Nos. 20-15398, 20-15399, 20-16045 and 20-35044

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CITY AND COUNTY OF SAN FRANCISCO, *Plaintiff-Appellee*,
v.
ALEX M. AZAR II, et al., *Defendants-Appellants*.

COUNTY OF SANTA CLARA, et al., *Plaintiffs-Appellees*,
v.
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., *Defendants-Appellants*.

STATE OF CALIFORNIA, *Plaintiff-Appellee*,
v.
ALEX M. AZAR, et al., *Defendants-Appellants.*

STATE OF WASHINGTON, *Plaintiff-Appellee*,
v.
ALEX M. AZAR II, et al., *Defendants-Appellants.*

On Appeal from the United States District Courts for the
Northern District of California and the Eastern District of Washington

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SUPPLEMENTAL EXCERPTS OF RECORD
VOLUME I OF X

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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STATE OF CALIFORNIA, BY AND THROUGH ATTORNEY GENERAL XAVIER BECERRA, Plaintiff, **v.** **ALEX M. AZAR, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DOES 1-100,** Defendants.	**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF** Administrative Procedure Act Case

INTRODUCTION

1. The State of California, by and through Attorney General Xavier Becerra, challenges the final rule titled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," RIN 0945-AA10, issued by the U.S. Department of Health and Human Services

(HHS) on May 2, 2019 (Rule), and published in the Federal Register on May 21, 2019.[1] 84 Fed. Reg. 23170 (May 21, 2019). The State seeks to have the Rule set aside because the Rule, in violation of the Administrative Procedure Act (APA), the Spending Clause, and the Establishment Clause of the United States Constitution, impedes access to basic healthcare, including reproductive and emergency care; threatens billions of dollars in federal funding for California's public healthcare and other federally funded programs; and encourages discrimination against vulnerable patients, including women; lesbian, gay, bisexual, transgender, and queer or questioning (LGBTQ) individuals; and other vulnerable populations.

2. The Rule creates a broad exemption that permits any individual, entity, or provider—from doctors to front office staff—to deny patients basic healthcare, including reproductive and emergency care, not just on the basis of federally protected conscience protections, but also on the basis of "ethical or other reasons." 84 Fed. Reg. at 23264. A provider can therefore deny service on the basis of a hunch or prejudice, without any supporting evidence, without notifying a supervisor of the denial of service, and without providing notice or alternative options and/or referrals to patients in need.[2] *Id.* (broadly defining "referral or referral for").

3. Allowing such denial of service would be contrary to federal and state laws enacted to ensure patient safety and nondiscriminatory access to care, and contrary to medical ethics. Further, the Rule will create rampant confusion about basic patient rights and federally entitled healthcare services, such as Medicaid and Medicare, while discouraging providers from offering safe, legal medical care to their patients.

4. In promulgating the Rule, Defendants failed to engage in reasoned decisionmaking, and there is no evidence that HHS considered the impact on patients. 84 Fed. Reg. at 23230-23239 (failing to quantify the impact of this Rule on patients). Moreover, the effects of the Rule would be widespread as it implicates "an action that has a specific, reasonable, and articulable connection to furthering a procedure or a part of a health service program or research activity

[1] Available at https://www.govinfo.gov/content/pkg/FR-2019-05-21/pdf/2019-09667.pdf.
[2] *See* American Medical Association, Policy E-1.1.1, "Patient-Physician Relationships," 1.1.2, "Prospective Patients," 1.1.3., "Patient Rights," 1.1.6, "Quality," and 1.1.7, "Physician Exercise of Conscience," available at https://www.ama-assn.org/system/files/2019-01/code-of-medical-ethics-chapter-1_0.pdf.

1 undertaken by or with another person or entity." 84 Fed. Reg. at 23263. The consequences of
2 this broad, vague Rule will disproportionately affect vulnerable populations, and will have a
3 chilling effect on those seeking to exercise their constitutionally protected healthcare rights.
4 5. The Rule is also unlawful because it threatens the termination of billions of dollars
5 (over half a trillion dollars) in federal funds to California for labor, education, health, and human
6 services programs unless the State surrenders to the Rule's unlawful, vague provisions. Its notice,
7 assurance and certification, recordkeeping, and reporting requirements needlessly impose
8 administrative burdens and onerous costs of implementation on the State. As such, the Rule is an
9 assault on California's sovereignty, which is directly targeted by the Rule, and poses a real risk to
10 the health and welfare of all Californians.
11 6. The State also seeks injunctive, declaratory, and other appropriate relief against HHS
12 to remedy HHS's violations of the Freedom of Information Act (FOIA), 5 U.S.C. § 552.
13 **JURISDICTION AND VENUE**
14 7. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (action arising under the
15 laws of the United States), 28 U.S.C. § 1346 (civil action against the United States founded upon
16 the Constitution, an Act of Congress, or an executive regulation), 28 U.S.C. § 1361 (action to
17 compel officer or agency to perform duty owed to Plaintiff), and 5 U.S.C. §§ 701-706
18 (Administrative Procedure Act). An actual controversy exists between the parties within the
19 meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and
20 other relief pursuant to 28 U.S.C. §§ 2201-2202 and 5 U.S.C. §§ 705-706.
21 8. Defendants' issuance of the Rule on May 21, 2019, constitutes a final agency action
22 and is therefore judicially reviewable within the meaning of the Administrative Procedure Act. 5
23 U.S.C. §§ 704, 706.
24 9. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e), because this is a
25 judicial district in which the State of California resides and this action seeks relief for the State
26 against federal agencies and officials acting in their official capacities.
27 / / /
28 / / /

1 **INTRADISTRICT ASSIGNMENT**

2 10. Pursuant to Civil Local Rules 3-2(c) and 3-5(b), there is no basis for assignment of
3 this action to any particular location or division of this Court.

4 **PARTIES**

5 11. Plaintiff, the State of California, by and through Attorney General Xavier Becerra,
6 brings this action. The Attorney General is the chief law officer of the State and has the authority
7 to file civil actions in order to protect public rights and interests. Cal. Const., art. V, § 13; Cal.
8 Bus. & Prof. Code § 321. This challenge is brought pursuant to the Attorney General's
9 independent constitutional, statutory, and common law authority to represent the public interest.

10 12. The State of California has an interest in ensuring that all healthcare is accessible to
11 all those within its borders. Regulating healthcare is within the police power of the States.
12 California is aggrieved by the actions of Defendants and has standing to bring this action because
13 of the injury to its state sovereignty caused by Defendants' issuance of the illegal Rule, and by
14 Defendants' threat to terminate billions of dollars in federal funding, including immediate and
15 irreparable injuries to its sovereign, quasi-sovereign, and proprietary interests. California is also
16 harmed by the Rule because it requires the State to establish a costly and onerous bureaucratic
17 structure to ensure that the Rule's expansive and unlawful provisions are complied with,
18 including compliance by any downstream sub-recipients. California will suffer concrete and
19 substantial harm because the Rule frustrates California's public health interests by, among other
20 things, curtailing access to contraceptive care, abortion, and other healthcare services. The Rule
21 will also burden the State with increased costs—for example, increased costs resulting from
22 unintended pregnancies and untreated medical conditions. The Rule's position on vaccinations
23 and its possible sanctioning of doctors opposed to efforts to ensure that all children and their
24 families follow the recommended childhood vaccination schedule could also adversely affect
25 California's public health efforts to control the spread of preventable diseases such as measles.
26 Additionally, the Rule will chill many Californians' (for example, transgender individuals' and
27 other LGBTQ community members') ability to access healthcare, further exacerbating long-term
28 health problems.

13. States have a sovereign interest in the power to create and enforce a legal code. Pursuant to that interest, California has an interest in challenging (1) HHS's assertions of authority to regulate matters within California's police power, and (2) HHS's interference with the enforcement of state law—particularly California's laws regulating behavior of and providing for the administration and regulation of state licensed professionals.

14. Defendant Alex M. Azar is Secretary of U.S. Department of Health and Human Services (HHS) and is sued in his official capacity. Secretary Azar has responsibility for implementing and fulfilling HHS's duties under the Constitution and other federal law, including the Patient Protection and Affordable Care Act (ACA) and the APA.

15. Defendant HHS is an agency of the United States government and bears responsibility, in whole or in part, for the acts complained of in this Complaint. The Office for Civil Rights (OCR) is an entity within HHS.

FACTUAL AND PROCEDURAL BACKGROUND

I. California Laws and Regulations

A. Laws Protecting Religious Freedoms

16. Ensuring access to healthcare is a key element in shaping overall health and well-being of California residents, and is therefore a critical component of the State's public health programs and laws. At the same time, and in enacting the California Religious Freedom Act in 2017,[3] California Government Code section 8310.3, the California Legislature found and declared that "California must uphold the protection of religious freedom enshrined in the United States Constitution for all of its people, and the state has a moral obligation to protect its citizens from religious persecution."

17. But the California Supreme Court has concluded that the right to freely exercise one's religious rights is not violated by laws ensuring full and equal access to healthcare. *N. Coast Women's Care Med. Group, Inc. v San Diego Cty. Superior Court*, 44 Cal.4th 1145 (2008);

[3] Generally, the California Religious Freedom Act prohibits California state and local governments from initiating, participating in, or assisting with any program to create a religious list, registry, or database, or using information about people's national origin or ethnicity to achieve the same basic purpose.

1 *Catholic Charities of Sacramento, Inc. v. Superior Court*, 32 Cal.4th 527 (2004). Toward this
2 end, California has struck a careful balance between the provision of healthcare and conscience
3 protections.

