCIENCE 521 (2013), <u>http://williamsinstitute.law.ucla.edu/research/health-and-hiv-aids/minority-stress-and-physical-health-among-sexual-minorities</u>.

⁵⁸ Id.; Jennifer Kates et al., Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender (LGBT) Individuals in the U.S. (2016), <u>http://files.kff.org/attachment/Issue-Brief-Health-and-Access-to-Care-and-Coverage-for-LGBT-Individuals-in-the-US</u>.

⁵⁹ Id. ⁶⁰ Id.; Human Rights Campaign et al., Health Disparities Among Bisexual People (2015), <u>http://hrc-assets.s3-website-us-</u>

⁶³ See, e.g., Complaint, Simoes v. Trinitas Reg'l Med. Ctr., No. UNNL-1868-12 (N.J. Super. Ct. filed May 23, 2012); Nat'l Women's Law Ctr., supra note 45.

⁶⁴ Abby Phillip, *Pediatrician Refuses to Treat Baby with Lesbian Parents and There's Nothing Illegal About It*, WASH. POST (Feb. 19, 2015), <u>https://www.washingtonpost.com/news/morning-mix/wp/2015/02/19/pediatrician-refuses-to-treat-baby-with-lesbian-parents-and-theres-nothing-illegal-about-it; see also Amicus Brief of Lambda Legal Defense and Education Fund et al., *Masterpiece Cakeshop et al. v. Colo. Civil Rights Comm'n et al.*, No. 16-111, 17–19 (Sup. Ct. filed Oct. 30, 2017).</u>

⁶⁵ Am. Civil Liberties Union, Health Care Denied: Patients and Physicians Speak out About Catholic Hospitals and the Threat to Women's Health and Lives (2016), <u>https://www.aclu.org/report/report/report-health-care-denied?redirect=report/healthcare-denied;</u> Nat'l. Women's Law Ctr., Denied Care When Losing a Pregnancy: Pharmacies Refuse to Fill Needed Prescriptions (Apr. 16, 2015), <u>http://www.nwlc.org/our-blog/denied-care-when-losing-pregnancy-pharmacies-refuse-fillneeded-prescriptions;</u> Nat'l Women's Law Ctr., Below the Radar: Health Care Providers' Religious Refusals Can Endanger Pregnant Women's Lives and Health (2011), <u>https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-</u>

content/uploads/2015/08/nwlcbelowtheradar2011.pdf, Samantha Lachman, Lawsuits Target Catholic Hospitals for Refusing to Provide Emergency Miscarriage Management, HUFFINGTON POST (June 10, 2016),

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As my being transgender is a relevant piece of medical information... I revealed this information to [the doctor] when he entered the treatment room. His immediate response was, "I believe the transgender lifestyle is wrong and sinful." ... The rest of the time between the examination and him writing the prescription, he asked questions about how transgender women find sexual intimacy. As he had yet to hand over the prescription, I felt compelled by the power dynamic to provide answers to questions I would normally tell an asker are none of his or her business.... [I]t was very creepy having this conversation with this person, and I felt I had the filthy end of the stick and was being subordinated by this doctor because he felt he could. – Karen S.⁶⁶

My Dignity Health insurance covered my hormones (because my doctor did not specifically note it as trans-related), and scheduled my top surgery before suddenly cancelling their coverage. Someone at their company had "connected the dots" and realized I was seeking transition-related services, which they denied due to their company's Catholic values. I was forced to pay for the surgery out of pocket, destroying my family's finance and putting me in considerable debt.⁶⁷

I was told by [mental health] professionals that I can only be "fixed" by "accepting Jesus" and denying who I really am when I sought assistance with beginning transition.⁶⁸

In addition, the personal beliefs of hospital administrators and other health care workers have been used to interfere with doctors' exercise of their medical judgment. Some hospitals have invoked their religious affiliation to not only refuse to provide emergency care related to miscarriages, transition-related medical care, and other needs, but also to prevent doctors from providing those treatments at the hospital, in spite of those doctors' best medical judgment.⁶⁹ For example, in 2016 a New Jersey hospital approved and scheduled Jionni Conforti's hysterectomy, then abruptly cancelled the procedure at the last minute and refused to allow his surgeon to perform it when an administrator discovered the patient was transgender despite his doctor's determination that the procedure was medically necessary.⁷⁰ These practices are especially concerning in light of the rapidly growing number of religiously affiliated hospitals. For example, the number of Catholic hospitals—which represent the largest denomination in the health care field—has increased by 22% since 2001, and Catholic hospitals now own one in six hospital beds across the country.⁷¹ Catholic hospitals must follow religious directives that often restrict the provision of certain treatments, including for emergency contraception, sterilization, abortion, fertility services, and ectopic

⁷⁰ Conforti v. St. Joseph's Healthcare System, No. 2:17-cv-00050-JLL-JAD (D.N.J. filed Jan. 5, 2017).

⁷¹ Lois Uttley & Christine Khaikin, Growth of Catholic Hospitals: 2016 Update of the Miscarriage of Medicine Report (2016), <u>http://static1.1.sqspcdn.com/static/f/816571/27061007/1465224862580/MW_Update-2016-MiscarrOfMedicine-report.pdf?token=54%2Fj8Gp90FWPtm7ExSkDGRuC770%3D</u>.

⁶⁶ Amicus Brief of Transgender Legal Defense and Education Fund et al., *Masterpiece Cakeshop et al. v. Colo. Civil Rights Comm'n et al.*, No. 16-111, 11 (Oct. 30, 2017).

⁶⁷ This quotation has been excerpted from a story shared by a 2015 U.S. Transgender Survey respondent after completing of the survey.

⁶⁸ This quotation has been excerpted from a story shared by a 2015 U.S. Transgender Survey respondent after their completion of the survey.

⁶⁹ For example, complaints have been filed against Catholic hospitals for refusing to allow doctors to provide care to transgender patients that the doctors are regularly allowed to provide for non-transgender people. *See, e.g.*, Complaint, *Hastings v. Seton Med. Ctr.*, No. CGC-07-470336 (Cal. Sf. Super. Ct. Dec. 19, 2007) (case settled). *See also Health Care Denied, supra* note 65.

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pregnancies.⁷² Providers at such hospitals often find that they are unable to provide the standard of care for treatments such as miscarriage managements,⁷³ and one study of physicians working at religiously affiliated hospitals found that nearly one in five (19%) experienced a conflict between the religious directives of their hospital and their ability to practice in accordance with medical standards and their clinical judgment.⁷⁴

Religious beliefs have also been invoked to justify refusals to provide critical human services for lesbian, gay, bisexual, and transgender (LGBT) individuals and families, as well as unmarried parents. The potential for harmful discrimination justified by religious beliefs is further illustrated by countless cases of religion being cited as a basis for denial of service or humiliating treatment toward LGBT people in restaurants, hotels, retail stores, and by individual government employees.⁷⁵

For many patients, such refusals do not merely represent an inconvenience: in many cases, they can result in necessary or even emergent care being delayed or denied outright, putting their health and in some instances their lives at risk. These refusals are particularly dangerous in situations where individuals have limited options, such as in emergencies, when needing specialized services, in many rural areas,⁷⁶ or in areas where religiously affiliated hospitals are the primary or sole hospital serving a community.⁷⁷

