EXHIBIT 33

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COUNTY OF SANTA CLARA

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Submitted electronically through www.regulations.gov

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

Attn: Docket HHS-OCR-2018-0002 (RIN 0945-ZA03)
Re: Protecting Statutory Conscience Rights in Health Care

Dear Secretary Azar:

The County of Santa Clara ("County") submits these comments in response to the Department of Health and Human Services' (HHS) proposed rule, Protecting Statutory Conscience Rights in Health Care.[1]

The County, established in 1850, is a charter county and political subdivision of the State of California. Its mission is to protect the health, safety, and welfare of 1.9 million County residents. The County owns and operates Santa Clara Valley Medical Center ("SCVMC"), a fully integrated and comprehensive public health care delivery system that provides critical health care to residents of Santa Clara County regardless of their ability to pay. SCVMC, which includes a 574-bed tertiary care hospital with a Level 1 trauma center and 11 ambulatory care clinics, is the only public safety-net health care provider in Santa Clara County, and the second largest such provider in California. SCVMC provides the vast majority of the health care services available to poor and underserved patients in the County. The County also owns and operates Valley Health Plan ("VHP"), which participates in California's health insurance marketplace under the Affordable Care Act.

[1] 83 Fed. Reg. 3880 (proposed Jan. 26, 2018).

As set forth below, the proposed regulation: (1) improperly attempts to broaden the substantive scope of statutory conscience-based protections; (2) if adopted, may be improperly interpreted to invite discrimination against patients who face significant barriers to care; and (3) if adopted, will impose unnecessary burdens on safety-net providers such as the County.

A. The Proposed Regulation Improperly Attempts to Broaden the Substantive Scope of Statutory Conscience-Based Protections

Existing law provides an adequate framework for the enforcement of conscience-based protections, which protect under certain circumstances health care workers who refuse to participate in certain procedures or services based on their religious beliefs or "moral convictions." In addition, Title VII of the Civil Rights Act of 1964 provides an employment law framework for religious accommodations. The proposed regulation is not only unnecessary in light of the current framework, but it also improperly attempts to legislate heightened conscience-based protections that Congress has not recognized. Through its "further definition of Federal health care conscience and associated anti-discrimination laws," the proposed regulation seeks to vastly expand the scope of conscience-based protections in a way that substantially increases the likelihood that already-marginalized patients will face additional barriers in accessing health care.[2] Such an effect on patients seeking care undermines HHS's mission "to enhance and protect the health and well-being of all Americans."[3]

1. *The proposed regulation improperly broadens the meaning of "referral or refer for," which may result in health care workers turning patients away from a facility when others at the facility are willing to provide care.*

The proposed regulation's broad definitions of "assist in the performance" and "referral or refer to" in sections 88.3(a)(2)(v) and 88.2 sweep beyond the statutory language and may be improperly interpreted as permitting individual health care workers to turn patients away from a facility, without providing *any* information, when the objected-to services are in fact provided at that facility.[4] The definition in Section 88.2 of "refer or refer to" as including "the provision of any information . . . by any method" goes beyond the County's understanding of what a referral is.[5] The County is concerned that individual health care workers might improperly interpret the proposed regulation as permitting them to refuse *any* form of patient assistance, including notifying them that such services are provided by the County at that facility. For example, a provider might interpret the proposed regulation as allowing her, based on "moral convictions," to turn away, without providing *any* information, a patient at SCVMC experiencing abdominal pain related to an intra-uterine device, when there are many other providers at SCVMC who are

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[2] *Id.* at 3891.

[3] *Introduction: About HHS*, HHS, https://www.hhs.gov/about/strategic-plan/introduction/index.html, attached as Exhibit 1.

[4] Protecting Statutory Conscience Rights in Health Care, 83 Fed. Reg. at 3925 (§ 88.3(a)(2)(v)); *id.* at 3924 (§ 88.2).

[5] *Id.*

willing to treat that patient. Health care professionals are obligated to provide their patients with complete and accurate information about their treatment options. Failure to do so could result in liability for the providers, incomplete or deficient treatment of patients, and violation of ethical and legal principles.

Nothing in the proposed regulation supports HHS's conclusion that Congress intended such a broad extension of statutory conscience-based protections. HHS contends in the commentary to the proposed regulation that because the statutes use the terms "make arrangements for" and "refer for" services, Congress intended a broad definition of "referrals."[6] But this is not persuasive evidence that Congress intended the definition of "referral or refer to" to be as broad as it is in the proposed regulation: "provision of *any information. . . by any method*."[7] Stating that the County provides the requested services, even if the particular health care worker objects to providing them, is not "making arrangements for" a service that the provider has a religious objection to performing. In particular, the conscience-based protections must be read in light of Congress's robust, generally applicable non-discrimination statutes, including Section 1557 of the Affordable Care Act, Titles II and III of the Americans with Disabilities Act, and Title VI of the Civil Rights Act of 1964, that apply in certain health care settings.

Although HHS states that its proposed definition of "referral or refer to" will "address confusion the Department perceives among the public about what sorts of actions may be properly regarded as referrals for the purposes of protecting rights of conscience under the statutes at issue in this proposed rule,"[8] the substantive rewriting of statutory rights will result in greater confusion, because patients will not know whether they are getting complete information or a full range of treatment options. In delegating to the Office of Civil Rights (OCR) enforcement authority over the conscience-based protection statutes, Congress did not delegate the authority to transform the statutes into a broad license to discriminate and to provide patients with incomplete, deficient, or no treatment options based on a boundless array of "moral convictions," some of which may be contrary to non-discrimination statutes, and many more of which may conflict with HHS's mission to improve the health care of *all* Americans.

2. *The proposed regulation's reinterpretation of the Weldon Amendment is likely to limit access to comprehensive health insurance options.*

As applied to the Weldon Amendment,[9] the proposed regulation's definition of "health care entity" is likely to create additional barriers to accessing care, because it will likely limit

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[6] *Id.* at 3895.

[7] *Id.* (emphasis added).