4 18. Under California law**,** a healthcare provider—defined as a person who is licensed,
5 certified, or otherwise authorized by state law to provide health care—may decline to comply with
6 an individual healthcare instruction or healthcare decision for reasons of conscience (but not on the
7 basis of discrimination). Cal. Prob. Code §§ 4621, 4734(a). Also, a healthcare institution—defined
8 as an institution, facility, or agency licensed, certified, or otherwise authorized by law to provide
9 healthcare—may decline to comply with an individual healthcare instruction if that is contrary to a
10 policy of the institution that is expressly based on reasons of conscience, if the policy was timely
11 communicated to the patient. Cal. Prob. Code §§ 4619, 4734(b). However, a healthcare provider
12 or institution that declines to comply with an individual healthcare instruction must (1) promptly so
13 inform the patient; (2) immediately make all reasonable efforts to assist in the transfer of the patient
14 to another provider or institution that is willing to comply with the instruction; and (3) provide
15 continuing care to the patent until the transfer is accomplished or until it appears that a transfer
16 cannot be accomplished. Cal. Prob. Code § 4736.

17 19. California laws also carefully balance protections for conscience protections and a
18 woman's right to reproductive health. For example, California law provides that no employer or
19 other person shall require a physician, a registered nurse, a licensed vocational nurse, or any other
20 person employed or with staff privileges at a hospital, facility, or clinic to directly participate in
21 the induction or performance of an abortion "if the employee or other person has filed a written
22 statement with the employer or the hospital, facility, or clinic indicating a moral, ethical, or
23 religious basis for refusal to participate." Cal. Health & Safety Code § 123420(a). No employee
24 or person shall be subject to any penalty or discipline for refusing to participate in the induction
25 or performance of an abortion. *Id.*

26 20. However, to balance the needs of the patient who may be in urgent need of care and
27 in recognition that emergency medical care is a vital public service, this provision does not apply
28 to "medical emergency situations and spontaneous abortions" (also known as miscarriages,

People v. Davis, 7 Cal. 4th 797, 840 n.14 (1994) (en banc)). Cal. Health & Safety Code § 123420(d); *see also* Cal. Health & Safety Code § 1317(a) & (e) (requiring that emergency services be provided to a patient for any condition in which the person is in danger of loss of life, or serious injury or illness, at any health facility that maintains and operates an emergency department; or if the facility does not maintain an emergency department, "its employees shall nevertheless exercise reasonable care to determine whether an emergency exists and shall direct the persons seeking emergency care to a nearby facility that can render the needed services, and shall assist the persons seeking emergency care in obtaining the services, including transportation services, in every way reasonable under the circumstances").

21. California law requires that a female survivor of sexual assault shall be provided with "the option of postcoital contraception by a physician or other health care provider" and that "[p]ostcoital contraception . . . be dispensed by a physician or other health care provider upon the request of the victim at no cost to the victim." Cal. Penal Code §§ 13823.11(e)(1), (e)(2), (g)(4)(A), (g)(4)(B). If a hospital is unable to comply, hospitals must adopt a protocol for the immediate referral of these individuals to a local hospital that complies with these requirements, and notify local law enforcement agencies, the district attorney, and local victim assistance agencies of the adoption of the referral protocol. Cal. Health & Safety Code § 1281.

22. Moreover, a California healthcare licentiate "shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient." Cal. Bus. & Prof. Code § 733(a); *see also Stormans, Inc. v. Wiesman*, 794 F.3d 1064, 1076-1088 (9th Cir. 2015) (rejecting First Amendment challenge to state regulation that requires pharmacists to timely dispense all prescription medications, even if the pharmacist has a religious objection), *cert. denied* 136 S.Ct. 2433 (2016). But a licentiate may decline to dispense a prescription drug or device on the basis of an ethical, moral, or religious objection, but only if the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation and establish protocols to address the licentiate's objection and also

ensure that the patient has timely access to the prescribed drug or device. Cal. Bus. & Prof. Code § 733(b)(3).

23. In keeping with the careful balance that California has struck, California laws protect employees from discrimination based on religious beliefs, unless accommodation of those beliefs would result in undue hardship to the employer.[4] FEHA (which applies to employers with five or more workers) requires that an employer reasonably accommodate an employee's bona fide religious beliefs, including moral and ethical beliefs about what is right and what is wrong. Cal. Gov't Code § 12926 (d) & (q); 29 C.F.R. § 1605.1, *Friedman v. So. Calif. Permanente Med. Group*, 102 Cal.App. 4th 39, 45 (2002). Depending on the circumstances, "reasonable" accommodation could include schedule changes, reassignment, and modification of work practices, among other options. 29 C.F.R. § 1605.2(d)(1); 2 C.C.R. § 11062(a). Undue hardship is defined as "an action requiring significant difficulty or expense" and the calculus requires that the employer consider a variety of factors, including the nature and cost of accommodation, the facility's financial resources, the number of employees, operational impacts, the type of operations, and the employer's overall financial resources and size. Cal. Gov't Code § 12926(u). However, a religious accommodation cannot cause the employer to violate other laws prohibiting discrimination or protecting civil rights, including, for example, California Civil Code § 51(b) (the Unruh Act) and California Government Code § 11135 (concerning discrimination by state agencies). Cal. Gov't Code § 12940(l)(3). Like Title VII, FEHA requires a dialogue, as needed, between the employer and the employee that permits the consideration of an accommodation's impact on a patient's right to care.

B. Laws Guaranteeing Access to Healthcare

24. Women have historically faced unfair and discriminatory insurance practices, such as being denied coverage for services that only women need—for example, maternity care. For this reason, California law requires that health care service and insurance plans provide coverage for

[4] In addition, for the purpose of Fair Employment and Housing Act or FEHA protections, "sex" includes, but is not limited to, "pregnancy or medical conditions related to pregnancy" and gender, which includes gender identity and gender expression ("gender-related appearance and behavior whether or not stereotypically associated with the person's assigned sex at birth."). Cal. Gov't Code § 12926(r).

maternity services. Cal. Health & Safety Code §§ 1345, 1367(i); Cal. Code Regs., tit. 28, § 1300.67; Cal. Ins. Code §§ 10123.865, 10123.866.

25. In 1972, California voters amended the state Constitution to include a right of privacy among the inalienable rights protected by article I, section 1. *Chico Feminist Women's Health Ctr. v. Butte Glen Med. Soc'y*, 557 F. Supp. 1190, 1201-1202 (E.D. Cal. 1983) (citing *White v. Davis*, 13 Cal. 3d 757 (1975)). Under article I, section 1, "all women in this state rich and poor alike possess a fundamental constitutional right to choose whether or not to bear a child." *Comm. to Defend Reprod. Rights v. Myers*, 29 Cal. 3d 252, 262 (1981). Under state law, private parties cannot interfere with the right to procreative choice under article I, section 1. *Chico*, 557 Supp. at 1202-03; *Hill v. Nat'l Collegiate Athletic Ass'n*, 7 Cal. 4th 1, 20 (1994). In addition, the right of procreative choice, guaranteed under article I, section 1, is protected from State interference. *Chico*, 557 F. Supp. at 1202; *Myers*, 29 Cal. 3d at 284. Therefore, California law requires coverage of all lawful abortions for enrollees and beneficiaries in both the Medi-Cal program and commercial health coverage.

26. Echoing these constitutional protections, the Reproductive Privacy Act of 2002 (RPA) declares as state public policy that "[e]very woman has the fundamental right to choose to bear a child or to choose and to obtain an abortion." Cal. Health & Safety Code § 123462(b). The RPA expressly provides that: "The state may not deny or interfere with a woman's right to choose or obtain an abortion . . . ." Cal. Health & Safety Code § 123466.

27. Contraceptives are among the most widely used medical services in the United States. They are much less costly than the medical consequences of pregnancy, including maternal deliveries, for patients, insurers, employers and states. The use of contraceptives has been shown to result in net savings to women and their employers.

28. Starting in 2012, the Women's Health Amendment to the ACA gave women across the country guaranteed access to preventive healthcare by requiring certain group health insurance plans to cover preventive care, including all Food and Drug Administration (FDA)-approved contraceptive methods and contraceptive counseling for women without cost-sharing

for beneficiaries. 42 U.S.C. § 300gg-13(a)(4).[5] In addition, the Women's Health Amendment requires coverage of other preventive care for women, including an annual well-woman preventive care visit, counseling and screening for HIV and domestic violence, and services for the early detection of reproductive cancers and sexually transmitted infections.

29. Under California law, it is unlawful for an insurance or health care service plan to refuse to enter into any contract, or to cancel or decline to renew or reinstate any contract, because of a person's race, color, national origin, ancestry, religion, sex, marital status, sexual orientation, or age. Cal. Health & Safety Code § 1365.5(a);[6] Cal. Ins. Code § 10140.2 (barring premium, price, or charge differentials due to insured's sex, including gender identity and expression); Cal. Penal Code § 422.56 ("gender" means sex and includes a person's gender identity and gender expression defined as a "person's gender-related appearance and behavior whether or not stereotypically associated with the person's assigned sex at birth"). It is also unlawful for an insurance or health care service plan to modify the terms of the contract or to impose any limitations, exceptions, exclusions, reductions, copayments, coinsurance, deductibles, reservations, or other modifications because of a person's race, color, national origin, ancestry, religion, sex, marital status, sexual orientation, or age. Cal. Health & Safety Code § 1365.5(b); Cal. Ins. Code § 10140.2.