Expanding exemptions beyond established law as the proposed rule attempts to do—and encouraging service providers receiving federal funds to discriminate against intended program beneficiaries—would aggravate these harms even further. Permitting a broader range of service providers that receive taxpayer money to use a religious or moral litmus test to determine which services they provide and who receives care would result in many patients in need being denied access to medical care and other essential

⁷⁵ See, e.g., Amicus Brief of Lambda Legal Defense and Education Fund et al., *Masterpiece Cakeshop*, No. 16-111 (documenting instances of discrimination against LGBT people, including discrimination based on religious objections, in a variety of settings); Amicus Brief of National LGBTQ Task Force, et al., *Masterpiece Cakeshop*, No. 16-111; Amicus Brief of Transgender Legal Defense and Education Fund et al., *Masterpiece Cakeshop*, No. 16-111 (same); Amicus Brief of Transgender Law Center et al., *Masterpiece Cakeshop*, No. 16-111, 12–13 (Sup. Ct. filed Oct. 30, 2017) (same).
⁷⁶ People living in rural areas often struggle to access care due to a variety of factors, including physician shortages,

financial and geographic barriers to transportation, and a lack of available specialists who can meet their needs. See, e.g., Martin MacDowell et al., A National View of Rural Health Workforce Issues in the USA, 10 RURAL REMOTE HEALTH 1531 (2010), <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3760483</u>; Carol Adaire Jones et al., Health Status and Health Care Access of Farm and Rural Populations, U.S. DEP'T OF AGRIC. ECON. RESEARCH SERV. (2009),

⁷⁷ See e.g., Ilealth Care Denied, supra note 65; Uttley et al., supra note 72.

⁷² See U.S. Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services* (2009), 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, Lois Uttley et al., *Miscarriage of Medicine: The Growth of Catholic Hospitals* and the Threat to Reproductive Health Care (2013),

http://static1.1.sqspcdn.com/static/f/816571/24079922/1387381601667/Growth-of-Catholic-Hospitals-2013.pdf?token=O2KPmDeCHsArsY1wqp0wEBigKC4%3D.

⁷³ Lori R. Freedman et al., When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals, AM. J. PUB. HEALTH (2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458.

⁷⁴ Debra B. Stulberg et al., *Religious Hospitals and Primary Care Physicians: Conflicts over Policies for Patient Care*, 25 J. GENERAL INTERNAL MED. 725–30 (2010), <u>http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2881970</u>.

https://www.crs.usda.gov/publications/pub-dctails/?pubid=44427; 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 SERVS. RESEARCH 135 (2005), <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1361130</u>; Corinne Peek-Asa et al., *Rural Disparity in Domestic Violence Prevalence and Access to Resources*, 20 J. OF WOMEN'S HEALTH 1743 (Nov. 2011), <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3216064</u>.

services—jeopardizing the welfare of many intended HHS program recipients and compromising the Department's ability to meet its legal obligations and fulfil its mission.

II. Expanding exemptions undermines the Department's mandate to protect the health and well-being of all Americans.

Reducing discrimination and other barriers to accessing health care services, as well as reducing the accompanying health disparities, is core to the Department's mission and its obligations under laws authorizing its programs. Weakening protections and limiting program access by expanding religion-based exemptions fundamentally runs contrary to this mission.

The Department's core mission is to "enhance and protect the health and well-being of all Americans...by providing for effective health and human services."⁷⁸ The foremost purpose of the Department is to provide for services and supports for individuals and communities who need them—a purpose that is statutorily prescribed by Congress in the statutes authorizing many of the Department's programs.⁷⁹ Ensuring that beneficiaries of Department programs and other patients have fair and equal access to services and reducing barriers to those services is an inseparable and necessary component of this responsibility. The Department's ability to ensure equal, nondiscriminatory access to services would be significantly weakened by the proposed rule. In order to meet its legal obligations and its statutory mission, HHS must prioritize the needs and rights of patients over those of organizations seeking federal funds. Creating new or expanded exemptions for recipients of federal funds at the cost of patients' access to health services prevents the Department from meeting its responsibilities to HHS program beneficiaries and patients around the country.

Protecting religious freedom is an important value, and many health care providers with deeply held religious or moral beliefs have played important roles in addressing our nation's health care needs. Yet the driving force of this value is the core constitutional principle of separation of church and state—a principle that is fundamentally undermined by the expansion of religious exemptions in health care. Health care providers, entities, and grantees should be allowed—and *are* allowed under current practices and policies—to maintain their distinct religious identities when providing health care services, so long as they comply with generally applicable requirements, including nondiscrimination laws, that exist to protect patients. Protecting the right to practice religion does not require the sweeping expansion of religion-based exemptions that this proposed rule attempts to implement, which would amount to government-funded discrimination and subvert HHS' mission and compelling interest in promoting public health and wellbeing.

III. The exemptions proposed in the rule go far beyond what the applicable statutes permit and exceed the Department's authority.

⁷⁸ Dep't. of Health & Human Servs., *About HHS* (2017), <u>https://www.hhs.gov/about/index.html</u>.

⁷⁹ See, e.g., 34 U.S. Code § 11201 (establishing Runaway and Homeless Youth programs because "youth who have become homeless or who leave and remain away from home without parental permission... are urgently in need of temporary shelter and services").

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The Department has the authority and responsibility to enforce laws as they are written, including laws creating and delimiting religious and moral exemptions. This rule, however, proposes exemptions that are far broader than permitted under the statutes that the Department cites. By redefining key terms, eliminating important limitations and requirements included in the law, and applying statutes outside of their intended scope, the proposed rule attempts to significantly expand existing exemptions. The Department does not have the statutory authority to expand or create new religious exemptions to its statutorily prescribed programs beyond the exemptions permitted by statutes. Reading additional exceptions into a statute where Congress already contemplated and enumerated specific ones, contrary to fundamental principles of statutory construction, is in excess of the statutory authority provided in the laws the Department seeks to enforce.⁸⁰

A. The Department's regulation proposes an impermissible and harmful reinterpretation of the Church Amendments.

The Department's rule proposes a reinterpretation of the Church Amendments that broadens their impact far beyond what the statute permits, potentially allowing a range of refusals that would severely compromise patients' access to medically necessary care.

Redefinition of "assist in the performance"

One of the most concerning transformations proposed by this regulation is the reinterpretation of what it means to "assist in the performance" of a procedure. In the 2008 rule, the Department defined the term as the participation in "any activity with a reasonable connection" to a procedure to which an individual objects.⁸¹ This definition itself is so broad that it could be applied to services and forms of "assistance" even beyond those contemplated by Congress when the law was enacted. The current rule, however, attempts to expand the application of the Church Amendments even further than the 2008 rule did by defining the statutory term to mean "any activity with an *articulable* connection" to a procedure to which an individual objects.⁸²

Although the preamble claims that this definition "mirrors the definition used for the term in the 2008 Rule,"⁸³ the definition is in fact an attempt to radically expand potential refusals. By allowing health care workers to refuse to engage in activities with a merely "articulable" connection to the service to which a provider or entity has an objection, the proposed rule opens the door to refusals to perform activities whose asserted nexus to the procedure being objected to is greatly attenuated and patently unreasonable, as long as it can be put into words.⁸⁴ Individuals wishing to obstruct access to care could seek to invoke

⁸³ Id. at 3892.

⁸⁰ See, e.g., U.S. v. Smith, 499 U.S. 160 (1991).