[8] *Id.*

[9] The Weldon Amendment, incorporated in the HHS appropriations acts, provides that "[n]one of the funds made available in this Act may be made available to a Federal agency or program, or to a state or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions."

access to health insurance with comprehensive coverage of reproductive services. The proposed regulation adds "a plan sponsor" to the definition of "health care entity" under the Weldon Amendment.[10] This would greatly expand the universe of entities permitted to challenge a state's requirement to "provide, pay for, provide coverage of, or refer for, abortion."[11] HHS's proposed justification for expanding the definition of "health care entity"—that "[t]he amendment's broad and non-exhaustive definition indicates that the amendment takes an inclusive approach with respect to the health care entities it protects and should not be interpreted narrowly,"[12]—is not based on any legislative history, nor is it a license to go beyond the plain meaning of the statute. Congress did not delegate authority to HHS to expand the scope of the Weldon Amendment.

It is even more problematic that the proposed regulation attempts to reinterpret the Weldon Amendment to broadly allow health care entities to refuse to "provide, pay for, provide coverage of, or refer for abortions,"[13] regardless of whether entities have a conscience-based objection to doing so. HHS offers no evidence that refusals unrelated to conscience-based objections—such as financial or operational motivations—are intended to be protected under the Weldon Amendment. Rather, both the legislative history of the Weldon Amendment, and judicial interpretations of it, compel the contrary conclusion.[14] And even though economically or operationally driven refusals to provide abortion-related services or referrals have nothing to do with civil rights, the proposed regulation would make OCR's enforcement authority available to entities that merely have an economic or operational objection to providing such services. Contrary to HHS's mission, such a delegation would likely serve only to decrease the availability of health insurance options that provide comprehensive coverage of reproductive services.

B. The Proposed Regulation, If Adopted, May Be Improperly Interpreted as Inviting Discrimination Against Patients Who Already Face Significant Barriers to Care

If adopted, the proposed regulation will likely invite discrimination against patients who already face significant barriers to accessing care, such as lesbian, gay, bisexual, transgender, or queer (LGBTQ) people. Although a full discussion of the myriad of health care consumers who may be affected by the proposed regulation is beyond the scope of this comment, the proposed

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Consolidated Appropriations Act, 2017, Public Law 115-31, § 507(d)(1), 131 Stat. 135. It defines "health care entity" to include "an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan." *Id.* at § 507(d)(2).

[10] Protecting Statutory Conscience Rights in Health Care, 83 Fed. Reg. at 3890–91, 3924 (§ 88.2).

[11] *Id.* at 3925–26 (§ 88.3(c)(2)).

[12] *Id.* at 3890.

[13] *Id.* at 3925–26 (§ 88.3(c)(2)).

[14] *See* Letter from Jocelyn Samuels, Director, OCR, to Catherine W. Short, Vice President, Life Legal Def. Found., et al. (June 21, 2016) (citing *California ex rel. Lockyer v. United States*, 450 F.3d 436, 441 (9th Cir. 2006); 150 Cong. Rec. H10090 (Statement of Rep. Weldon) (Nov. 20, 2004)).

regulation's likely effect on LGBTQ people, who frequently encounter discrimination and other barriers to accessing medical care, serves as an example of the harmful impact the regulation is likely to have.

Discrimination against LGBTQ people in health care settings is well documented. In one study, more than half of all respondents had experienced at least one of the following when seeking health care: refusals of needed care, providers refusing to touch them or using excessive precautions, harsh or abusive language, providers blaming them for their health status, or physically rough or abusive conduct.[15] In that study, eight percent of lesbian, gay, or bisexual respondents reported they had been refused needed health care because of their sexual orientation, and nearly 27 percent of transgender respondents reported being refused care because of their transgender status.[16] The percentages of LGBT people of color and low-income LGBT people who reported being refused care are much higher than the percentages for survey respondents as a whole.[17]

One respondent to a survey of transgender people reported, "I have been refused emergency room treatment even when delivered to the hospital by ambulance with numerous broken bones and wounds."[18] Another study, based on a review of complaints filed with OCR, describes a situation in which a transgender woman was recovering from an appendectomy, and the treating doctor, who "does not deal with 'these kinds' of patients," refused to call her by the correct pronouns.[19] Some medical providers have explicitly asserted religious-based reasons for denying care to LGBTQ people or their families, such as a pediatrician who refused to treat the newborn daughter of a lesbian couple.[20]

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[15] Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination Against LGBT People and People with HIV* 10 (2010), *available at* https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf, attached as Exhibit 2.

[16] *Id.*

[17] *Id.* at 12. The County generally uses the acronym LGBTQ but uses "LGBT" when referring to the cited study, which uses that acronym.

[18] Jaime Grant et al., Nat'l Center for Transgender Equality & Nat'l Gay and Lesbian Task Force, *Injustice at Every Turn: A Report of the National Transgender Discrimination Survey* 73 (2011), *available at* http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf, excerpt attached as Exhibit 3.

[19] Sharita Gruberg & Frank J. Bewkes, Ctr. for Am. Progress, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial* (Mar. 7, 2018), *available at* https://cdn.americanprogress.org/content/uploads/2018/03/06122027/ACAnondiscrimination-brief2.pdf, attached as Exhibit 4.

[20] Abby Phillip, *Pediatrician Refuses to Treat Baby with Lesbian Parents and There's Nothing Illegal about It*, Washington Post (Feb. 19, 2015), 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/?utm_term=.a59cf2f3df0a, attached as Exhibit 5.