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[5] On October 6, 2017, HHS issued two interim final rules purporting to implement the ACA's contraceptive coverage requirement. The regulations, which went into effect immediately, permit nearly any employer with any moral or religious objection to contraception to exempt themselves from the requirement. The rules thus transformed an important legal entitlement to no-cost contraceptive coverage into a conditional benefit subject to the employer's veto. The States of California, Delaware, Maryland, New York, and Virginia immediately sought and received an injunction. *California v. HHS*, 281 F. Supp. 3d 806 (N.D. Cal. 2017); *California v. Azar*, 911 F.3d 558 (9th Cir. 2018) (largely affirming district court); *see also Pennsylvania v. Trump*, 281 F. Supp. 3d 553 (E.D. Pa. 2017), appeal pending (3rd Cir.). Final rules issued on November 15, 2018, have now also been enjoined. *California v. HHS*, 351 F. Supp. 3d 1267 (N.D. Cal. 2019); *Pennsylvania v. Trump*, 351 F. Supp. 3d 791 (E.D. Pa. 2019).

[6] In enacting this provision as part of Assembly Bill 1586 (2005-2006), the California Legislature considered a 2002 report from the Transgender Law Center and the National Center for Lesbian Rights entitled "Trans Realities: A Legal Needs Assessment of San Francisco's Transgender Communities," in which nearly one in three respondents stated that they had experienced some form of healthcare-related gender identity discrimination, including routine denial of coverage by health insurers for transition-related procedures, and discriminatory or inappropriate behavior by healthcare providers and staff. *See* September 8, 2005 Assembly Floor Analysis available at http://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=200520060AB1586.

1 30. California, through its Department of Management Health Care (DMHC), also
2 regulates licensed health plans under the Knox-Keene Health Care Service Plan Act of 1975. Cal.
3 Health & Safety Code §§ 1340-1399.818. The Knox-Keene Act requires coverage of all FDA-
4 approved contraceptive drugs, devices, and other products for women, including all FDA-
5 approved contraceptive drugs, devices, and products available over the counter, as prescribed by
6 the insured's provider; patient education and counseling on contraception; and any follow-up care
7 for same, including, but not limited to, management of side effects, counseling for continued
8 adherence, and device insertion and removal. Cal. Health & Safety Code § 1367.25. However,
9 pursuant to Health and Safety Code section 1367.25(c), a religious employer may request a health
10 care service plan contract without coverage for FDA-approved contraceptive methods that are
11 contrary to the religious employer's religious tenets, and, if so requested, a health care service
12 plan contract shall be provided without coverage for contraceptive methods.

13 31. California further regulates insurers through its Department of Insurance. Insurance
14 Code section 10123.196(b)(1) requires coverage of all FDA-approved contraceptive drugs,
15 devices, and other products for women, including all FDA-approved contraceptive drugs, devices,
16 and products available over the counter, as prescribed by the insured's provider; patient education
17 and counseling on contraception; and any follow-up care for same, including, but not limited to,
18 management of side effects, counseling for continued adherence, and device insertion and
19 removal. However, pursuant to Insurance Code section 10123.196(e), a religious employer may
20 request an insurance policy without coverage for contraceptive methods that are contrary to the
21 religious employer's religious tenets, and, if so requested, an insurance policy shall be provided
22 without coverage for contraceptive methods.

23 32. To further access to family planning services, California offers such services to those
24 eligible for Medicaid (known as Medi-Cal), administered by the Office of Family Planning
25 (OFP). *See* Cal. Welf. & Inst. Code § 14501(a) (OFP is tasked with ensuring that citizens of
26 childbearing age have comprehensive medical knowledge, assistance, and services relating to the
27 planning of families). For those not eligible for Medicaid, OFP also administers the Family
28 Planning, Access, Care, and Treatment (Family PACT) program for persons with incomes at or

below 200% of the federal poverty guidelines and who have no other source of healthcare coverage for family planning services. And while access to contraceptive coverage has increased under the ACA, the Rule's likely reversal of this progress[7] will burden the State with increased costs of providing contraceptive care through programs like Family PACT and the increased costs resulting from unintended pregnancies.[8]

C. Regulation of Medical Professions

33. California regulates its medical professionals, including physicians, physician assistants, nurses, nurse practitioners, psychologists, midwives, and pharmacists, among others. Cal. Bus. & Prof. Code § 101 (composition of the Department of Consumer Affairs includes the Medical, Pharmacy, Nursing, Behavioral Sciences, and Psychology Boards, and the Physician Assistant Committee, among others); *see also* Cal. Bus. & Prof. Code § 101.6 (the purpose of the boards of the Department of Consumer Affairs is to ensure the public health, safety and welfare by establishing minimum qualifications and levels of competency, and to provide a means for redress of grievances by investigating allegations of unprofessional conduct, incompetence, fraudulent action, or unlawful activity and, as necessary, to institute disciplinary action against licensees).

34. California licensed doctors, as part of their continuing medical education, are required to meet cultural competency standards that include "understanding and applying cultural and ethnic data to the process of clinical care, including, as appropriate, information pertinent to the appropriate treatment of, and provision of care to, the lesbian, gay, bisexual, transgender, and intersex communities." Cal. Bus. & Prof. Code § 2190.1(c)(1)(D).

[7] The Rule's impact on California's family planning efforts only increases harms that will result from Defendants' recent Title X regulations, 84 Fed. Reg. 7714 (2019). *See California v. Azar*, No. 3:19-cv-01184-EMC, 2019 WL 1877392, *10-11 (N.D. Cal. Apr. 26, 2019).
[8] In 2010, for example, 64% of the 393,000 unintended pregnancies in California were paid for by Medicaid and other public insurance programs, costing the State approximately $689 million and the federal government approximately $1.06 billion. Kathryn Kost, Unintended Pregnancy Rates at the State Level: Estimates for 2010 and Trends Since 2002, Guttmacher Institute (2015), 8, https://www.guttmacher.org/report/unintended-pregnancy-rates-state-level-estimates-2010-and-trends-2002. Adam Sonfield and Kathryn Kost, Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010, Guttmacher Institute (2015), 13, https://www.guttmacher.org/report/public-costs-unintended-pregnancies-and-role-public-insurance-programs-paying-pregnancy.

35. A California licensed healthcare professional is subject to discipline "if, because of any characteristic listed or defined in subdivision (b) or (e) of Section 51 of the Civil Code [sex, race, color, religion, ancestry, national origin, disability, medical condition, genetic information, marital status, sexual orientation, citizenship, primary language, or immigration status], he or she refuses to perform the licensed activity or aids or incites the refusal to perform that licensed activity by another licensee, or if, because [of such characteristics], he or she makes any discrimination, or restriction in the performance of the licensed activity." Cal. Bus. & Prof. Code § 125.6.

36. By promulgating the Rule, HHS has infringed upon California's interest in the laws it has enacted to regulate matters concerning the health and safety of its residents and its medical professions, which are integral to ensuring Californians' access to healthcare.

37. "[T]he structure and limitations of federalism . . . allow the States great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) (internal quotation marks and citation omitted). But the Rule encourages California licensed physicians and other healthcare professionals to disregard their licensure requirements, and freely interfere with patients' access to healthcare while disregarding anti-discrimination protections, thereby threatening California's sovereign and quasi-sovereign interests in regulating healthcare and California licensed entities and professionals.

38. The Rule is a direct assault on California's sovereign and quasi-sovereign interests in regulating healthcare and California licensed entities and professionals because it broadly defines "discriminate or discrimination" to include the acts of making unavailable or denying any license, certification, accreditation, title, or other similar interest. 84 Fed. Reg. at 23263.

39. The Rule has likely already impacted the provision of healthcare by encouraging healthcare professionals to refuse to provide care. In fall 2018, a pharmacy refused a Michigan woman a prescription to treat her miscarriage.[9] In summer 2018, an Arizona transgender woman

[9] https://www.aclumich.org/en/press-releases/aclu-files-complaint-meijer-after-pharmacist-refused-fill-prescription-customer-who.

was refused a prescription for hormone therapy.[10] These incidents highlight discrimination that takes place even without this Rule, and that could be encouraged by the Rule's provisions.

40. California's Unruh Civil Rights Act, Civil Code sections 51 *et seq*., bars business establishments from discriminating in the delivery of services and goods, including discrimination based on sex, which includes gender identity and gender expression. Cal. Civ. Code § 51(b);[11] *N. Coast*, 44 Cal.4th at 1145, 1158 (the Unruh Act furthers California's compelling interest in ensuring full and equal access to medical treatment irrespective of sexual orientation).

II. HHS's Unlawful New Rule

A. Current Regulatory Scheme and Background

41. On December 19, 2008, Defendants issued a final rule to "provide for the enforcement of the Church Amendments…the Public Health Service Act [Coats-Snowe Amendment] and the Weldon Amendment." 73 Fed. Reg. 78072, 78074 & 78098. The regulation purported to authorize HHS to terminate and/or compel the return of all HHS funds from state and local governments that violate its prohibition against "discrimination on the basis that the health entity does not provide, pay for, provide coverage of, or refer for abortion. *Id*. at 78074 & 78098. The 2008 final rule went into effect on January 20, 2009 except that its certification requirement never took effect, as it was subject to information collection approval process under the Paperwork Reduction Act, which was never completed. 76 Fed. Reg. 9968, 9971 (Feb. 23, 2011).

42. On March 10, 2009, HHS proposed a rule to rescind the 2008 rule. 74 Fed. Reg. 10207 (Mar. 10, 2009). In it, HHS discussed that commenters of the previous rule "raised a number of questions that warrant[ed] further careful consideration." *Id*. In that proposed rule and

[10] https://www.aclu.org/blog/lgbt-ri ghts/transgender-rights/my-pharmacist-humiliated-me-when-he-refused-fill-my-hormone.
[11] "For purposes of this section . . .'Sex' includes, but is not limited to, pregnancy, childbirth, or medical conditions related to pregnancy or childbirth. 'Sex' also includes, but is not limited to, a person's gender. 'Gender' means sex, and includes a person's gender identity and gender expression. 'Gender expression' means a person's gender-related appearance and behavior whether or not stereotypically associated with the person's assigned sex at birth." Cal. Civ. Code § 51 (e)(5).