^{81 45} C.F.R. § 88 (2008).

⁸² Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3923 (proposed Jan. 26, 2018) (to be codified at 45 C.F.R. pt. 88) [hereinafter Proposed Rule].

⁸⁴ Compare, e.g., Erzinger v. Regents of Univ. of Cal., 137 Cal. App. 3d 389, 394 (Ct. App. 1982), cert. denied 462 U.S. 1133 (1983) ("The proscription [of the Church Amendments] applies only when the applicant must participate in acts

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the rule to refuse to perform functions whose connection to a sterilization or abortion is extremely remote—such as bringing a meal to a patient after a procedure, handling scheduling tasks that may include booking follow-up appointments for sterilization or abortion procedures, or preparing a patient room. The proposed definition may also be invoked by health care workers or entities who refuse to treat unrelated conditions simply because a patient has had an abortion or sterilization procedure or may have one in the future. For example, it may be invoked by a cardiologist, oncologist, or even an emergency room doctor—as well as nurses, other medical staff, and administrative staff—to refuse to treat a patient for an unrelated condition because they object to asking about or taking into account an abortion or sterilization procedure that a patient has had in the past or intends to have in the future.

Implied redefinition of "sterilization"

The expanded exemptions proposed in the rule might even be construed to permit refusals related to medical treatments that are needed to treat a disease or disorder that may have a merely *incidental* effect of impacting fertility, including certain types of treatments for gender dysphoria. Although the Church Amendments were never intended to reach such medical treatments, the breadth and vagueness of several provisions in the proposed rule may be interpreted to support such an application. For example, twice in the proposed rule, the Department cites Minton v. Dignity Health, a case involving denial of care for gender dysphoria, as a purported example of a violation of existing religious exemptions.⁸⁵ In this case, a hospital abruptly canceled a hysterectomy for a patient, Evan Minton, after discovering he was transgender and that the procedure was recommended to treat gender dysphoria. The procedure was cancelled in spite of Mr. Minton's doctor's objections and previous determination that the treatment was medically necessary.⁸⁶ The same hospital routinely permitted Mr. Minton's physician and other physicians to perform hysterectomies-and in fact, his doctor performed another hysterectomy at the hospital for a non-transgender patient on the very same day that Mr. Minton's hysterectomy was scheduled⁸⁷—but it refused to allow Mr. Minton's procedure to be performed because hospital administrators asserted a religious objection to the use of the procedure to treat gender dysphoria. While Mr. Minton was fortunate to be able to reschedule his procedure—with the same surgeon—at another hospital, many patients who are so abruptly refused care are not so lucky and may face medical complications from delayed treatment.

Applying the Church Amendments in this context—as the Department's citation to the *Minton* case implies—would exceed and contradict the plain meaning of the statute. Like treatments for many other conditions, certain treatments for gender dysphoria, such as hormone treatments and certain surgeries, can have an incidental effect of temporarily or permanently reducing fertility and in some cases eliminating fertility entirely. The primary purpose of such procedures, however, is not to sterilize, but to treat an unrelated medical condition. Similarly, a range of other conditions have treatments that can lead to sterilization. For example, forms of chemotherapy and certain other cancer treatments can and in some cases will necessary lead to permanent sterilization, and many medications, including a variety of antibiotic and seizure control medications, can also have an incidental effect of reducing or eliminating fertility. If religious or moral exemptions related to sterilization were construed to encompass treatments

related to the actual performance of abortions or sterilizations. Indirect or remote connections with abortions or sterilizations are not within the terms of the statute.").

⁸⁵ Proposed Rule, 83 Fed. Reg. at 3888–89.

⁸⁶ Complaint at 6-7, Minton v. Dignity Health, No. 17-558259 (Calif. Super. Ct. filed Apr. 19, 2017).

⁸⁷ Id. at 2.

that have an incidental effect of affecting fertility, this reinterpretation could lead to refusals that substantially exceed the plain language of the statute and open the door for patients to be denied a dangerously wide range of medically necessary treatments.

Application to other services other than abortion or sterilization

We are also concerned that the proposed rule's sweeping and ambiguous language, in conjunction with the preamble, may lead to an expansive misinterpretation of sections (c)(2) and (d) of the Church Amendments that may encourage refusals of *any* health care service for a religious or moral reason, even those with no connection to sterilization or abortion at all—far exceeding the longstanding application of this statute.⁸⁸ This ambiguity may lead covered entities to believe that they can refuse to provide or refer for any service—such as vaccines, psychiatric medication, infertility treatments, and HIV-related care—that is inconsistent with their personal beliefs, jeopardizing the health of numerous Americans. It may also lead covered entities to believe that they can refuse based on objections about who the patient is: it can encourage, for example, a provider who has a moral or religious objections to providing services for LGBT people, women, people with disabilities, or people of color to refuse to treat them at all, regardless of the treatment they require.

B. The proposed rule impermissibly expands the Coats-Snowe and Weldon Amendments.

Redefinition of "referral"

We are deeply troubled by the Department's proposal to reverse its long-standing interpretation of the application of the Weldon Amendment. We are particularly concerned about the Department's attempt to radically redefine what it means to provide a referral for a patient. There is no legal basis to support the proposed transformation of the term from its plain meaning as it is used in medicine—that is, transferring the care of a patient to a particular health care provider⁸⁹—to "the provision of *any* information…pertaining to a health care service" so long as the health care entity believes that the health care service is a "possible outcome" of providing that information.⁹⁰ This breathtakingly broad definition attempts to exempt providers not only from transferring care to another health provider, but from supplying information that has even an exceedingly remote connection to a procedure they object to, so long as they simply believe that it is *not impossible* that doing so may lead the patient to receive the objected-to treatment—even if they do not believe that it is likely or plausible. For example, it may embolden a health care provider to refuse to inform a woman about a pregnancy complication she is experiencing, even if it can be treated, based on their belief that it is *possible* though unlikely she will opt to terminate the pregnancy. While the Department claims that statutory language—such as references to "referring for" an abortion or "making arrangements to provide referrals"—suggests that Congress

⁸⁹ See, e.g., American Acad. of Family Physicians, Consultations, Referrals, and Transfers of Care (2017),

⁸⁸ See, e.g., Elbaum v. Grace Plaza of Great Neck, 148 A.D.2d 244, 255–56 (N.Y. App. Div. 1989) (finding that a nursing home's reliance on the Church Amendments to justify refusal to remove feeding tube was "misplaced" because the statute only pertains to sterilization and abortion procedures).

https://www.aafp.org/about/policies/all/consultations-transfers.html ("A referral is a request from one physician to another to assume responsibility for the management of one or more of a patient's specific problems.... This represents a temporary or partial transfer of care to another physician for a particular condition.")

⁹⁰ Proposed Rule, 83 Fed. Reg. at 3924.

intended for this term to be interpreted broadly,⁹¹ the definition that it proposes extends so far beyond the plain meaning of the term that it amounts to a radical revision of the statutory language that undermines rather than effectuates Congress' intent.