Refusing to provide medical care to consumers based on sex, sexual orientation, or gender identity is a form of sex discrimination prohibited by federal law. As an entity covered by the Affordable Care Act, the County complies with the ACA's non-discrimination protections in Section 1557, 42 U.S.C. § 18116(a), which prohibits discrimination based on sex and other protected characteristics in health programs and activities. In addition, as a local government that seeks to ensure the health, safety, and welfare of its 1.9 million residents, the County has a significant interest in eliminating discrimination and barriers to health care for *all* of its residents. To understand the health needs of the County's LGBTQ residents, the County's Public Health Department performed an LGBTQ Health Assessment in 2013.[21] Among other things, the study showed that 12 percent of LGBTQ survey respondents were "denied or given lower quality health care" in the 12 months preceding the survey due to their sexual orientation and/or gender identity.[22]

The County is concerned that the proposed regulation, if adopted, will invite medical providers to discriminate against LGBTQ health care consumers, among others, in violation of federal non-discrimination law. Not only does the proposed regulation appear to invite discriminatory conduct by expanding the reach of statutory conscience-based protections as discussed above, but it also oversimplifies them in the language it proposes to use to raise awareness among providers. The Notice in Appendix A tells providers they "have the right to decline to participate in, refer for, undergo, or pay for certain health care-related treatments, research, or services . . . which violate your conscience, religious beliefs, or moral convictions under Federal law."[23] This is not limited to the types of procedures contemplated in the statutory provisions discussed in the proposed rule. Such notice might encourage a provider, for example, to refuse to treat a transgender patient who comes to the emergency room seeking care for a broken arm based on the provider's "moral convictions," even though such refusal of service would violate federal non-discrimination law and the Emergency Medical Treatment and Labor Act.[24] And, if the notice is seen by a patient, this might discourage open communication with the provider, for fear that services will be denied. If HHS adopts the proposed regulation, it must address the empirical evidence which strongly suggests that marginalized patients will face heightened barriers in accessing care. And the notice must be compliant with all other applicable laws.

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[21] Santa Clara Cnty Pub. Health Dep't, *Status of LGBTQ Health: Santa Clara County 2013* (2013), *available at* https://www.sccgov.org/sites/phd/hi/hd/Documents/LGBTQ%20Report%202012/LGBT%20Health%20Assessment.pdf, attached as Exhibit 6.

[22] *Id.*

[23] Protecting Statutory Conscience Rights in Health Care, 83 Fed. Reg. at 3931.

[24] 42 U.S.C. § 18116(a); 42 U.S.C. § 1395dd.

C. The Proposed Regulation, If Adopted, Would Be an Unnecessary Burden to Safety-Net Providers Such as the County of Santa Clara

The proposed regulation's projected costs, which HHS states will be $815 million over the course of five years, far outweigh any expected benefits that could possibly stem from the expected increase in the supply of health care providers who maintain conscience-based objections. As a result, the proposed regulation, if adopted, would be an unnecessary burden to safety-net providers such as the County, which rely on limited public funds to provide essential health care services to *all* patients on a non-discriminatory basis. As illustrated above, an effect of the proposed regulation will likely be increased discrimination against patients who already face barriers in accessing care.

The proposed regulation's discussion of "ancillary benefits for patients," such as "assist[ing] patients in seeking counselors who share their deepest held convictions,"[25] ignores the much more substantial harm that the proposed regulation will likely cause to patients who are refused medical services, referrals to services, information about such services or referrals, or even information about where such information might be obtained, based on the religious beliefs or "moral convictions" of providers. The proposed regulation asserts that "[f]acilitating open communication between providers and their patients also helps to eliminate barriers to care, particularly for minorities."[26] But providers may interpret the regulation as allowing them to refuse to communicate *any* information to patients based on the provider's "moral convictions."

Surprisingly, the proposed regulation's cost-benefit analysis does *not* consider the potential impact or costs directly impacting patients, including costs resulting from "health outcomes or other effects of protecting conscience rights."[27] Studies show that discrimination, and the potential for discrimination, deter marginalized populations such as LGBTQ people from seeking medical care.[28] And discrimination negatively impacts health outcomes. As HHS's HealthyPeople 2020 initiative has noted, LGBTQ people "face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights."[29]

In addition, the proposed regulation vastly underestimates the costs of compliance for safety-net providers such as the County. Because the proposed regulation vastly expands the

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[25] Protecting Statutory Conscience Rights in Health Care, 83 Fed. Reg. at 3916–17.

[26] *Id.* at 3917.

[27] *Id.* at 3916, 3918.

[28] Shabab Ahmed Mirza & Caitlin Rooney, Ctr. for Am. Progress, *Discrimination Prevents LGBTQ People from Accessing Health Care* (Jan. 18, 2018), *available at* https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/, attached as Exhibit 7.

[29] HHS Office of Disease Prevention & Health Promotion, *Lesbian, Gay, Bisexual, and Transgender Health*, HealthyPeople 2020, https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health, attached as Exhibit 8.

substantive scope of statutory conscience-based protections, the projected estimate of *one* attorney hour to review the final rule[30] grossly underestimates the time that would be required to fully examine the rule's implications for existing County policies and practices related to conscience-based protections, as well as applicable non-discrimination policies at the federal, state, and local level. Similarly, the projected estimate for time required to post approximately five notices[31] ignores the reality of large health and hospital systems like the one operated by the County, which encompasses many facilities in many locations. The burden of this requirement is particularly unnecessary for entities like the County, which already ensures that employees are provided notice of their right to assert conscience-based protections through robust policies that allow employees to opt-out of participation in certain services in advance if those services conflict with a staff member's cultural values, ethics, or religious beliefs.[32]

D. Conclusion

As discussed above, the proposed regulation is an unlawful and unnecessary burden on providers and may invite discrimination against vulnerable populations who already face barriers to health care. The County urges HHS to rescind the proposed regulation.

Very truly yours,

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[30] Protecting Statutory Conscience Rights in Health Care, 83 Fed. Reg. at 3912.

[31] *Id.* at 3914.

[32] *See, e.g.*, Memorandum from Paul Lorenz to SCVMC Employees, Non-Participation in Certain Patient Care (Aug. 9, 2017); Memorandum from Paul Lorenz to SCVMC Employees, Medically Ineffective Interventions, Requests Concerning (May 8, 2015); Agreement Between Cnty. of Santa Clara & Registered Nurses Prof'l Ass'n (Nov. 10, 2014 through Oct. 20, 2019).

EXHIBIT 34

CALLEN-LORDE

March 27, 2018

Attention: Conscience NPRM

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

Dear Secretary Azar:

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

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

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

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

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

the care they need. For these reasons, the National Health Law Program calls on the Department and OCR to withdraw the proposed rule in its entirety.