1 the resulting 2011 final (and current) rule, HHS also noted "[n]o statutory provision, however,
2 requires promulgation of a rule." *Id.*; 76 Fed. Reg. 9968, 9975 (Feb. 23, 2011) (the Church,
3 Weldon, and Coat-Snowe Amendments do not require "promulgation of regulations for their
4 interpretation.").

5 43. The 2011 rule changed the 2008 rule by indicating that its purpose was to provide for
6 the enforcement of Church, Weldon, and Coat-Snowe Amendments and by removing provisions
7 containing definitions of terms, requirements, prohibitions, and a certification requirement. *See*
8 73 Fed. Reg. 78072 and 76 Fed. Reg. 9968, generally. The 2011 rule also provided that the
9 Office for Civil Rights (OCR) of HHS is designated to "receive complaints based on the Federal
10 health care provider conscience protection statutes," and is further directed to "coordinate the
11 handling of complaints with [HHS] funding components from which the entity, to which a
12 complaint has been filed, receives funding." 76 Fed. Reg. at 9975, 9977. But the 2011 rule also
13 made clear that "[f]ederal provider conscience statutes…were never intended to allow providers
14 to refuse to provide medical care to an individual because the individual engaged in behavior the
15 health care provider found objectionable." *Id.* at 9973-74.

16 44. And since receiving the aforementioned designation on 2011, OCR had received a
17 total of 44 complaints by the time Defendants issued their Notice of Proposed Rulemaking
18 (NPRM) on January 26, 2018. 83 Fed. Reg. 3880, 3886 (Jan. 26, 2018).

19 **B. Proposed Rule and Public Comments**

20 45. In the January 26, 2018 NPRM, HHS proposed to revise the 2011 rule to ensure that
21 "persons or entities are not subjected to certain practices or policies that violate conscience,
22 coerce, or discriminate, in violation of such Federal laws." 83 Fed. Reg. at 3880. The NPRM
23 proposed a broad exemption to opt out of any healthcare service on the basis of "conscience,
24 religious beliefs, or moral convictions" to medical providers but also to anyone with an
25 "articulable connection" to the provision of that service, including helping to make a referral for
26 that service. Specific scenarios included in the NPRM included abortion, sterilization,
27 euthanasia, certain vaccinations if there is an "aborted fetal tissue" connection, contraception,
28

gender transition/gender dysphoria, tubal ligations, hysterectomies, assisted suicide, and referrals for advanced directives, and "other health services." 83 Fed. Reg. at 3903.

46. HHS also proposed to grant overall responsibility for ensuring that those who participate in HHS programs or activities comply with Federal conscience laws to its Office for Civil Rights by initiating compliance reviews, conducting investigations, supervising and coordinating compliance, and using enforcement tools otherwise available in civil rights law to address violations and resolve complaints, including:

> (i) Temporarily withholding cash payments, in whole or in part, pending correction of the deficiency;
>
> (ii) Denying use of Federal financial assistance or other Federal funds from the Department, including any applicable matching credit, in whole or in part;
>
> (iii) Wholly or partly suspending award activities;
>
> (iv) Terminating Federal financial assistance or other Federal funds from the Department, in whole or in part;
>
> (v) Withholding new Federal financial assistance or other Federal funds from the Department, in whole or in part, administered by or through the Secretary for which an application or approval is required, including renewal or continuation of existing programs or activities or authorization of new activities;
>
> (vi) Referring the matter to the Attorney General for proceedings to enforce any rights of the United States, or obligations of the recipient or subrecipient, created by Federal law; and
>
> (vii) Taking any other remedies that may be legally available.

84 Fed. Reg. at 23272.

47. In response to the NPRM, HHS received over 242,000 comments.[12] Comments opposed to the NPRM came from a broad array of individuals, medical associations, state and

[12]Comments are available at https://www.regulations.gov/docketBrowser?rpp=50&so=DESC&sb=postedDate&po=0&dct=PS&D=HHS-OCR-2018-0002. Although the website shows 72,417 comment submissions, some are batch comments comprising thousands of individual comments. The Rule provides a total of over 242,000 as of the date the Rule was published. 84 Fed. Reg. at 23180, n. 41.

local governments, reproductive rights organizations, children's rights organizations, disease advocates, and civil liberties organizations.

48. The nation's trusted major medical organizations raised grave concerns about the legality and reasonableness of the proposed regulation. For example, the American Medical Association (AMA) commented that the proposed rule "would undermine patients' access to medical care and information, impose barriers to physicians' and health care institutions' ability to provide treatment, impede advances in biomedical research, and create confusion and uncertainty among physicians, other health care professionals, and health care institutions about their legal and ethical obligations to treat patients." The Association stated that the proposed rule "would legitimize discrimination against vulnerable patients and in fact create a right to refuse to provide certain treatments or services."[13]

49. The American Academy of Family Physicians (AAFP), which represents 129,000 physicians and medical students across the country, noted it was "concerned that the [proposed rule] could restrict access to care for vulnerable patients seeking the aid of their family physician or other health care professionals."[14]

50. The American Nurses Association (ANA) and the American Academy of Nursing (AAN) stated that while they "strongly support the right and prerogative of nurses—and all healthcare workers—to heed their moral and ethical values," they had concerns that the proposed rule would "lead to inordinate discrimination against certain patient populations—namely individuals seeking reproductive health care services and lesbian, gay, bisexual, transgender, and queer or questioning (LGBTQ) individuals." This proliferation of discrimination could "result in reduced access to crucial and medically necessary health care services and the further exacerbation of health disparities between these groups and the overall population."[15]

[13] AMA comment at 1, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70564.
[14] AAFP comment at 1, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-34646.
[15] ANA-AAN comment at 1-2, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-55870.

51. The American Congress of Obstetricians and Gynecologists (ACOG) noted that under the American Medical Association's Code of Medical Ethics, responsibility to the patient is paramount for all physicians, and that providers with moral or religious objections should ensure that processes are in place to protect access to and maintain a continuity of care for all patients; but in an emergency in which referral is not possible or might negatively impact the patient's physical or mental health, providers have an obligation to provide medically indicated and requested care.[16]

52. The American College of Emergency Physicians (ACEP), on behalf of its 37,000 members, expressed concerns that the proposed rule failed to reflect the moral and legal duty of emergency physicians to treat everyone "who comes through our doors," stating that [b]oth by law and by oath, emergency physicians care for all patients seeking emergency medical treatment," and concluding that "[d]enial of emergency care or delay in providing emergency services on the basis of race, religion, sexual orientation, gender identity, ethnic background, social status, type of illness, or ability to pay, is unethical."[17]

53. The American Academy of Pediatrics (AAP), which represents 66,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists, urged HHS to ensure that children have appropriate access to needed healthcare in the areas of vaccines, mental health services, newborn hearing screening, reproductive health, medical neglect, treatment for sexual assault, including screening for sexually transmitted diseases and pregnancy prevention, and supportive care for LGBTQ youth.[18]

54. On behalf of more than 123,000 physician assistants, the American Academy of PAs (AAPA) expressed concerns that the proposed rule could have a negative impact on access to healthcare for patients, especially those who are most vulnerable and those who may live in rural

[16] ACOG comment at 1-2, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70647.
[17] ACEP comment at 1, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71219.
[18] AAP comment at 4-14, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71022.

or underserved areas, and that the new paperwork requirements related to the assurance and certification provisions could be excessively burdensome to healthcare providers.[19]

55. The American Health Care Association (AHCA) and National Center for Assisted Living (NCAL) expressed concerns that the increased regulatory burden of the proposed rule for long term and post-acute care providers could reduce time for providing high quality patient-centered care.[20]

56. The American Physical Therapy Association (APTA) urged that the proposed rule not be finalized because discrimination under the guise of religion or morality runs counter to their Code of Ethics and the principle of patient-centered care, both of which are foundational to the physical therapy profession. In their view, the proposed rule also would severely compromise patient access to medically necessary healthcare services.[21]

57. Physicians for Reproductive Health (PRH) warned that the proposed rule unlawfully exceeds HHS's authority by impermissibly expanding federal conscience laws, creates barriers to healthcare and exacerbates already existing inequities, and will cause severe consequences for providers while undermining the provider-patient relationship.[22]

58. The American Hospital Association (AHA)[23] and hospital associations from around the country, including the Wisconsin Hospital Association, Inc. (WHA),[24] the Greater New York Hospital Association (GNYHA),[25] the Texas Hospital Association (THA),[26] the Ohio Hospital

[19] AAPA comment at 1, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-65085.
[20] AHCA-NCAL comment at 1, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-29924.
[21] APTA comment at 2-3, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-28624.
[22] PRH comment at 2-7; 9-11, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71284.
[23] AHA comment at 4, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-65761.
[24] WHA comment at 3-4, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-66144.
[25] GNYHA comment at 2; 4-5, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71154.
[26] THA comment at 1-2, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-67485.

Association (OHA),[27] and the Massachusetts Health and Hospital Association (MHA)[28] objected to the proposed rule imposing regulatory burdens on hospitals that should instead be focused on providing patient care; also the overbroad and expanded definitions further run the risk of creating unintended consequences for patient care and run counter to hospital policies not to discriminate in the delivery of emergency, urgent, and necessary care on the basis of a patient's race, color, national origin, citizenship, alienage, religion, creed, sex, sexual orientation, gender identity, age, or disability.