Redefinition of "health care entity"

The Department's broad redefinition of the term "health care entity" also ignores Congress' clear intent to limit the entities affected by these statutes. For example, the Coats-Snowe Amendment defines "health care entity" as an "individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions."⁹² In contrast, the Department has proposed a far-reaching definition of this term, applicable to all statutes, that combines definitions from multiple statutes.⁹³ This attempt to supplant the varying statutory definitions of this term with a catch-all list creates confusion about the health care entities that must comply with each statute. It also disregards the congressional intent to cabin the application of each statute, evidenced by the fact that Congress took the time to create separate definitions for each statute rather than to create a universally applicable definition of the term, and by its deliberate decision to include some types of health care entities in each definition while excluding others.

C. The proposed rule impermissibly expands exemptions for Medicare and Medicaid organizations.

The essential care that Medicaid and Medicare programs provide to many Americans are already riddled with expansive exemptions for grantees and other participants, leaving many beneficiaries with no avenue to receive the care they need.⁹⁴ It is deeply concerning, therefore, that the proposed rule attempts to expand several exemptions applicable to these programs beyond the statutory language, including the counseling and referral provisions of 42 U.S.C. 1396u-2(b)(3)(B) and 42 U.S.C. 1395w-22(j)(3)(B) and the provisions of the Consolidated Appropriations Act of 2017 related to Medicare Advantage. Expanding religious exemptions in the manner proposed both exceeds the Department's authority and undermines its statutorily prescribed mission to serve beneficiaries and facilitate their access to needed medical care.

Redefinition of "referral"

First, we are troubled by the impact that the expansive redefinition of "referral" could have on patient care for Medicaid and Medicare Advantage recipients. In the context of the counseling and referral

⁹¹ Id. at 3895.

⁹² 42 U.S.C. § 238n(c)(2). See also Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009).

⁹³ Proposed Rule, 83 Fed. Reg. at 3924.

⁹⁴ See, e.g., Amy Littlefield, How a Catholic Insurer Built a Birth Control Obstacle Course in New York, REWIRE NEWS (Jan. 26, 2017), <u>https://rewire.news/article/2017/01/26/catholic-insurer-built-birth-control-obstacle-course-new-york</u> (describing the refusal of New York's largest Medicaid plan to cover a range of services based on religious objections). See also Catholic Health Association of the United States, Catholic Health Care in the United States (2018), <u>https://www.chausa.org/docs/default-source/default-document-</u>

<u>library/cha_2018_miniprofile7aa087f4dff26ff58685ff00005b1bf3.pdf?sfvrsn=2</u> (noting that Catholic hospitals, which are required to comply with ethics guidelines that limit access to reproductive and other care, reported one million Medicaid discharges in 2017).

provisions, the proposed rule may be interpreted as allowing Medicaid managed care organizations and Medicare Advantage organizations not only to refuse to cover a counseling or referral service that they object to, but also to refuse to cover or provide for any provider-patient communication that they believe can *possibly* lead to a service to which they object, no matter how remote the connection. Similarly, this novel definition of "referral" suggests that the Consolidated Appropriations Act of 2017 exempts not only Medicare Advantage organizations who refuse to refer for abortions in the natural reading of the term—that is, to transfer care of the patient to another provider—but also those who refuse to provide or cover the provision of any information that they believe can possibly lead to a patient obtaining an abortion. This attempt to rewrite the statutory language is unsupported by statutory language or congressional intent and threatens the health and safety of the program beneficiaries whom these programs are required to serve.

Attempt to transform a statutory construction provision into a freestanding exemption

Further, the proposed rule misinterprets the counseling and referral provisions of 42 U.S.C. § 1396u-2(b)(3)(B) and 42 U.S.C. § 1395w-22(j)(3)(B) by turning a statutory construction provision into a freestanding religious exemption. The Department's proposed exemption relies on narrow provisions that are intended only to qualify the statutes' prohibition on interference with doctor-patient communications. The provisions that the Department cites are pulled from a section whose primary purpose is to prohibit covered entities from interfering with a health care provider's ability to advise an enrollee about their health status or available treatments, regardless of whether those treatments are covered.95 These provisions clarify a limitation to that prohibition: namely, that a covered entity's refusal to cover a procedure or service does not constitute interference with doctor-patient communication under this section. These provisions are not intended to create a general religious exemption for Medicaid MCOs and Medicare Advantage organizations, but rather they are statutory construction clauses that explain specifically how the prohibition on interference with communication is meant to be construed. Congress' limited intent when enacting these statutes is underscored not only by the plain language of this subsection, which clearly qualifies only a specific requirement of the statute, but also by the choice to explicitly label 42 U.S.C. § 1396u-2(b)(3)(B) as "Construction." The proposed rule, however, disregards the congressional intent evidenced in the statutory language and isolates this section from its context, misrepresenting its limited scope and instead presenting it as a standalone religious exemption that allows Medicaid managed care organizations and Medicare Advantage organizations to refuse to cover any counseling or referral service that they disapprove of.

Omission of critical, patient-protective statutory language

⁹⁵ 42 U.S.C. 1396u-2(b)(3)(A) ("Subject to subparagraphs (B) and (C), under a contract under section 1396b(m) of this title a medicaid managed care organization (in relation to an individual enrolled under the contract) shall not prohibit or otherwise restrict a covered health care professional...from advising such an individual who is a patient of the professional about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the contract..."); 42 U.S.C. 1395w-22(j)(3)(A) ("Subject to subparagraphs (B) and (C), a Medicare Choice organization (in relation to an individual enrolled under a Medicare Choice plan offered by the organization under this part) shall not prohibit or otherwise restrict a covered health care professional...from advising such an individual who is a patient of the professional about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the plan...").

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Additionally, the proposed rule omits requirements, enumerated in both 42 U.S.C. § 1396u-2(b)(3)(B) and 42 U.S.C. § 1395w-22(j)(3)(B), that organizations that decline to cover certain treatments notify enrollees of their policy. The statutory construction clauses do not exempt an organization merely on the basis that it has a religious or moral objection to covering a service: it also requires, as a condition of the exemption, that the organization "make available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization adopts a change in policy regarding such a counseling or referral service."⁹⁶ The Department's omission of this requirement from its proposed rule will create confusion regarding organizations' legal obligations to disclose their policies to potential and current enrollees and may lead to or encourage noncompliance with the law. Without sufficient enforcement of notification requirements, potential enrollees may be unable to make an informed choice about their health care, and current enrollees may find themselves unable to access care that they would reasonably expect to be covered.

Similarly, the proposed rule misrepresents the exemption provided to entities participating in Medicare Advantage in the Consolidated Appropriations Act of 2017, omitting requirements in the law that ensure that enrollees and the Department itself are notified of objections to covering abortions. The proposed rule asserts that an exemption exists when an "entity will not provide, pay for, provide coverage of, or provide referrals for abortions."⁹⁷ In contrast, the statute itself provides an exemption when "the entity *informs the Secretary* that it will not provide, pay for, provide coverage of, or provide referrals for abortions."⁹⁸ By excising this important language, the Department may create ambiguity about covered entities' obligations to notify the Department of its objections to covering abortions—a requirement that is necessary to allow the Department to meet its statutory obligation to "make appropriate prospective adjustments to the capitation payment" to entities declining to cover abortions.⁹⁹ The statute, furthermore, explicitly states that "a Medicare Advantage organization described in this section shall be responsible for informing enrollees where to obtain information about all Medicare covered services"¹⁰⁰—a notification requirement that the proposed rule omits, potentially creating confusion regarding a Medicare Advantage organization's responsibilities to inform enrollees about the scope of their coverage.