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

Civil rights laws and Constitutional guarantees, such as due process and equal protection, are designed to ensure full participation in civil society. The proposed rule, while cloaked in the language of non-discrimination, is designed to deny care and exclude disadvantaged and vulnerable populations. The adverse consequences of health care refusals and other forms of discrimination are well documented. As the Department stated in its proposed rulemaking for § 1557,

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

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

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

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

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

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[2] Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172, 54,194 (Sept. 8, 2015) (codified at 45 C.F.R. pt. 2).
[3] 83 Fed. Reg. 3917.
[4] *Id.*
[5] Brian P. Ward et al., *Sexual Orientation and Health Among U.S. Adults: National Health Interview Survey*, NAT'L CTR. FOR HEALTH STATISTICS, 2013 9 (2014), https://www.cdc.gov/nchs/data/nhsr/nhsr077.pdf.

CALLEN-LORDE

care disparities such as high rates of cervical cancer and are disproportionately impacted by HIV.[6] Meanwhile, people of color in rural America are more likely to live in an area with a shortage of health professionals, with 83% of majority-Black counties and 81% of majority-Latino/a counties designated by the federal Health Resources and Services Administration (HRSA) as Health Professional Shortage Areas (HPSAs).

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

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

a. <u>The proposed rule would harm LGBTQ Communities who continue to face rampant discrimination and health disparities</u>

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

LGBTQ people continue to face discrimination in many areas of their lives, including health care, on the basis of their sexual orientation and gender identity. The Department's Healthy People 2020 initiative recognizes, "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights."[7] LGBTQ people still face discrimination in a wide variety of services affecting access to health care, including reproductive services, adoption and foster care services, child care, homeless shelters, and transportation services – as well as physical and mental health care services.[8] In a recent study published in *Health Affairs*, researchers examined the

[6] In 2014, Latinas had the highest rates of contracting cervical cancer and Black women had the highest death rates. *Cervical Cancer Rates By Rates and Ethnicity*, CTRS. FOR DISEASE CONTROL & PREVENTION, (Jun. 19, 2017), https://www.cdc.gov/cancer/cervical/statistics/race.htm.;At the end of 2014, of the total number of women diagnosed with HIV, 60 percent were Black. *HIV Among Women,* CTRS. FOR DISEASE CONTROL & PREVENTION, Nov. 17, 2017, https://www.cdc.gov/hiv/group/gender/women/index.html.
[7] *Healthy People 2020, Lesbian, Gay, Bisexual, and Transgender Health*, U.S. DEPT. HEALTH & HUMAN SERV., https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health, (last accessed on Mar. 8, 2018).
[8] HUMAN RIGHTS WATCH, *All We want is Equality: Religious Exemptions and Discrimination against LGBT People in the United States*, (Feb. 2018), https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people.

intersection of gender identity, sexual orientation, race, and economic factors in health care access.[9] They concluded that discrimination as well as insensitivity or disrespect on the part of health care providers were key barriers to health care access and that increasing efforts to provide culturally sensitive services would help close the gaps in health care access.[10]

b. Discrimination against the transgender community

Discrimination based on gender identity, gender expression, gender transition, transgender status, or sex-based stereotypes is necessarily a form of sex discrimination.[11] Numerous federal courts have found that federal sex discrimination statutes reach these forms of gender-based discrimination.[12] In 2012, the Equal Employment Opportunity Commission (EEOC) likewise held that "intentional discrimination against a transgender individual because that person is transgender is, by definition, discrimination based on sex and such discrimination therefore violates Title VII."[13]

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

[10] *Id.*

[11] *See, e.g.*, *EEOC v. R.G. & G.R. Harris Funeral Homes*, No. 16-2424 (6th Cir. Mar. 7, 2018); *Whitaker v. Kenosha Unified Sch. Dist.*, 858 F.3d 1034 (7th Cir. 2017) (Title IX and Equal Protection Clause); Doddsv. U.S. Dep't of Educ., 845 F.3d 217 (6th Cir. 2016) (Title IX and Equal Protection Clause); *Barnes v. City of Cincinnati*, 401 F.3d 729 (6th Cir. 2005) (Title VII of the 1964 Civil Rights Act); Smith v. City of Salem, 378 F.3d 566 (6th Cir. 2004) (Title VII); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213 (1st Cir. 2000) (Equal Credit Opportunity Act); *A.H. ex rel. Handling v. Minersville Area School District*, 3:17-CV-391, 2017 WL 5632662 (M.D. Pa. Nov. 22, 2017) (Title IX and Equal Protection Clause); *Stone v. Trump*, ---F.Supp.3d ---, No. 17–2459 (D. Md. Nov. 21, 2017) (Equal Protection Clause); Doe v. Trump, ---F.Supp.3d ---, 2017 WL 4873042 (D.D.C. Oct. 30, 2017) (Equal Protection Clause); *Prescott v. Rady Children's Hospital-San Diego*, ---F.Supp.3d ---, 2017 WL 4310756 (S.D. Cal. Sept. 27, 2017) (Section 1557); *E.E.O.C. v. Rent-a-Center East, Inc.*, ---F.Supp.3d ---, 2017 WL 4021130 (C.D. Ill. Sept. 8, 2017) (Title VII); *Brown v. Dept. of Health and Hum. Serv.*, No. 8:16DCV569, 2017 WL 2414567 (D. Neb. June 2, 2017) (Equal Protection Clause); *Smith v. Avanti*, 249 F.Supp.3d 1194 (D. Colo. 2017) (Fair Housing Act); *Students & Parents for Privacy v. U.S. Dep't of Educ.*, No. 16-cv-4945, 2016 WL 6134121 (N.D. Ill. Oct. 18, 2016) (Title IX); *Mickens v. Gen. Elec. Co.* No. 16-603, 2016 WL 7015665 (W.D. Ky. Nov. 29, 2016) (Title VII); *Fabian v. Hosp. of Cent. Conn.*, 172 F.Supp.3d 509 (D. Conn. 2016) (Title VII); *Cruz v. Zucker*, 195 F.Supp.3d 554 (S.D.N.Y. Jul. 5, 2016) (Section 1557); *Doe v. State of Ariz.*, No. CV-15-02399-PHX-DGC, 2016 WL 1089743 (D. Ariz. Mar. 21, 2016) (Title VII); *Dawson v. H&H Elec., Inc.*, No. 4:14CV00583 SWW, 2015 WL 5437101 (E.D. Ark. Sept. 15, 2015) (Title VII); *U.S. v. S.E. Okla. State Univ.*, No. CIV–15–324–C, 2015 WL 4606079 (W.D. Okla. 2015) (Title VII); *Rumble v. Fairview Health Serv.*, No. 14–cv–2037, 2015 WL 1197415 (D. Minn. Mar. 16, 2015) (Section 1557); *Finkle v. Howard Cty.*, 12 F.Supp.3d 780 (D. Md. 2014) (Title VII); *Schroer v. Billington*, 577 F. Supp. 2d 293 (D.D.C. 2008) (Title VII); *Lopez v. River Oaks Imaging & Diagnostic Grp.*, Inc., 542 F.Supp.2d 653 (S.D. Tex. 2008) (Title VII); *Mitchell v. Axcan Scandipharm,* Inc., No. Civ.A. 05-243, 2006 WL 456173 (W.D. Pa. 2006) (Title VII); *Tronettiv. Healthnet Lakeshore Hosp.*, No. 03–CV–0375E, 2003 WL 22757935 (W.D.N.Y. Sept. 26, 2003) (Title VII).