59. The Association of American Medical Colleges (AAMC) asked that the proposed rule be withdrawn because there is no demonstrable need for the proposed rule due to existing laws and protections. AAMC asserted that the paucity of complaints does not justify an expansion of enforcement authority, that the proposed rule is overly expansive in its reach and incongruous with medical professionalism, and that it will do harm to lower-income Americans, racial and ethnic minorities, the LGBTQ community, and patients in rural areas.[29]

60. The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) opposed the proposed rule as unnecessary to protect the rights of providers, and noted that the existing rule issued in 2011 adequately protects the conscience of providers while also protecting patients; the proposed rule also undermines the Title X program.[30]

61. Other major medical organizations also submitted comments, including the National Association of Councils on Developmental Disabilities,[31] the National Association of Pediatric Nurse Practitioners,[32] the National Community Pharmacists Association,[33] and the National Family Planning & Reproductive Health Association.[34]

[27] OHA comment at 1, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70015.
[28] MHA comment at 1-3, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71172.
[29] AAMC comment at 1-2; 4-5, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-67592.
[30] AWHONN comment at 1-2, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71214.
[31] Available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-66494.
[32] Available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71063.
[33] Available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71176.
[34] Available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70260.

1 62. Numerous comments raised concerns regarding the proposed rule's impact on
2 healthcare access, noting that refusal of care would be especially dangerous for those already
3 facing barriers in healthcare, including patients in rural communities where there may be no other
4 sources of health and life preserving medical care.[35] Others expressed similar concerns:

5 - "As a transgender individual, I have been refused important treatment at local
6 doctors. I have to drive for 2 hours in order to receive basic medical care, because I
7 cannot find a doctor who will help me in my town. Someday this very well might
8 kill me if I need immediate, life-saving care."[36]
9 - "Because I am gay and live in a rural area, my son (who is not gay) and I have been
10 refused healthcare by our local clinic. As a result, we have been forced to seek a
11 physician in another town rather than receive treatment from our local provider."[37]
12 - "If a doctor can refuse to treat me, then I know I will be at my most vulnerable in
13 emergency medicine situations….If this is passed, I will no longer feel safe
14 traveling the 1700 miles between my home and where my family lives. My family
15 is poor and can't afford to come see me. Effectively, I will be cut off from my
16 loved ones for fear of what might happen to me in transit."[38]
17 - "My wife was born intersexed. She is considered transgender and we rely on trans
18 healthcare for her daily medications. We already drive 2 hours from Colorado
19 Springs to Denver for qualified doctors that take our insurance. She needs this care
20 to be able to function without pain at work. Reducing the number of doctors and
21 prescriptions available will only make it harder for us to continue working and will
22 further drain our time and money."[39]
23 - "I live in an area where I have few health insurance options (currently two). If
24 healthcare providers are allowed to opt out of providing care to me because I am a

25 [35] National Council of Jewish Women New York comment at 4-5, available at
26 https://www.regulations.gov/document?D=HHS-OCR-2018-0002-56027.
[36] Available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-34687.
27 [37] Available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-54505.
[38] Available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-56725.
[39] Available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71419.
28

gay American, My chronic disease could become a much more expensive life threatening disease that would ultimately cost me, other tax payers and/or the government more money for treatment."[40]

- "When I was coming out as transgender, I had a difficult time finding a doctor who was willing to treat me, and I live in the San Francisco Bay Area. I cannot imagine how difficult it is for transgender people in more conservative areas of the country to find healthcare providers who are willing to treat them."[41]

63. Several comments highlighted the negative impacts the proposed rule would have on the interests of Californians:

- The California Attorney General commented that the proposed rule violated the APA because it construed numerous terms, including "assist in the performance," "health care entity," and "referral or refer for," so broadly as to materially alter well-established statutory language in the Church Amendments, the Coats-Snowe Amendment, and the Weldon Amendment. Further, California explained that the proposed rule violated several constitutional provisions, including the Spending Clause, and the Establishment Clause, and would result in significant negative impacts on California, its residents, and California state entities that receive federal funding.[42]
- The California Insurance Commissioner's comment letter emphasized that existing state and federal law provide healthcare provider conscience protections; however, these laws rightly do not allow objectors to interfere with patient access to care or civil rights protections that prohibit discrimination. In contrast, the proposed rule would harm patients and encourage discrimination against people on the basis of

[40] Available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71960.
[41] Available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-72133.
[42] California Attorney General comment at 2-6, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70182.

race, sex, sexual orientation, gender, gender identity, and almost any other kind of bias due to its overbroad scope.[43]

- The California Medical Association, on behalf of its 43,000 physician members and medical students, cautioned that the proposed rule could lead to discrimination prohibited under federal and state law, insert politics into the patient-physician relationship, increase administrative burdens on doctors, and, due to its broad application, allow any entity or individual to use their personal beliefs to dictate patient care.[44]
- The California Primary Care Association, which represents over 1,300 not-for-profit community clinics and health centers in California, expressed concern about the proposed rule's potential disparate impact on vulnerable groups such as those seeking end-of-life care, persons affected by HIV/AIDS, women, persons of color, and the LGBTQ community. The Association cautioned that the proposed rule is so broad and ambiguous that medical staff may interpret it to allow them to decline to tell a patient where s/he would be able to obtain lifesaving services, putting them and others at risk, and further, threatening patient informed consent.[45]
- California county public safety-net healthcare providers, including the Santa Clara Valley Medical Center[46] and the San Francisco Department of Public Health,[47] also opposed the proposed rule due to its impermissible expansion of federal laws that could sanction discrimination against vulnerable communities, including the

[43] California Insurance Commissioner comment at 1-2; 5-6, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70956.
[44] CMA comment at 1-5, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71550.
[45] CPCA comment at 1-2, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70654.
[46] County of Santa Clara comment at 2-8, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-54930.
[47] SFDPH comment at 2-3, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-69109.

1 LGBTQ community, and the proposed rule's unnecessary new burdens on public
2 healthcare providers.[48]

3 - The California LGBT Health & Human Services Network, a coalition of 60 non-
4 profit providers, community centers, and researchers, expressed that the proposed
5 rule "tramples on California's efforts to protect patients' health and safety, including
6 through the California Insurance Gender Nondiscrimination Act" and other rules
7 that make clear that all people have the right to access coverage for necessary
8 healthcare regardless of their gender identity or gender expression.[49]

9 - The Latino Coalition for a Healthy California objected to the proposed rule's broad
10 and poorly defined language in comparison to existing law that already provides
11 ample protections to healthcare workers that refuse to participate in a healthcare
12 service to which they have a moral objection, and warned that the proposed rule
13 could result in medical, behavioral and oral health care that fails to comply with
14 established medical practice guidelines; also the proposed rule fails to account for
15 the significant burden that will be imposed on patients, a burden that will fall
16 disproportionately on women, people of color, persons with disabilities, and
17 LGBTQ individuals, communities that already experience severe health disparities
18 and discrimination.[50]

19 - The American Civil Liberties Union Foundation of California cautioned that the
20 proposed rule's expansion of definitions, covered entities, and enforcement
21 mechanisms invite violation of California laws that safeguard patients from
22 substandard healthcare and ensure patients' health, access, and choice. These
23 include state laws that mandate minimum educational requirements for licensed
24 medical professionals, medically necessary services in emergency situations,

25 [48] See also comments submitted by the National Association of County and City Health Officials; available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70228.
26 [49] California LGBT Health and Human Services Network comment at 2-3, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-56435.
27 [50] LCHC comment at 1-2, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-67994.
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managed care health plans' coverage of abortion as basic healthcare under the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene Act), and informing patients when they are not offered all medical options.[51]

64. On February 15, 2019, California representatives met with HHS's Office of Budget Management to discuss California's concerns regarding the proposed rule, including concerns that the proposed rule unfairly targets California and interferes with the State's policy making, encourages discrimination, impedes access to healthcare and information, violates various federal laws, and imposes administrative burdens and costs on states and other entities. The California representatives also raised California's outstanding FOIA request to HHS (discussed further below) and provided a copy of the FOIA request with the State's numerous follow-up communications.

C. HHS Issues a Largely Unchanged and Arbitrary and Capricious Rule

65. On May 21, 2019, HHS issued its final rule. Like the proposed rule, the final rule conflicts with existing law and impedes the provision of and access to medical information and healthcare by attempting to create limitless categories under which medical information and care can be refused. The final Rule (which did little to address the proposed rule's errors in this respect, notwithstanding the large volume of intervening comments) so conflicts by misconstruing and exceeding the bounds of federal statutes, including well-established statutory language and definitions.

66. Although the Rule states that it seeks to only clarify federal conscience protection laws—particularly the Church Amendments, 42 U.S.C. 300a–7; the Coats-Snowe Amendment, 42 U.S.C. 238n; and the Weldon Amendment in HHS's yearly appropriations acts, *e.g.,* the Consolidated Appropriations Act, 2018, Pub. L. 115–141 (H.R. 1625)—the Rule greatly expands the breadth of these laws, which (at most) address only exemptions to abortion and sterilization procedures. *See Chrisman v. Sisters of St. Joseph of Peace*, 506 F.2d 308, 312 (1974).[52]

[51] ACLU of California comment at 3-5; 10-11, available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71871.