IV. The proposed exemptions run counter to numerous federal and state laws and raise serious constitutional questions.

A. Conflict with the Establishment Clause of the Constitution

Expanding religious exemptions in the manner proposed may run afoul of constitutional restrictions on the scope of religious exemptions. The Supreme Court has noted that there are limits to permissible accommodations based on religious beliefs, and that "at some point, accommodation may devolve into an unlawful fostering of religion."¹⁰¹ To comply with the Constitution, "an accommodation must be

⁹⁶ 42 U.S.C. 1396u-2(b)(3)(B)(ii); 42 U.S.C. 1395w-22(j)(3)(B)(ii).

⁹⁷ Proposed Rule, 83 Fed. Reg. at 3926.

⁹⁸ Consolidated Appropriations Act of 2017, Pub. L. 115-31, Div. H, Tit. II, sec. 209 (emphasis added).
⁹⁹ Id.

¹⁰⁰ Id.

¹⁰¹ Corp. of the Presiding Bishop v. Amos, 483 U.S. 327, 334-35 (1986) (internal quotation marks omitted).

measured so that it does not override other significant interests"¹⁰² or "impose unjustified burdens on other[s],"¹⁰³ and any "detrimental effect on any third party" must be seriously considered.¹⁰⁴ The exemptions proposed in the rule—which would allow many providers and entities to take taxpayer dollars and then refuse to provide a range of needed medical services—would *by definition* impose significant burdens on many intended HHS program recipients. The rule, however, includes no discussion or consideration of the impact its proposed exemptions may have on patients and other third parties, and in fact undermines important statutory limitations on those exemptions that are intended to prevent or mitigate the harms patients may face, thereby raising serious constitutional concerns.

B. Conflict with federal statutes

Additionally, many of the exemptions proposed in the rule may conflict with a range of patient protections included in other federal laws. While these protections are subject to the religious exemptions provided under federal law, they are not subject to exemptions whose scope exceeds federal law, including the expanded exemptions proposed in this rule. Adopting an interpretation of religious exemption laws that conflicts with the requirements of other federal laws would compromise the Department's ability to enforce existing law as required. Further, doing so will cause confusion for covered entities about how to navigate seemingly inconsistent obligations under different laws, and subject them to increased liability.

Emergency Medical Treatment and Active Labor Act (EMTALA)

For example, if the proposed rule is implemented, it can subject hospitals to standards that conflict with their obligations under the Emergency Medical Treatment and Active Labor Act (EMTALA), which requires hospitals that have a Medicare provider agreement and an emergency department to provide medical screening and stabilizing treatments to patients in emergency conditions (including labor).¹⁰⁵ The proposed rule contemplates no exceptions to the broad, automatic exemptions it promotes, such as exceptions for emergencies or life-threatening conditions. A hospital could therefore reasonably interpret the proposed rule as requiring it to exempt essential personnel from providing, for example, comprehensive care for a patient experiencing emergent pregnancy-related complications, even when doing so means that the hospital is unable to provide the patient with stabilizing care, in violation of its obligations under EMTALA. The Department provides no guidance about how a hospital can comply with the expanded refusal rights suggested by this proposed rule in cases where doing so would result in an EMTALA violation—potentially putting the hospital in the impossible position of having to somehow satisfy two conflicting requirements. Indeed, the preamble underscores the potential conflict between EMTALA and the Department's approach when it criticizes an American College of Obstetrics and Gynecologists statement reaffirming that physicians must provide emergency care when a safe transfer

 ¹⁰² Cutter v. Wilkinson, 544 U.S. 709, 722 (2005); see also Estate of Thornton v. Caldor, Inc. 472 U.S. 703, 709-10 (1985)
 ("unyielding weighting" of religious interests of those taking exemption "over all other interests" violates Constitution).
 ¹⁰³ Cutter, 544 U.S. at 726; see also Texas Monthly, Inc. v. Bullock, 480 U.S. 1, 18 n.8 (1989) (religious accommodations may not impose "substantial burdens on nonbeneficiaries").

¹⁰⁴ Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751, 2781 n.37 (2014) (citing Cutter, 544 U.S. at 720). Indeed, every member of the Court, whether in the majority or in dissent, reaffirmed that religious accommodations cannot unduly burden third parties. See id. at 2786–87 (Kennedy, J., concurring); id. at 2790, 2790 n.8 (Ginsburg, J., joined by Breyer, Kagan, and Sotomayor, JJ., dissenting). See also Holt v. Hobbs, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring). ¹⁰⁵ 42 U.S.C. § 1395dd.

is not possible, regardless of their personal beliefs. The preamble suggests that this position—a simple recitation of a widely accepted legal and professional obligation for physicians—is "evidence of discrimination toward, and attempted coercion of, those who object to certain health care procedures based on religious or moral convictions" and its implementation "could constitute a violation of Federal health care conscience laws."¹⁰⁶

Affordable Care Act

The proposed rule is also inconsistent with several provisions of the Affordable Care Act, including Section 1554 and Section 1557. Section 1554 prohibits the Department from promulgating any regulation that "creates any unreasonable barriers to… appropriate medical care" or "impedes timely access to health care services"; that "restricts the ability of health care providers to provide full disclosure of all relevant information to patients" or interferes with their ability to communicate about "a full range of treatment options", that "violates the principles of informed consent and the ethical standards of health care professionals"; or that "limits the availability of health care treatment for the full duration of a patient's medical needs."¹⁰⁷ This proposed rule violates each and every one of these requirements. Additionally, by pursuing broad exemptions that would likely result in discrimination against patients, the proposed rule conflicts with Section 1557 of the Affordable Care Act, which prohibits discrimination in health care on the basis of race, national origin, disability, age, and sex,¹⁰⁸ and runs counter to clear congressional intent evidenced in this section and throughout the ACA to protect the rights of patients and reduce barriers to accessing health care.

Title VII of the Civil Rights Act of 1964

Further, the proposed rule's approach, which appears to allow for no limitations even when those exemptions unjustifiably harm patients or employers, conflict with the well-established standard under other federal laws, such as Title VII of the Civil Rights Act, creating confusion and increased liability for hospitals and other health care employers. As the Supreme Court has long held, Title VII requires that employers reasonably accommodate employees' religious exercise unless doing so would impose undue hardship on the employer, ensuring that the employer can consider the effect that an accommodation would have on clients, patients, co-workers, and its own operations, as well as factors such as public safety, patient health, and other legal obligations.¹⁰⁹ A standard that appears to allow for none of these considerations, and instead appears to require broad and automatic exemptions regardless of the consequences, would create confusion for employers and undermine the federal government's

¹⁰⁶ Proposed Rule, 83 Fed. Reg. at 3887–3888 (criticizing an American College of Obstetrics and Gynecologists ethics committee that reaffirms a physicians' duty to provide emergency care when transfer is not feasible and suggesting that it is "evidence of discrimination toward, and attempted coercion of, those who object to certain health care procedures based on religious or moral convictions" and "could constitute a violation of Federal health care conscience laws").
¹⁰⁷ 42 U.S.C. § 18114.

¹⁰⁸ 42 U.S.C. § 18116.