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

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

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Twenty-nine percent of transgender individuals were refused to be seen by a health care provider on the basis of their perceived or actual gender identity and 29 percent experienced unwanted physical contact from a health care provider.[14] Additionally, the 2015 U.S. Transgender Survey found that 23 percent respondents did not see a provider for needed health care because of fears of mistreatment or discrimination.[15]

Data obtained by Center for American Progress (CAP) under a FOIA request indicates the Department's enforcement was effective in resolving issues of anti-LGBTQ discrimination. CAP received information on closed complaints of discrimination based on sexual orientation, sexual orientation-related sex stereotyping, and gender identity that were filed with the Department under Section 1557 of the ACA from 2012 through 2016.

- "In approximately 30% of these claims, patients alleged denial of care or insurance coverage simply because of their gender identity – not related to gender transition."
- "Approximately 20% of the claims were for misgendering or other derogatory language."
- "Patients denied care due to their gender identity or transgender status included a transgender woman denied a mammogram and a transgender man refused a screening for a urinary tract infection."[16]

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

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

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[14] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR. FOR AMERICAN PROGRESS, (Jan. 18, 2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/?link_id=2&can_id=d90c309ac9b5a0fa50d294d0b1cdf0b2&source=email-rx-for-discrimination&email_referrer=&email_subject=rx-for-discrimination.

[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 [hereinafter *2015 U.S. Transgender Survey*].

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

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

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

Testimonies of Transgender Discrimination

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

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

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

c. Discrimination Based Upon Sexual Orientation

Many LGBTQ people lack insurance and providers are not competent in health care issues and obstacles that the LGBTQ community experiences.[17] LGBTQ people still face discrimination. According to one survey, 8 percent of lesbian, gay, bisexual, and queer individuals had an experience within the year prior to the survey where a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation and 7 percent experienced unwanted physical contact and violence from a health care provider.[18]

[17] Medical schools often do not provide instruction about LGBTQ health concerns that are not related to HIV/AIDS. Jen Kates et al., *Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender Individuals in the U.S*, KAISER FAMILY FOUND.12 (2017), http://files.kff.org/attachment/Issue-Brief-Health-and-Access-to-Care-and-Coverage-for-LGBT-Individuals-in-the-US.
[18] Mirza, *supra* note 34.

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Fear of discrimination causes many LGB people to avoid seeking health care, and, when they do seek care, LGB people are frequently not treated with the respect that all patients deserve. The study "When Health Care Isn't Caring" found that 56 percent of LGB people reported experiencing discrimination from health care providers – including refusals of care, harsh language, or even physical abuse – because of their sexual orientation.[19] Almost ten percent of LGB respondents reported that they had been denied necessary health care expressly because of their sexual orientation.[20] Delay and avoidance of care due to fear of discrimination compound the significant health disparities that affect the lesbian, gay, and bisexual population. These disparities include:

- LGB individuals are more likely than heterosexuals to rate their health as poor, have more chronic conditions, and have higher prevalence and earlier onset of disabilities.[21]
- Lesbian and bisexual women report poorer overall physical health than heterosexual women.[22]
- Gay and bisexual men report more cancer diagnoses and lower survival rates, higher rates of cardiovascular disease and risk factors, as well as higher total numbers of acute and chronic health conditions.[23]
- Gay and bisexual men and other men who have sex with men (MSM) accounted for more than half (56 percent) of all people living with HIV in the United States, and more than two-thirds (70 percent) of new HIV infections.[24]
- Bisexual people face significant health disparities, including increased risk of mental health issues and some types of cancer.[25]

Testimonies of Sexual Orientation Discrimination

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

This discrimination affects not only the mental health and physical health of LGBTQ people, but that of their families as well. One pediatrician in Alabama reported that "we often see kids who haven't seen a pediatrician in 5, 6, 7 years, because of fear of being judged, on the part of either their

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

[20] *Id.*

[21] David J. Lick, Laura E. Durso & Kerri L. Johnson, *Minority Stress and Physical Health Among Sexual Minorities*, 8 PERS. ON PSYCHOL. SCI. 521 (2013), *available at* http://williamsinstitute.law.ucla.edu/research/health-and-hiv-aids/minority-stress-and-physical-health-among-sexual-minorities/.