[52] Indeed, the case studies referenced in the Rule indicate that it is intended to include refusals for gender transition-related services (reference to *Minton v. Dignity Health,* San Francisco Superior

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67. The Rule defines "assist in the performance" of an activity to encompass an action that has a "specific, reasonable, and articulable connection" to furthering a procedure, health service program, or research activity, including "counseling, referral, training, or otherwise making arrangements" for the procedure, health program, or research activity. 84 Fed. Reg. at 23263. Only the Church Amendments refer to "assist in the performance" of an activity, and nothing in that statutory scheme envisions the broad definition in the Rule. 42 U.S.C. § 300a-7. Congress's specific references to "counsel[ing]" in a separate Church Amendment provision, "training" in the Coats-Snowe Amendment, and "refer for" in the Weldon Amendment evidence Congress's intent to keep these actions separate in meaning from the performance of a procedure and confirm that the Rule's expansive definition of "assist in the performance" should not include a panoply of additional activities.

68. Similarly, "health care entity" is defined in the Coats-Snowe Amendment and the Weldon Amendment, yet the Rule expands these definitions to include "health care personnel," as distinct from a "health care professional," such as a doctor, nurse or other licensed medical provider.[53] Thus, the Rule suggests significantly broader categories of personnel could refuse to

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Court Case No. CGC 17-558259, 2017 WL 7733922 at 84 Fed. Reg. at 23176, n. 27) and circumstances that may involve California's End of Life Option Act, California Health and Safety Code sections 443, *et seq*. (84 Fed. Reg. at 23177). But as discussed in section I, the Rule is unnecessary because the End of Life Option Act, like other California provisions, contains a conscience exemption: "Participation in activities authorized pursuant to this part shall be voluntary. Notwithstanding Sections 442 to 442.7, inclusive, a person or entity that elects, for reasons of conscience, morality, or ethics, not to engage in activities authorized pursuant to this part is not required to take any action in support of an individual's decision under this part." Cal. Health & Safety Code § 443.14 (e)(1). Moreover, the Act specifically provides that that a conscientious objector cannot be sanctioned, disciplined, or penalized "for refusing to inform a patient regarding his or her rights under this part, and not referring an individual to a physician who participates in activities authorized under this part." Cal. Health & Safety Code § 443.14(e)(2).

[53] *Compare* 42 U.S.C. § 238n(c)(2) (defining "health care entity" to include "an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions") *and* P.L. 115-141, the Consolidated Appropriations Act of 2018 (H.R. 1625), Div. H, sec. 507(d)(2) (defining "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") *with* 84 Fed. Reg. at 23264 (defining "health care entity" to include "health care personnel" and describing listed entities included in the definition as "illustrative, not exhaustive").

provide services—potentially including even a receptionist at a doctor's office making an appointment for a patient, for example—based on his or her moral objections.

69. The Rule's definition of "health care entity" is also overbroad, given that it includes "a plan sponsor, issuer, or third-party administrator, or any other kind of health care organization, facility, or plan." 84 Fed. Reg. at 23264. Such a broad definition, well beyond the definition in the statutory text, could result in limitless categories of individuals and entities with absolutely no ethical obligation to the patient or involvement in direct patient care to sabotage and delay the provision of healthcare to patients.

70. The Rule's definition of "referral or refer for" is particularly broad, including "the provision of information in oral, written, or electronic form (including names, addresses, phone numbers, email or web addresses, directions, instructions, descriptions, or other information resources), where the purpose or reasonably foreseeable outcome of provision of the information is to assist a person in receiving funding or financing for, training in, obtaining, or performing a particular health care service, program, activity, or procedure." Thus, under the Rule, even the posting of notices, would be considered a "referral." 84 Fed. Reg. at 23264.

71. Reading and interpreting these statutes in such an overly broad manner will permit unlawful refusals of any healthcare service by almost any individual, even those not at all involved in the provision of healthcare; whereas the Weldon, Church, and Coats-Snowe Amendments refer to only specific circumstances in which healthcare providers or certain enumerated healthcare entities may not be required to participate in abortions, sterilizations, or certain health service programs and research activities.

72. In addition, the Rule's implementation of specific penalties for noncompliance is unmoored from any statutory text. Although the Weldon Amendment purports to strip noncompliant states of broad categories of federal funding (which raises its own legal problems), nothing in the Weldon Amendment, or elsewhere in federal law, supports the separate, discretionary enforcement mechanisms asserted in the Rule. P.L. 115-141, the Consolidated Appropriations Act of 2018 (H.R. 1625), Div. H, sec. 507(d)(1).

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1 73. Defendants justify the Rule in part on "presidential priority of protecting conscience
2 and religious freedom." 84 Fed. Reg. at 23227, *citing* Executive Order 13798, 82 FR 21675 (May
3 4, 2017). But the validity of the Rule depends on its relationship to legislative, not executive,
4 action: if the underlying federal statutes do not support the Rule, additional executive action
5 cannot change this basic fact.

6 74. The Rule also conflicts with several other federal statutes, and is written so broadly it
7 implicates several others. For starters, the Rule clashes with the following provisions of the
8 ACA:

9 • Section 1554, which prohibits the Secretary of HHS from promulgating any
10 regulation that (1) creates unreasonable barriers to the ability of individuals to
11 obtain appropriate medical care; (2) impedes timely access to healthcare; (3)
12 interferes with communications regarding a full range of treatment options; (4)
13 restricts the ability of providers to provide full disclosure of all relevant information
14 to patients making healthcare decisions; (5) violates the principles of informed
15 consent and the ethical standards of medical professionals; or (6) limits the
16 availability of treatment for the full duration of a patient's medical needs (42 U.S.C.
17 § 18116); and

18 • Section 1557, which prohibits discrimination in health programs or activities,
19 including gender discrimination (42 U.S.C. § 18116).

20 75. The Rule further fails to address and acknowledge the employers' legal obligations
21 under Title VII of the Civil Rights Act of 1964. Title VII (which applies to employers with 15 or
22 more employees) prohibits an employer from discriminating on the basis of religion, and absent
23 undue hardship (*e.g.*, "more than a de minimis cost"), imposes a duty that an employer reasonably
24 accommodate an employee's religion, including all aspects of religious belief, observance and
25 practices. 42 U.S.C. § 2000e (a); *Opuku-Boateng v. State of California*, 95 F.3d 1461, 1467-1468
26 (9th Cir. 1996). An undue hardship may also exist if accommodating the employee would result
27 in the employer violating state or federal law or if it would have a discriminatory impact on the
28 rights of other employees. *Sutton v. Providence St. Joseph Med. Ctr.*, 192 F.3d 826, 830 (9th Cir.

1999); *Peterson v. Hewlett Packard Co.,* 358 F.3d 599, 606-607 (9th Cir. 2004). Yet under the Rule, there is no workable requirement that there be dialogue between the employer and employee. The Rule's requirement that an employer "may," no more than once a year, require an employee to "inform it of objections to performing, referring for, participating in, or assisting in the performance of specific procedures, programs, research, counseling, or treatments, but only to the extent that there is a reasonable likelihood that the protected entity may be asked in good faith to perform, refer for, participate in, or assist in the performance of, any act or conduct just described," 84 Fed. Reg. at 23263, fails to comport with the accommodation process under Title VII. The Rule thus suggests that an employee can simply opt out of providing comprehensive healthcare to a patient, depriving the patient of emergency medical care or of state- and federally entitled healthcare rights, without consequence and without considering alternatives that would accommodate both the employee's religion and the patient's needs. Such a deprivation creates unnecessary tension with state and federal laws barring discrimination of the basis of other protected categories, including sex and gender.[54]

76. The Rule also contravenes Title X of the Public Health Service Act, 42 U.S.C. §§ 300-300a-6, which provides federal funding for family-planning services. Congress required Title X grantees to operate "voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services." 42 U.S.C. § 300(a). Title X appropriations bills, e.g., 2019 Continuing Appropriations Act, Pub. L. No. 115-245, Div. B., Tit. II, 132 Stat. 2981, 3070-71 (2018), require that "all pregnancy counseling shall be nondirective"; in other words, funded projects are to offer pregnant women neutral, non-judgmental information and counseling regarding their options, including prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination.

77. In the preamble to the Rule, Defendants justify their action in part by explaining that they have "amended the Title X regulations to remove the requirements for abortion counseling, information, and referrals." 84 Fed. Reg. at 23200. But Defendants' attempted amendment to

[54] Title VII prohibits both discrimination on the basis of sex and gender. *Schwenk v. Hartford*, 204 F.3d 1187, 1202 (9th Cir. 2000) (Title VII extends protections to transgender individuals).