 ¹⁰⁹ See, e.g., Ansonia Bd. of Educ. v. Philbrook, 479 U.S. 60, 70 (1986) ("In enacting [Title VII], Congress was understandably motivated by a desire to assure the individual additional opportunity to observe religious practices, but it did not impose a duty on the employer to accommodate at all costs"). See also, e.g., Wilson v. U.S. West Communications, 58 F.3d 1337 (8th Cir. 1995) (affirming that Title VII requires reasonable accommodation employee only when the accommodation does not create an undue hardship on the employer); Noesen v. Med. Staffing Network, Inc., 2006 WL 152996, at *4 (W.D. Wis. June 1, 2006), aff'd 232 F. App'x 581 (7th Cir. 2007); Grant v. Fairview Hosp. & Healthcare Servs., 2004 WL 326694 at *4 (D. Minn. Feb. 18, 2004).

ability to properly enforce federal laws.¹¹⁰ Such a standard could require health care employers to hire individuals who refuse to do essential components of their job. For example, it could require small hospitals to staff their emergency rooms with employees who are unwilling to provide emergency treatment to pregnant or transgender patients even when doing so makes it impossible for the hospital to provide life-saving care to patients or comply with other legal obligations such as under EMTALA. Similarly, this standard could require a clinic that is funded under Title X—and that is therefore statutory required to provide non-directive pregnancy options counseling¹¹¹—to employ medical or administrative staff who refuse to discuss or even simply schedule appointments for pregnancy counseling, even when doing so prevents the clinic from serving its patients or complying with other laws.

C. Conflict with state and local laws

Finally, the proposed rule threatens to interfere with the enforcement of hundreds of state and local laws—including laws that protect patients from malpractice and discrimination, laws requiring providers to disclose important information to patients, and laws that prohibit unfair insurance practices and set other minimum standards for private insurance or Medicaid programs. The Department's claims that "this rulemaking does not impose substantial direct effects on States or political subdivision of States" and "does not implicate" federalism concerns under Executive Order 13,132¹¹² are, as a factual matter, false: as the Department itself recognizes in the preamble, the principles and requirements espoused in its proposed rule conflict with many state and local laws,¹¹³ and the Department challenges several state laws and policies throughout its preamble.¹¹⁴ While the Department argues that it is merely enforcing existing law and thus minimally impacts state and local governments, its proposed rule in fact represents a significant and unwarranted expansion of existing federal laws—an expansion that is fundamentally at odds with the prevailing interpretation on which many state and local governments have relied when enacting laws to protect their residents.

V. The proposed rule erodes core tenets of the medical system.

The propose rule undermines longstanding ethical and legal principles of informed consent. Informed consent—a fundamental principle of patient-centered care—relies on the disclosure of medically accurate information by providers in order to allow patients to make competent and voluntary decisions about their medical treatment.¹¹⁵ Health care providers must provide information that is accurate and sufficient to allow a patient to provide informed consent to a course of treatment or lack of treatment, and a health care provider's refusal to provide adequate information can constitute a violation of both medical

¹¹⁰ Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel raised concerns about potential conflict with established Title VII standards and emphasized that Title VII should remain the legal standard for determining religious accommodations. Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), https://www.ecoc.gov/ecoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html

¹¹¹ See, e.g., Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).

¹¹² Proposed Rule, 83 Fed. Reg. at 3919.

¹¹³ Id. at 3888.

¹¹⁴ See, e.g., id. at 3886.

¹¹⁵ See, e.g., Tom Beauchamp & James Childress, Principles of Biomedical Ethics (4th ed. 1994).

standards of care¹¹⁶ and legal standards.¹¹⁷ The proposed rule, however, encourages providers to flout their obligations to provide patients with necessary medical information. By encouraging health care providers and entities to refuse to provide key information and disregarding statutory requirements that patients be given notice that they may not receive complete and accurate information, the proposed rule degrades trust and open communication between doctors and patients and prevents patients from being able to make an informed decision about their health care.

For example, by proposing to expand the definition of "referral" to the provision of *any* information by a health care worker who believes that it could *possibly* lead a patient to obtain a treatment to which they object, the Department encourages health care providers to withhold critical information about available treatments, their risks and benefits, or even the patient's diagnosis. As discussed above, the proposed rule even omits statutory requirements that health care entities inform patients of their objections to certain treatments or policies of refusing to provide or cover them. By omitting these notification requirements from its proposed rule, the Department creates confusion about what information health care providers must give to patients about their or their employees' religious or moral objections and encourages entities to ignore these obligations. Especially in light of studies indicating that most patients are unaware that religiously affiliated health care institutions might refuse to provide treatments based on religious objections, ¹¹⁸ the Department's apparent reluctance to fully enforce disclosure requirements jeopardizes patients' ability to make informed decisions about their health care.

VI. The Department's failure to follow required rulemaking procedures and base its rule on available evidence suggests an arbitrary and capricious process.

The Department failed to follow normal rulemaking procedures in issuing the proposed rule in several respects and to consider important evidence regarding the rule's impact. Together with the fact that the rule exceeds the Department's statutory authority, runs counter to existing laws, and undermines the constitutional and other legal rights of patients, this rushed and inadequate rulemaking procedure strongly suggests a violation of the Administrative Procedure Act.¹¹⁹

¹¹⁶ See, e.g., The AMA Code of Medical Ethics' Opinions on Informing Patients: Opinion 9.09 – Informed Consent, 14 AM. MED. J. ETHICS 555-56 (2012), <u>http://journalofethics.ama-assn.org/2012/07/coet1-1207.html</u> ("The physician's obligation is to present the medical facts accurately to the patient.... The physician has an ethical obligation to help the patient make choices from among therapeutic alternatives consistent with good practice."); Am. Nurses Ass'n, *Code of Ethics for Nurses with Interpretive Statements* (2001), <u>https://www.truthaboutnursing.org/research/codes/code_of_ethics_for_nurses_US.html</u> ("Patients have the moral and legal right to determine what will be done with their own person; 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 treatments...."); Am. Pharmacists Ass'n, *Code of Ethics for Pharmacists* (1994).

¹¹⁷ See., e.g., Brownfield v. Daniel Freeman Marina Hosp., 256 Cal. Rptr. 240 (Ct. App. 1989).

¹¹⁸ Ensuring that disclosure requirements are rigorously enforced is particularly important in light of research indicating that most patients are unaware that some religiously affiliated health care entities may refuse to provide treatments based on their religious beliefs. *See, e.g.,* Nadia Sawicki, *Mandating Disclosure of Conscience-Based Limitations on Medical Practice,* 42 AM. J. LAW & MED. 85 (2016), http://journals.sagepub.com/doi/pdf/10.1177/0098858816644717.

¹¹⁹ The Administrative Procedure Act instructs a reviewing court to hold agency actions as unlawful when they are found to be "(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (D) without observance of procedure required by law; (E) unsupported by substantial evidence...; or (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court." 5 U.S.C. § 706.

A. Failure to include the rule in the Department's Unified Regulatory Agenda

First, under longstanding Executive Orders governing the rulemaking process, proposed rules must first appear in the agency's Regulatory Agenda.¹²⁰ Executive Order 13,771, signed by President Trump, reaffirms that "no regulation shall be issued by an agency if it was not included on the most recent version or update of the published Unified Regulatory Agenda...unless the issuance of such regulation was approved in advance in writing by the Director" of the Office of Management and Budget.¹²¹ We are aware of no circumstance that would justify the Director approving an exception to this normal process in this instance. We are concerned that the failure of the Department to comply with these requirements reflects a hasty development of the rule that lacked sufficient review of its impact and factual and legal basis.