[22] *Id.*

[23] *Id.*

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

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

immediate family or them [identifying as LGBTQ]".[26] It is therefore crucial that LGBTQ individuals who have found unbiased and affirming providers, be allowed to remain with them. If turned away by a health care provider, 17 percent of all LGBTQ people, and 31 percent of LGBTQ people living outside of a metropolitan area, reported that it would be "very difficult" or "not possible" to find the same quality of service at a different community health center or clinic.[27]

The proposed rule allowing providers to deny needed care would reverse recent gains in combatting discrimination and health care disparities for LGBT persons. Refusals also implicate standards of care that are vital to LGBTQ health. Medical professionals are expected to provide LGBTQ individuals with the same quality of care as they would anyone else. The American Medical Association recommends that providers use culturally appropriate language and have basic familiarity and competency with LGBTQ issues as they pertain to any health services provided.[28] The World Professional Association for Transgender Health guidelines provide that gender-affirming interventions, when sought by transgender individuals, are medically necessary and part of the standard of care.[29] The American College of Obstetricians and Gynecologists warns that failure to provide gender-affirming treatment can lead to serious health consequences for transgender individuals.[30] LGBTQ individuals already experience significant health disparities, and denying medically necessary care on the basis of sexual orientation or gender identity exacerbates these disparities.

In addition, LGBTQ individuals face disparities in medical conditions that may implicate the need for reproductive health services. For example, lesbian and bisexual women report heightened risk for and diagnosis of some cancers and higher rates of cardiovascular disease.[31] The LGBTQ community is significantly at risk for sexual violence.[32] Eighteen percent of lesbian, gay, bisexual students have reported being forced to have sex.[33] Transgender women, particularly women of color, face high rates of HIV.[34]

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[26] HUMAN RIGHTS WATCH, *supra* note 28.
[27] Mirza, *supra* note 34.
[28] *Community Standards of Practice for the Provision of Quality Health Care Services to Lesbian, Gay, Bisexual, and Transgender Clients*, GAY LESBIAN BISEXUAL & TRANSGENDER HEALTH ACCESS PROJECT, http://www.glbthealth.org/CommunityStandardsofPractice.htm (last visited Jan. 26, 2018, 12:59 PM); *Creating an LGBTQ-friendly Practice*, A.M.A., https://www.ama-assn.org/delivering-care/creating-lgbtq-friendly-practice#Meet a Standard of Practice (last visited Jan. 26, 2018, 12:56 PM).
[29] *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People*, WORLD PROF. ASS'N FOR TRANSGENDER HEALTH (2011), https://s3.amazonaws.com/amo_hub_content/Association140/files/Standards%20of%20Care%20V7%20-%202011%20WPATH%20(2)(1).pdf.
[30] *Committee Opinion 512: Health Care for Transgender Individuals*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (Dec. 2011), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-for-Transgender-Individuals.
[31] Kates, *supra* note 37, at 4.
[32] Forty-six percent of bisexual women have been raped and 47 percent of transgender people are sexually assaulted at some point in their lifetime. This rate is particularly higher for transgender people of color. Kates, *supra* note 37, at 8.; *2015 U.S. Transgender Survey*, *supra* note 35, at 5.
[33] *Health Risks Among Sexual Minority Youth*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/healthyyouth/disparities/smy.htm (last updated May 24, 2017).
[34] More than 1 in 4 transgender women are HIV positive. Kates, *supra* note 37, at 6.

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

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

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

The proposed rule threatens informed consent, a necessary principle of patient-centered decision-making. Informed consent relies on disclosure of medically accurate information by providers so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.[35] This right relies on two factors: access to relevant and medically-accurate information about treatment choices and alternatives, and provider guidance based on generally accepted standards of practice. Both factors make trust between patients and health care professionals a critical component of quality of care.

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

In recent decades, the U.S. medical community has primarily looked to informed consent as key to assuring patient autonomy in making decisions.[36] Informed consent is intended to help balance the unequal balance of power between health providers and patients and ensure patient-centered decision-making. Moreover, consent is not a yes or no question but rather is dependent upon the patient's understanding of the procedure that is to be conducted and the full range of treatment options for a patient's medical condition. Without informed consent, patients will be unable to make medical decisions that are grounded in agency, their beliefs and preferences, and that meet their personal needs. This is particularly problematic as many communities, including women of color and women living with disabilities, have disproportionately experienced abuse and trauma at the hands of providers and institutions.[37] In order to ensure that patient decisions are based on free will, informed

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

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

[37] Gutierrez, E. R. *Fertile Matters: The Politics of Mexican Origin Women's* Reproduction, 35-54 (2008) (discussing coercive sterilization of Mexican-origin women in Los Angeles); Jane Lawrence, *The Indian*

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consent must be upheld in the patient-provider relationship. The proposed rule threatens this principle and may very well force individuals into harmful medical circumstances.

According to the American Medical Association: "The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice."[38]The American Nursing Association similarly requires that patient autonomy and self-determination are core ethical tenets of nursing. "Patients have the moral and legal right to determine what will be done with their own persons; to be given accurate, complete and understandable information in a manner that facilitates an informed judgment; to be assisted with weighing the benefits, burdens and available options in their treatment."[39] Similarly, pharmacists are called to respect the autonomy and dignity of each patient.[40]

Various state and federal laws require that health care professionals inform and counsel patients on specific issues such as preventing the spread of HIV/AIDS, non-directional information on family planning and abortion options, and emergency contraception to prevent pregnancy from rape.[41] In *Brownfield v. Daniel Freeman Marina Hospital*, a California court addressed the importance of patients' access to information in regard to emergency contraception. The court found that:

> "The duty to disclose such information arises from the fact that an adult of sound mind has 'the right, in the exercise of control over [her] own body, to determine whether or not to submit to lawful medical treatment.' Meaningful exercise of this right is possible only to the extent that patients are provided with adequate information upon which to base an intelligent decision with regard to the option available."[42]

Health Service and the Sterilization of Native American Women, 24 AM. INDIAN Q. 400, 411-12 (2000) (referencing one 1974 study indicating that Indian Health Services would have coercively sterilized approximately 25,000 Native American Women by 1975); Alexandra Minna Stern, *Sterilized in the Name of Public Health*, 95 AM. J. PUB. H. 1128, 1134 (July 2005) (discussing African-American women forced to choose between sterilization and medical care or welfare benefits and Mexican women forcibly sterilized). *See also Buck v. Bell*, 274 U.S. 200, 207 (1927) (upholding state statute permitting compulsory sterilization of "feeble-minded" persons); Vanessa Volz, *A Matter of Choice: Women With Disabilities, Sterilization, and Reproductive Autonomy in the Twenty-First Century*, 27 WOMEN RTS. L. REP. 203 (2006) (discussing sterilization reform statutes that permit sterilization with judicial authorization).