1 Title X regulations has, as of the date of this complaint, been rejected by three separate district
2 courts on the grounds that it likely violates federal law and is an arbitrary and capricious exercise
3 of agency authority. *See, e.g.*, *California v. Azar*, No. 3:19-cv-01184-EMC, 2019 WL 1877392
4 (N.D. Cal. Apr. 26, 2019), appeal docketed, No. 19-15974 (9th Cir. May 6, 2019); *Oregon v.*
5 *Azar*, 6:19-cv-00317-MC, 2019 WL 1897475 (D. Or. Apr. 29, 2019), appeal docketed, No. 19-
6 35386 (9th Cir. May 6, 2019); *Washington v. Azar*, No. 1:19-cv-03040-SAB, 2019 WL 1868362
7 (E.D. Wash. Apr. 25, 2019), appeal docketed, No. 19-35394 (9th Cir. May 6, 2019) (all granting
8 preliminary injunction of new rule regarding Title X).
9 78. Additionally, the Rule disregards the Emergency Medical Treatment & Labor Act
10 (EMTALA) enacted by Congress in response to growing concern about the provision of adequate
11 medical services to individuals, particularly the indigent and the uninsured, who seek care from
12 hospital emergency rooms. 42 U.S.C. § 1395dd(a); *Jackson v. East Bay Hosp*., 246 F.3d 1248,
13 1254 (9th Cir. 2001). In this case, the Rule places conscience protection over patient care without
14 exception, even for emergencies. Defendants summarily dismissed these concerns, merely stating
15 that "[w]ith respect to EMTALA, the Department generally agrees with its explanation in the
16 preamble to the 2008 Rule that the requirement under EMTALA that certain hospitals treat and
17 stabilize patients who present in an emergency does not conflict with Federal conscience and anti-
18 discrimination laws." 84 Fed. Reg. at 23183. By disregarding these concerns, Defendants failed
19 to meaningfully respond to comments and "failed to consider an important aspect of the
20 problem[.]" *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S.
21 29, 43 (1983).
22 79. Defendants also minimize concerns regarding the Rule's impact on patients in rural
23 communities. While conceding that "patients in rural area are more likely than patients in urban
24 areas to suffer adverse health outcomes as a result of being denied care, 84 Fed. Reg. at 23253,
25 Defendants, without any actual evidence, conclude that rural residents would be better off
26 because providers will enter and stay in the field due to the Rule's protections; and in any event,
27 rural resident are less likely to request potentially objectionable care and/or may share the same
28 values with objecting providers. But this Court recently concluded that Defendants' failure to

adequately consider the patient harms renders a rule arbitrary and capricious. *See California v. Azar*, 2019 WL 1877392, at *29-32 (N.D. Cal. Apr. 26, 2019) (also rejecting unsubstantiated assertions of providers waiting in the wings to enter the field as a result of Defendants' regulations).

80. Nor do the estimated costs of the Rule justify its benefits, revealing it to be greatly wasteful of public funds. Defendants admit in their NPRM that OCR received only 44 complaints over the last 10 years of alleged instances of violations of conscience rights. 83 Fed. Reg. at 3886.[55] Yet, as HHS further admits, it will cost nearly $1.06 billion over the first years to implement the Rule, and for the affected entities to comply with the new assurance and certification requirements.[56] 84 Fed. Reg. at 23240. And these costs fail to account for cost to patients that will result from refusals of care. Meanwhile, HHS disclaims any ability to specifically quantify the benefits. *Id.* at 23227, 23246-23254.

III. CALIFORNIA'S SOVEREIGNTY AND FEDERAL FUNDING TARGETED BY RULE

81. California and its laws balancing conscience protections and patient rights are expressly targeted by the Rule. The Rule's suggestion that California laws "discriminate" is based on a faulty and biased read of these laws, meant to justify an unlawful expansion of federal laws. The threat to revoke California's federal health, education and labor federal funds is a direct assault on state sovereignty and puts the state in an illusory choice—comply with the Rule that conflicts with California's laws and policies or risk losing half a trillion dollars in funds for critical programs that help residents—it is not a choice at all.

82. The Rule states that the Rule resolves confusion caused by OCR's "sub-regulatory guidance" issued through OCR's "high-profile" closing of three Weldon Amendment complaints

[55] Although Defendants report receiving 343 complaints in fiscal year 2018, 84 Fed. Reg. at 23229, they have refused to comply with FOIA requests for records of complaints to OCR (as discussed further below).

[56] And as the California Medical Association correctly notes, the Departments' estimated costs of implementation fail to consider the significant time and resources it will take to continuously implement and enforce the Rule, as well as the numerous other administrative and regulatory burdens physicians and providers already face and the degree to which each additional burden detracts from actual care to patients and improving quality. CMA comment at 8, available at available at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71550. 84 Fed. Reg. at 23230-23246.

against California. 84 Fed. Reg. at 23178-23179. The three complaints,[57] which were filed by a religious organization, churches and a church-run school, and employees of a religiously affiliated university, alleged that the Department of Managed Health Care (DMHC) (the state agency responsible for regulating California's managed care health plans) contacted seven health plans offering products without abortion coverage on August 22, 2014, and required those health plans to include abortion coverage.[58]

83. On June 21, 2016, OCR closed the three complaints in favor of California, finding that the Weldon Amendment was not violated because the seven health plans that received the letter had not objected to providing such coverage on religious or moral grounds, a requirement for protection under the Weldon Amendment. Additionally, OCR noted that after receipt of DMHC's August 22, 2014 letter, the health plans modified their health products, without objection.[59] Citing *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) (*NFIB*), OCR also determined that this approach avoided a potentially unconstitutional application of Weldon, given Weldon's threat to rescind "all funds appropriated under the Appropriations Act to the State of California – including funds provided to the State not only by HHS but also by the Departments of Education and Labor, as well as other agencies."[60]

84. In closing the complaints in favor of California, OCR also noted that one of the health plans, Blue Cross of California, subsequently sought and received from California an exemption to allow it to offer a plan product excluding abortion services for "religious employers" as defined under California law, specifically, California Health and Safety Code section 1367.25(c)(1).

85. Although litigation is still ongoing, California has been successful in challenges stemming from DMHC's 2014 letters. *See Missionary Guadalupanas of the Holy Spirit, Inc., v. Rouilllard*, Sacramento Superior Court Case No. 34-2015-80002226 (rejecting claim under the California APA because its provisions do not apply when the agency's action merely confirms

[57] OCR Complaint Nos. 14–193604, 15–193782, and 15–195665.
[58] DMHC explained in its August 22, 2014 letter that the Knox-Keene Act requires the provision of basic healthcare services and the California Constitution prohibits health plans from discriminating against women who choose to terminate a pregnancy.
[59] Letter from OCR Director to Complainants (June 21, 2016), https://perma.cc/G4WP-V69V.
[60] *Id.*

1 law and the agency's application of the law is the only legally tenable interpretation), appeal
2 pending to the Third District Court of Appeal, Case No. C083232; *Skyline Wesleyan Church v.*
3 *Rouillard*, United States District Court for the Southern District of California, Case No. 3:16-cv-
4 00501 (granting defendants' motion for summary judgment because plaintiffs lacked standing and
5 claims were not ripe); Ninth Circuit appeal pending, Case No. 18-55451; *Foothill Church v.*
6 *Department of Health Care*, United States District Court for the Eastern District of California,
7 Case No. 2:15-cv-02165-KJM-EFB (granting defendants' motion to dismiss), Ninth Circuit
8 appeal pending, Case No. 19-15658.

9 86. The Rule states that, based on its review of OCR's previous closure of complaints
10 against California's August 22, 2014 letter, it has concluded that the aforementioned "sub-
11 regulatory guidance" previously issued by OCR with respect to interpretation of the Weldon
12 Amendment no longer reflects the current position of HHS, OCR, or the HHS Office of the
13 General Counsel. 84 Fed. Reg. at 23179. The Rule states that HHS "continues to hold the views
14 it expressed" in the NPRM, *Id.*, which noted that despite the constitutional concerns cited in
15 OCR's June 21, 2016 letter, HHS nonetheless remained obligated "to not make certain funding
16 available to covered entities that discriminate in violation of the Weldon Amendment." 83 Fed.
17 Reg. at 3890.

18 87. Starting on August 30, 2018, OCR sent a letter to California informing it that OCR
19 has reviewed a September 2017 complaint based on the previously closed complaints stemming
20 from the August 22, 2014 DMHC letter to health plans and determined that OCR has sufficient
21 authority and cause to investigate the allegations raised under the Weldon Amendment, the Coats-
22 Snowe Amendment, and the Church Amendments.

23 88. As noted *infra*, although "health care entity" is defined by the Weldon Amendment
24 (and the Coats-Snowe Amendment), the Rule includes a far broader definition that includes "a
25 plan sponsor, issuer, or third party administrator," thus allowing an employer, as expressly stated
26 by the Rule, to deny coverage for reproductive services to its employees. And the Rule also
27 expands Weldon protection to *any* reason for refusing such coverage, not just religious and moral
28 objections.

1 89. Both the promulgation of the proposed and final rule shows OCR's intent to not only
2 target the State of California and its residents, healthcare system and laws, but also sets up an
3 unavoidable clash. Evidence of this has been demonstrated to California throughout the
4 trajectory of this rulemaking.
5 90. And on January 17, 2019, OCR issued a letter, entitled a Notice of Violation,
6 regarding California's Reproductive FACT Act, and concluded that California violated the
7 Weldon Amendment and the Coats-Snowe Amendment.[61] In its letter, OCR claimed it
8 investigated complaints by four California clinics. The letter concluded that California "engaged
9 in impermissible discrimination" by subjecting the complainants to "potential fines" under the
10 Reproductive FACT Act. But in light of the permanent court injunctions entered against the
11 FACT Act and the State's statement that it has no intention of enforcing the Act, OCR concluded
12 that no further remedial action is warranted.
13 91. Thus although Defendants state in the Rule that they do "not opine upon, and [have]
14 not yet made a judgment on the compatibility of California's policy with the Weldon
15 Amendment," 84 Fed. Reg. at 23179, California has reason to believe its state sovereignty and
16 federal funding are at risk under the Rule given the direct attack on California, the Rule's
17 impermissibly broad interpretation of Weldon which permits a non-covered entity to claim
18 discrimination against the State, and the subsequent receipt of a letter from OCR finding
19 California in violation. That is because section 88.6(d)(iii) of the Rule makes clear that an OCR
20 "determination of noncompliance [will be used] to inform [HHS's] decision whether to approve,
21 renew, or modify Federal funding to the recipient," and the Rule notes that OCR has already
22 made a determination of noncompliance against California. 84 Fed. Reg. at 23177, 23262. These
23 actions thus place California in the difficult position of either continuing to uphold its
24 Constitution and state laws or risking loss of billions of dollars of critical federal funds.
25 92. California received billions of dollars in funds under the Public Law 115-245, the
26 Department of Defense and Labor, Health and Human Services, and Education Appropriations
27 Act, 2019 and Continuing Appropriations Act, 2019 (H.R. 6157)—and billions more under future