B. Failure to conduct a meaningful federalism analysis

The Department also failed to comply with the requirements of Executive Order 13,132, which requires agencies to conduct a thorough review of any federalism implications of its regulations, including by identifying effects the regulation would have on existing state and local laws and on the ability of states to exercise power in realms traditionally reserved for them, as well as identifying and in some cases providing funding for costs that would be incurred by state and local governments.¹²² The Department's cursory review of federalism implications meets none of those basic requirements. Its conclusion that the regulation has *no* federalism implications is directly contradicted the Department's own statements that its regulation could upend numerous existing state and local laws and policies, require changes to state programs such as Medicaid, and limit the manner in which many states can regulate health care in the future.¹²³ Regardless of the merits of the Department's interpretation of existing federal law, it is required to make a fact-based federalism assessment that recognizes these impacts of the regulation on state and local laws.

C. Failure to assess the costs of denied or delayed health care

Additionally, the Department failed to comply with Executive Order 13,563, which permits agencies to propose a rule only after conducting an accurate assessment of costs and benefits, and after reaching a reasoned determination that the benefits outweigh the costs and that the regulations are tailored "to impose the least burden on society."¹²⁴ While the Department considered the substantial financial costs that its new notification requirements may have on certain health care entities, it failed to even attempt to assess the most significant cost its rule would have if adopted: the cost incurred by patients whose access to care may be denied, delayed, or limited, including substantial financial and health-related costs to patients, to health care entities, and to government-funded health programs. Neglecting to take this cost into consideration or even acknowledge it—despite the Department's past recognition of the pervasiveness of barriers to health care faced by many patients¹²⁵—is suggestive of an arbitrary and

¹²⁰ E.g., Exec. Order No. 13,771, 82 Fed. Reg. 9339, 9340 (Jan. 30, 2017); Exec. Order No. 12,866, 58 Fed. Reg. 190 (Oct. 4, 1993).

¹²¹ Id.

¹²² Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 4, 1999).

¹²³ See, e.g, Proposed Rule, 83 Fed. Reg. at 3886–3888.

¹²⁴ Exec. Order No. 13,563, 76 Fed. Reg. 3821 (Jan. 21, 2011).

¹²⁵ See, e.g., Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376 (2016).

capricious process that entirely failed to consider a crucially important aspect of the issued addressed in the rule.

D. Failure to adequately consider comments from the Department's closely related RFI

We are further concerned that the timing of the publication of the proposed rule reflects an insufficient consideration of public comments to the Department's recent Request for Information on a closely related topic, "Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding." The Department completed its comment period on the Request for Information in November 24, only two months before the publication of this rule, and received over 12,000 comments—the vast majority of which were not posted publicly until mid-December.¹²⁶ Many, if not most, of these public comments focused on the precise topic of this proposed rule: religious exemptions for health care workers and institutions. Yet despite the clear and close connection between the RFI and the proposed rule, the brief period of time between them suggests that it is unlikely that the proposed rule reflects a serious, reasoned analysis of the many comments the Department received on the RFI.

This hasty rule development stands in sharp contrast with the typical process for HHS and other agency rules, which commonly spans over several months or years instead of only a few weeks. An illustrative example is the Department's rulemaking process implementing Section 1557 of the Affordable Care Act, which began with a Request for Information in 2013, a proposed rule in 2015, and a final rule in 2016 issued after thorough consideration of more than 25,000 public comments.¹²⁷ Given that this proposed rule invokes dozens of distinct statutes, affects numerous areas of both health care service provision and coverage, and imposes sweeping and burdensome new notice and certification requirements—all without any change in the governing statutory or case law—it deserves at least as much deliberation.

VII. Expanding religion-based exemptions is unnecessary.

In addition to raising legal and constitutional questions, an expansion of religion-based exemptions is unnecessary as a matter of policy. Federal statutes and existing regulations, including the existing OCR conscience rule, already provide a broad range of special exemptions for health care providers or entities with religious or moral objections to many services, and these exemptions provide more than adequate protections, as evidenced by the large number of faith-based organizations that have received and continue to receive federal grants and other federal funding.

Among the laws and regulations that protect health care entities, in addition to the statutes cited by the proposed rule, is the Religious Freedom Restoration Act (RFRA). RFRA protects any grantee from any government action (including a denial or limitation of a grant or contract) that substantially burdens their exercise of religion, unless the government can meet the high burden of demonstrating that the action is narrowly tailored to serve a compelling interest. The protections in RFRA are more than sufficient to ensure that faith-based organizations and providers with religious or moral objections to certain procedures can receive case-by-case accommodations, as appropriate, to have a fair opportunity to

¹²⁶ Dan Diamond, *HHS Defends Withholding Comments Critical of Abortion, Transgender Policy*. POLITICO (Dec. 18, 2017), https://www.politico.com/story/2017/12/18/hhs-faith-based-rule-withholding-comments-236759.

¹²⁷ Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. at 31,376.

receive federal funds. Existing Department regulations explicitly acknowledge that their requirements are subject to limitations under RFRA and other federal laws.¹²⁸

Conclusion

We strongly urge the Department to refrain from expanding health care refusal rights as proposed in this rule. Doing so would undermine vulnerable populations' access to essential health services and compromise the Department's ability to meet its responsibilities to legal beneficiaries and its legal obligations. Protecting religious freedom is important, and a range of existing laws and regulations already provide more than adequate protections for individuals and entities with religious or moral objections to providing specific services. It is therefore unwise and unnecessary for the Department to put patients at risk by allowing them to be mistreated or denied care using the federal dollars that are intended to help them. Moreover, the proposed rule is contrary to law in numerous respects. We strongly urge the Department to abandon this unnecessary, untenable, and harmful proposed rule and instead maintain the existing 2011 rule on the topic, while preserving OCR's primary focus on enforcing the civil rights and privacy rights of patients.

Thank you for your consideration.

¹²⁸ See, e.g., 45 C.F.R. pt. 92 §92.2(b)(2).

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Exhibit 121

March 27, 2018

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

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

To Whom it May Concern:

I am writing on behalf of the National Coalition for LGBT Health in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26. The National Coalition for LGBT Health is committed to improving the health and wellbeing of lesbian, gay, bisexual and transgender individuals through federal and local advocacy, education, and research. The Coalition addresses the entire LGBT community, including individuals of every sexual orientation, gender, gender identity, race, ethnicity, and age regardless of disability, income, education, and geography.

Every day too many LGBTQ people face discrimination and other barriers to accessing lifesaving care. These barriers are especially pronounced for transgender patients. The proposed regulation ignores the prevalence of discrimination and damage it causes and will undoubtedly lead to increased discrimination and flat-out denials of care for some of the most vulnerable members of our community. We all deeply value freedom of religion, but sweeping exemptions that obstruct access to care are a fundamental distortion of that principle. Americans deserve better.

1. Expanding religious refusals can exacerbate the barriers to care that LGBTQ individuals already face.

LGBTQ people, women, and other vulnerable groups around the country already face enormous barriers to getting the care they need.¹ Accessing quality, culturally competent care and

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¹ See, e.g., Institute of Medicine, The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding (2011), <u>http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx;</u> Sandy E. James et al., The Report of the U.S. Transgender Survey 93–126 (2016), <u>www.ustranssurvey.org/report;</u> 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; Shabab Ahmed Mirza & Caitlin Rooney,

overcoming outright discrimination is even a greater challenge for those living in areas with already limited access to health providers. The proposed regulation threatens to make access even harder and for some people nearly impossible.