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

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

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

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

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

In addition, the proposed rule does not provide any protections for health care professionals who want to provide, counsel, or refer for health care services that are implicated in this rule, for example, reproductive health or gender affirming care. Due to the rule's aggressive enforcement mechanisms and its vague and confusing language, providers may fear to give care or information. The inability of providers to give comprehensive, medically accurate information and options that will help patients make the best health decisions violates medical principles such as, beneficence, no maleficence, respect for autonomy, and justice. In particular, the principle of beneficence "requires that treatment and care do more good than harm; that the benefits outweigh the risks, and that the greater good for the patient is upheld."[43] In addition, the proposed rule undermines principles of quality care. Health care should be safe, effective, patient-centered, timely, efficient, and equitable.[44] Specifically, the provision of the care should not vary due to the personal characteristics of patients and should ensure that patient values guide all clinical decisions.[45] The expansion of religious refusals as envisioned in the proposed rule may compel providers to furnish care and information that harms the health, well-being, and goals of patients.

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

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

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

The opioid epidemic continues to claim too many lives. According to the Centers for Disease Control and Prevention (CDC), over 63,000 people in the U.S. died from drug overdose in 2016.[46] The latest

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

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

[45] *Id.*

[46] Holly Hedegaard M.D., et al. *Drug Overdose Deaths in the United States, 1999-2016*, NAT'L CTR. FOR HEALTH STATISTICS1-8 (2017).

numbers show a 2017 increase in emergency department overdose admissions of 30% across the country, and up to 70% in some areas of the Midwest.[47]

The clear, evidence-based treatment standard for opioid use disorder (OUD) is medication-assisted treatment (MAT).[48] Buprenorphine, methadone, and naltrexone are the three FDA-approved drugs for treating patients with opioid use disorder. MAT is so valuable to treatment of addiction that the World Health Organization considers buprenorphine and methadone "Essential Medications."[49] Buprenorphine and methadone are, in fact, opioids. However, while they operate on the same receptors in the brain as other opioids, they do not produce the euphoric effect of other opioids but simply keep the user from experiencing withdrawal symptoms. They also keep patients from seeking opioids on the black market, where risk of death from accidental overdose increases. Patients on MAT are less likely to engage in dangerous or risky behaviors because their physical cravings are met by the medication, increasing their safety and the safety of their communities.[50] Naloxone is another medication key to saving the lives of people experiencing an opioid overdose. This medication reverses the effects of an opioid and can completely stop an overdose in its tracks.[51] Information about and access to these medications are crucial factors in keeping patients suffering from SUD from losing their jobs, losing their families, and losing their lives.

However, stigma associated with drug use stands in the way of saving lives.[52] America's prevailing cultural consciousness, after decades of treating the disease of addiction as largely a criminal justice and not a public health issue, generally perceives drug use as a moral failing and drug users as less deserving of care. For example, a needle exchange program designed to protect injection drug users from contracting blood borne illnesses such as HIV, Hepatitis C, and bacterial endocarditis was shut down in October 2017 by the Lawrence County, Indiana County Commission due to their moral objection to drug use, despite overwhelming evidence that these programs are effective at reducing

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

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

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

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

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

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

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harm and do not increase drug use.[53] One commissioner even quoted the Bible as he voted to shut it down. Use of naloxone to reverse overdose has been decried as "enabling these people" to go on to overdose again.[54]

In this frame of mind, only total abstinence is seen as successful treatment for SUD, usually as a result of a 12-step or faith-based program. MAT is considered by many to be simply "substituting one drug for another drug."[55] This belief is so common that even the former Secretary of the Department is on the record as opposing MAT because he didn't believe it would "move the dial," since people on medication would be not "completely cured."[56] The scientific consensus is that SUD is a chronic disease, and yet many recoil from the idea of treating SUD with medication like any other illness such as diabetes or heart disease.[57] The White House's own opioid commission found that "negative attitudes regarding MAT appeared to be related to negative judgments about drug users in general and heroin users in particular."[58]

People with SUD already suffer due to stigma and have a difficult time finding appropriate care. For example, it can be difficult to find access to local methadone clinics in rural areas.[59] Other roadblocks, such as artificial caps on the number of patients to whom doctors can prescribe buprenorphine, further prevent people with SUD from receiving appropriate care.[60] Only one-third of treatment programs across the country provide MAT, even though treatment with MAT can cut overdose mortality rates in half and is considered the gold standard of care. [61] The current Secretary of the Department has noted that expanding access to MAT is necessary to save lives and that it will be

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

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

[55] Lopez, *supra* note 75.

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

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

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

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

[60] 42 C.F.R. §8.610.

[61] Matthais Pierce, et al., *Impact of Treatment for Opioid Dependence on Fatal Drug-Related Poisoning: A National Cohort Study in England*, 111:2 ADDICTION 298 (Nov. 2015); Luis Sordo, et al., Mortality Risk During and After Opioid Substitution Treatment: Systematic Review and Meta-Analysis of Cohort Studies, BMJ (2017), http://www.bmj.com/content/357/bmj.j1550.; Alex Azar, Secretary, U.S. Dep't of Health & Hum. Serv., Plenary Address to National Governors Association, (Feb. 24, 2018), https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/plenary-addres-to-national-governors-association.html.

"impossible" to quell the opioid epidemic without increasing the number of providers offering the evidence-based standard of care.[62] This rule, which allows misinformation and personal feelings to get in the way of science and lifesaving treatment, will not help achieve the goals of the administration; it will instead trigger countless numbers of deaths.

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

Medical practice guidelines and standards of care establish the boundaries of medical care that patients can expect to receive and that providers should be expected to deliver. The health services impacted by refusals are often related to reproductive and sexual health, which are implicated in a wide range of common health treatment and prevention strategies. Information, counseling, referral and provisions of contraceptive and abortion services are part of the standard of care for a range of common medical conditions including heart disease, diabetes, epilepsy, lupus, obesity, and cancer. Many of these conditions disproportionately affect women of color.[63] The expansion of these refusals as outlined in the proposed rule will put women, particularly women of color, who experience these medical conditions at greater risk for harm.

Moreover, a 2007 survey of physicians working at religiously-affiliated hospitals found that nearly one in five (19 percent) experienced a clinical conflict with the religiously-based policies of the hospital.[64] While some of these physicians might refer their patients to another provider who could provide the necessary care, one 2007 survey found that as many as one-third of patients (nearly 100 million people) may be receiving care from physicians who do not believe they have any obligations to refer their patients to other providers.[65]

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[62] Azar, *supra* note 84.

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

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

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

a. Sexually transmitted infections (STIs)

Religious refusals also impact access to sexual health care more broadly. Contraceptives and access to preventative treatment for sexually transmitted infections are a critical aspect of health care. The CDC estimates that 20 million new sexually transmitted infections occur each year. Chlamydia remains the most commonly reported infectious disease in the U.S., while HIV/AIDS remains the most life threatening. Women, especially young women, and Black women, are hit hardest by Chlamydia—with rates of Chlamydia 5.6 times higher for Black than for white Americans.[66] Consistent use of condoms results in an 80 percent reduction of HIV transmission, and the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the World Health Organization all recommend the condom use be promoted by providers.[67]

b. HIV Health

For HIV, in addition to consistent condom use, pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) are an important part of prevention for those at high risk for contracting HIV. The American College of Obstetricians and Gynecologists recommends that PrEP be considered for individuals at high risk of contracting HIV.[68] Under the proposed rule, an insurance company could refuse to cover PrEP or PEP because of a religious belief. Refusals to promote and facilitate condom use because of religious beliefs and refusals to prescribe PrEP or PEP because of a patient's perceived or actual sexual orientation, gender identity, or perceived or actual sexual behaviors is in violation of the standards of care and harms patients already at risk for experiencing health disparities. Both PrEP and PEP have been shown to be highly effective in preventing HIV infection. Denying access to this treatment would adversely impact vulnerable, highest risk populations including gay and bisexual men.

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

[66] *Sexually Transmitted Disease Surveillance 2016*, CTR. FOR DISEASE CONTROL & PREVENTION (Sept. 2017), https://www.cdc.gov/std/stats16/CDC_2016_STDS_Report-for508WebSep21_2017_1644.pdf.
[67] American Academy of Pediatrics Committee on Adolescence, *Condom Use by Adolescents*, 132 PEDIATRICS (Nov. 2013), http://pediatrics.aappublications.org/content/132/5/973; American Academy of Pediatrics, American College of Obstetricians and Gynecologists, March of Dimes Birth Defects Foundation. Guidelines for perinatal care. 6th ed. Elk Grove Village, IL; Washington, DC: American Academy of Pediatrics; American College of Obstetricians and Gynecologists; 2007; American College of Obstetricians and Gynecologists. Barrier methods of contraception. Brochure (available at http://www.acog.org/publications/patient_education/bp022.cfm). Washington, DC: American College of Obstetricians and Gynecologists; 2008 July; World Health Organization, UNAIDS, UNFPA, *Position statement on condoms and HIV prevention*, UNICEF (2009), https://www.unicef.org/aids/files/2009_position_paper_condoms_en.pdf.
[68] ACOG *Committee Opinion 595: Preexposure Prophylaxis for the Prevention of Human Immunodeficiency Virus*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (May 2014), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Preexposure-Prophylaxis-for-the-Prevention-of-Human-Immunodeficiency-Virus.

The regulations dangerously expand the application of the underlying statutes by offering an extremely broad definition who can refuse and what they can refuse to do. Under the proposed rule, any one engaged in the health care system could refuse services or care. The proposed rule defines workforce to include "volunteers, trainees or other members or agents of a covered entity, broadly defined when the conduct of the person is under the control of such entity."[69] Under this definition, could any member of the health care workforce refuse to serve a patient in any way – could a nurse assistant refuse to serve lunch to a transgender patient, could a billing specialist refuse to help a patient who had sought contraceptive counseling?

a. Discrimination

The failure to define the term "discrimination" will cause confusion for providers, and as employers, expose them to liability. Title VII already requires that employers accommodate employees' religious beliefs to the extent there is no undue hardship on the employer.[70] The regulations make no reference to Title VII or current EEOC guidance, which prohibits discrimination against an employee based on that employee's race, color, religion, sex, and national origin.[71] The proposed rule should be read to ensure that the long-standing balance set in Title VII between the right of individuals to enjoy reasonable accommodation of their religious beliefs and the right of employers to conduct their businesses without undue interference is to be maintained.

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

Finally, the proposed rule's lack of clarity regarding what constitutes discrimination, may undermine non-discrimination laws. Because of the potential harm to individuals if religious refusals were allowed, courts have long rejected arguments that religiously affiliated organizations can opt out of anti-discrimination requirements.[72] Instead, courts have held that the government has a compelling interest in ending discrimination and that anti-discrimination statutes are the least restrictive means of doing so. Indeed, the majority opinion in *Burwell v. Hobby Lobby Stores, Inc.* makes it clear that the decision should not be used as a "shield" to escape legal sanction for discrimination in hiring on the

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[69] 83 Fed. Reg. 3894.

[70] 42 U.S.C. § 2000e-2.; *Title VII of the Civil Rights Act of 1964*, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.

[71] *Id.*

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

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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."[73] The uncertainty regarding how the proposed rule will interact with non-discrimination laws is extremely concerning.

Conclusion

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

Thank you for your attention to our comments. If you have any questions, please reach out to the following:

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