Patients living in less densely populated areas already face a myriad of barriers to care including less access to health insurance coverage, lower incomes, and lower rates of paid sick leave. This is in addition to the universal costs of transportation, taking time from work, and other incidentals that go along with obtaining care in the first place. For many, the sheer distance to a healthcare facility can be a significant barrier to getting care. For example, more than half of rural women live more than 30 minutes away from a hospital that provides basic obstetric care.² Patients seeking more specialized care like that required for fertility treatments, endocrinology, or HIV treatment or prevention are often hours away from the closest facility offering these services. For example, a 2015 survey of nearly 28,000 transgender adults nationwide found that respondents needed to travel much further to seek care for gender dysphoria as for other kinds of care.³

This means if these patients are turned away or refused treatment, it is much harder—and sometimes simply not possible—for them to find a viable alternative. In a recent study, nearly one in five LGBTQ 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 LGBTQ people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider.⁴ 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.

2. The regulation attempts to inappropriately broaden religious exemptions in a way that can lead to dangerous denials of medically necessary treatments.

The regulation purports, among other things, to clarify current "religious refusal clauses" related to abortion and sterilization in three federal statutes. Each of these statutes refers to specific, limited circumstances in which health care providers or health care entities may not be required

Discrimination Prevents LGBTQ People from Accessing Health Care (2016),

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

² American College of Obstetrics and Gynecologists, *Health Disparities in Rural Women* (2014), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Disparities-in-Rural-Women#17.

³ Sandy E. James et al., The Report of the U.S. Transgender Survey 99 (2016), www.ustranssurvey.org/report

⁴ Shabab Ahmed Mirza & Caitlin Rooney, Discrimination Prevents LGBTQ People from Accessing Health Care (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-peopleaccessing-health-care.

to participate in abortion and sterilization procedures. The regulation, however, creates ambiguity about these limited circumstances and encourages an overly broad misinterpretation that goes far beyond what the statutes permit.

For example, section (d) of the Church Amendments refers to circumstances when a person may refuse to participate in any part of a health service program or research activity that "would be contrary to his religious beliefs or moral convictions." Even though longstanding legal interpretation applies this section singularly to participation in abortion and sterilization procedures, the proposed rule does not make this limitation clear. This ambiguity can encourage an overly broad interpretation of the statute that empowers a provider to refuse to provide *any* health care service or information for a religious or moral reason—potentially including not just sterilization and abortion procedures, but also Pre-Exposure Prophylaxis (PrEP), infertility care, treatments related to gender dysphoria, and even HIV treatment. Some providers may try to claim even broader refusal abilities, as a recent analysis of complaints to HHS showed that transgender patients are most often discriminated against simply for being who they are rather than for the medical care they are seeking.⁵

Doctors may be misled into believing they may refuse on religious grounds to administer an HIV test or prescribe PrEP to a gay or bisexual man, or refuse screening for a urinary tract infection for a transgender man.⁶ In fact, medical staff may interpret the regulation to indicate that they can not only refuse, but decline to tell the patient where he would be able to obtain these lifesaving services or even inform patients of their treatment options. This puts the health of the patient, and potentially that of others, at risk. The regulation could lead a physician to refuse to provide fertility treatments to a same-sex couple, or a pharmacist to refuse to fill a prescription for hormone replacement therapy for a transgender customer. In addition, by unlawfully redefining the statutory term "assisting in the performance" of a procedure, the rule could encourage health care workers to obstruct or delay access to a health care service even when they have only a tangential connection to delivering that service, such as scheduling a procedure or running lab tests to monitor side-effects of a medication. The extension and broadening of this clause will impair LGBTQ patients' access to care services if interpreted—as the proposed rule improperly appears to do—to permit providers to choose patients based upon sexual orientation, gender identity, or family structure.

We are particularly concerned that the proposed rule will be used to refuse medically necessary care to transgender patients. We are concerned that the rule's sweeping terms and HHS's troubling discussions of a case involving a transgender patient will encourage the mistaken belief that treatments that have an incidental impact on fertility, such as some procedures used to treat

⁵ https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/

⁶ https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/

gender dysphoria, are sterilization procedures. Treatments for serious medical conditions may have the incidental effect of causing or contributing to infertility: for example, a hysterectomy to treat gender dysphoria, chemotherapy to treat cancer, and a wide range of medications can have the incidental effect of temporarily or permanently causing infertility. The primary purpose of such procedures, however, is not to sterilize, but to treat an unrelated medical condition. If religious or moral exemptions related to sterilization are misinterpreted to include treatments that have simply an incidental effect on fertility—as the vague and sweeping language of this rule encourages—it can lead to refusals that go even further beyond what federal law allows and unlawfully encourages individuals and institutions to refuse a dangerously broad range of medically needed treatments.

3. The proposed rule tramples on states' and local governments' efforts to protect patients' health and safety, including their nondiscrimination laws.

The Department claims that its unwarranted new interpretations of federal law supersede laws passed by state and local governments to ensure patients' access to health care. By claiming to allow individuals and institutions to refuse care to patients based on the providers' religious or moral beliefs in such a sweeping way, the proposed rule creates conflicts with hundreds of state and local nondiscrimination laws around the country that apply to health care. It therefore is disingenuous for the Department to claim that the proposed rule "does not impose substantial direct effects on States," "does not alter or have any substantial direct effects on the relationship between the Federal government and the States," and "does not implicate" federalism concerns under Executive Order 13132.

4. The regulation lacks safeguards to protect patients from harmful refusals of care.

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

Indeed, the Establishment Clause of the First Amendment requires the government to adequately account for burdens a religious accommodation may impose on others, including patients, and prohibits granting accommodations when they would materially harm any third party. As detailed at length above, the proposed regulation would cause significant harm by interfering with patients' access to healthcare and thus, conflicts with this constitutional bar.

The expanded religious exemptions in the proposed regulations also conflict with many patient protections in federal laws like the Affordable Care Act and the Emergency Medical Treatment and Active Labor Act. While protections under these laws are subject to religious exemptions

provided under federal statute, they are not subject to exemptions whose scope goes beyond federal law—including many of the exemptions expanded in this rule. Additionally, the proposed regulation's approach to religious exemptions—which appears to allow for no limitations even when those exemptions unjustifiably harm patients or employers—conflict with the well-established standard under other federal laws, like Title VII of the Civil Rights Act. Title VII ensures that employers can consider the effect that providing a religious accommodation would have on coworkers, customers, and patients, as well as factors like public safety, public health, and other legal obligations. A standard that appears to allow for none of these considerations, and instead appears to require broad, automatic exemptions, would create confusion and undermine the federal government's ability to properly enforce federal laws.

5. The Department's rushed rulemaking process failed to follow required procedures.

The Department rushed to publish this rule without first publishing any notice regarding in its Unified Regulatory Agenda, as is normally required. The failure to follow proper procedure reflects an inadequate consideration of the rule's impact on patients' health.

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, a 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.

Conclusion

The proposed rule goes far beyond established law, appears to have been developed in a rushed and arbitrary manner, and most importantly will put the health and potentially even the lives of patients at risk. We urge you to withdraw the proposed rule.

Sincerely,

The National Coalition for LGBT Health