28 [61] https://www.hhs.gov/sites/default/files/california-notice-of-violation.pdf.

appropriations acts—for labor, education, and health and human services. This crucial funding necessary for multiple state agencies and their programs is now at risk Threatened funding includes:[62]

- The Elementary and Secondary Education Act of 1965, Title I (funding for schools with a high percentage of students with low-income families, 20 U.S.C. § 6301 et. seq.); and Title II, part B, subpart 2 (federal support to states to develop, revise, or update comprehensive literacy, evidence-based, instruction plans, 20 U.S.C. § 6641);
- The Social Security Act, Title XIX, to operate and make payments for Medicaid which provides healthcare coverage for low-income adults, families and children, pregnant women, the elderly, and people with disabilities;
- The Social Security Act, the State Unemployment Insurance Program, to provide payments to laid-off workers;
- The Individuals with Disabilities Education Act to ensure free appropriate public education to children with disabilities, including special education and related services to those children;
- The Child Care and Development Block Grant Act of 1990 to help low-income parents obtain childcare so they are able to work or go to school;
- The Child Support Enforcement and Family Support Programs for child support enforcement and family support programs;

[62] Section 507(d)(1) of Division B of H.R. 6157 states: "None 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." And as is specified in Section 3 of H.R. 1625, "[e]xcept as expressly provided otherwise, any reference to 'this Act' contained in any division of this Act shall be treated as referring only to the provisions of that division." Public Law 115-245, the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (H.R. 6157), Division B, https://www.congress.gov/bill/115th-congress/house-bill/6157.

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- The Workforce Innovation and Opportunity Act, including grants to states for adult employment and training activities, youth activities, and dislocated worker employment and training activities;
- The Wagner-Peyser Act of 1933 to establish a nationwide system of public employment offices to assist individuals seeking employment;
- The Occupational Safety and Health Act, section 23(g), to assist states in administering and enforcing programs for occupational safety and health;
- The Jobs for Veterans State grants program under 38 U.S.C. 4102A(b)(5) to support disabled veterans' outreach program specialists;
- The National Apprenticeship Act to expand apprenticeship and on-the-job training programs;
- The Social Security Block Grant Program to assist states in delivering social services by helping reduce dependency, increase self-sufficiency, prevent abuse and neglect, and limit institutional care, if possible;[63]
- The Older Americans Act of 1965, Section 361, for disease prevention and health promotion programs and activities;
- The 21st Century Cures Act, section 1003(c), and the State Opioid Response Grants Program to assist state response to the opioid crisis;
- The Ryan White HIV/AIDS Program to provide primary medical care and essential support for people with HIV/AIDS;
- The Rehabilitation Act of 1973 to ensure that disabled individuals have access to programs and activities that are funded by federal agencies and to federal employment;
- The Helen Keller National Center Act to assist deaf-blind persons; and
- The McKinney-Vento Homeless Assistance Act to provide assistance to the homeless, especially elderly persons, handicapped persons, and families with children.

[63] https://www.benefits.gov/benefit/775.

93. Specific programs at risk include, among many others: (1) the Public Health Emergency Preparedness Program, which coordinates preparedness and response activities for all public health emergencies, including natural disasters, acts of terrorism, and pandemic diseases and plans and supports surge capacity in the medical care and public health systems to meet needs during emergencies, (2) Chronic Disease Prevention and Health Promotion programs, which work to prevent and control chronic diseases, injuries, and violence, (3) the Health Facilities Licensing Program, which, among other functions regulates the quality of care in over 10,000 public and private health facilities, clinics, and agencies throughout the State, and (4) refugee social services programs for elder care, school impact services, and youth mentoring programs.

94. In addition, California's public universities receive hundreds of millions of dollars of grant funding for medical and scientific research from the National Institutes of Health and the Centers for Disease Control and Prevention, among other agencies within HHS. Institutions and their net amount in grant funding from HHS in fiscal year 2018 include:[64]

- California Polytechnic State University, San Luis Obispo: $1,352,184
- California State University, Bakersfield: $356,689
- California State University, Northridge: $8,895,002
- California State University, San Marcos: $2,460,508
- San Francisco State University: $8,501,370
- University of California, Berkeley: $132,824,700
- University of California, Davis: $251,243,608
- University of California, Irvine: $155,496,306
- University of California, Los Angeles: $435,373,496
- University of California, Merced: $5,707,704
- University of California, Riverside: $30,725,968
- University of California, San Diego: $462,800,222
- University of California, San Francisco: $694,071,148
- University of California, Santa Barbara: $17,647,751

[64] Data from HHS TAGGS database, available at https://taggs.hhs.gov/SearchRecip.

- University of California, Santa Cruz: $38,331,998

95. Yet despite the substantial amounts of funding and critical programs at risk, California, and other regulated entities, cannot reasonably anticipate what actions Defendants might deem a violation of the Rule. The Rule's vague and subjective standards, based on overbroad definitions without regard to statutory definitions and ill-reasoned reversals of prior policy and determinations, invite inconsistent and biased enforcement by Defendants. Defendants' previous recent enforcement efforts of federal conscience laws have been arbitrary and discriminatory, and targeted California unfairly.

96. And although the Rule says it "adopts the enforcement procedures" of Title VI of the Civil Rights Act of 1964, the Rule ignores many of that scheme's procedural protections, including findings on the record after opportunity for hearing (45 C.F.R. § 80.7), and the Rule's potential fund termination based on the conduct of sub-recipients seems unrestrained by the "pinpoint provision" in which Congress limited termination of funding to the "particular political entity, or part thereof, or other recipient as to whom such a finding has been made and, shall be limited in its effect to the particular program, or part thereof, in which such noncompliance has been so found" (42 U.S.C. § 2000d–1). Furthermore, whereas a complaint under Title VI "must be filed not later than 180 days from the date of the alleged discrimination" (unless extended), 45 C.F.R. § 80.7, the Rule seeks to re-adjudicate a complaint against California's Department of Managed Health Care under the illegal Rule. 84 Fed. Reg. at 23179.

IV. THE RULE IMPOSES ADMINISTRATIVE BURDENS AND ONEROUS IMPLEMENTATION COSTS

97. The Rule includes burdensome assurance and certification, recordkeeping, and reporting requirements which will impose unreasonable costs of implementation on California. 84 Fed. Reg. at 23233-23246. The State must submit certifications and assurance, maintain detailed records, and ensure compliance with the Rule on an ongoing basis.

98. In order to be deemed in compliance, the Rule also requires that providers post lengthy notices on their website and in conspicuous physical locations, and to continuously take

steps to ensure that such notices are not altered, defaced, or covered by other material.[65] 84 Fed. Reg. at 23270. The Rule also appears to require inclusion of the notice in personnel manuals, applications, benefits material, training materials, and handbooks in order to be deemed in compliance. *Id.*

99. This Rule will result in further fiscal harm to California because it makes California responsible for policing others' compliance, including independent political entities, with the Rule. This would include, for example, ensuring compliance by California's 58 counties, which are separate legal entities from the State (Cal. Gov. Code § 23000, et seq.). Here, the Rule asserts "that recipients are responsible for their own compliance with Federal conscience and anti-discrimination laws and implementing regulations, *as well as for ensuring their sub-recipients comply with these laws*." 84 Fed. Reg. at 23180 (emphasis added). The Rule also asserts that the State may be liable for the conduct of any entity it contracts with: "The Department notes, however, that the conduct and activities of contractors engaged by the Department, a Departmental program, or a State or local government is attributable to such Department, program, or government for purposes of enforcement or liability under the Weldon amendment." *Id.* at 23207.

100. Under the Rule, the term "sub-recipients" is defined to include "any State, political subdivision of any State, instrumentality of any State or political subdivision thereof, or any person or any public or private agency, institution, organization, or other entity in any State, including any successor, assign, or transferee thereof, to whom there is a pass-through of Federal financial assistance or Federal funds from the Department through a recipient or another sub-recipient, but such term does not include any ultimate beneficiary. The term may include a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies)." 84 Fed. Reg. at 23264.

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[65] Although the Rule states that the notice requirement is voluntary, it also states that "OCR will consider the posting of notices as "non-dispositive" evidence of compliance. 84 Fed. Reg. at 23270.

101. The Rule thus requires California to create a costly bureaucratic structure to ensure that the Rule's expansive and unlawful provisions are complied with, including compliance by any downstream sub-recipients, public or private.

102. The high costs of implementation and administrative burdens (which will also impact providers, patients, and insurers) are also unnecessary because existing laws already protect conscience rights, while also balancing patient rights to access lawful medical care.

102. California estimates that the costs of compliance will be well into the millions.

103. Indeed, the Rule itself estimates that compliance will cost affected entities a total of approximately $1.06 billion in the first five years. 84 Fed. Reg. at 23240.

104. And the Rule makes clear that OCR will aggressively pursue all remedial actions, including temporarily withholding, suspending, denying, or terminating federal funds, "[i]f OCR determines that there is a failure to comply with Federal conscience and anti-discrimination laws." 84 Fed. Reg. at 23272.

FOIA STATUTORY FRAMEWORK AND FACTUAL BACKGROUND

I. STATUTORY FRAMEWORK

105. FOIA promotes open government by providing every person with a right to request and timely receive federal agency records. 5 U.S.C. § 552(a)(3)(A).

106. In furtherance of its purpose to encourage open government, FOIA imposes strict deadlines on agencies to provide responsive documents to FOIA requests. *Id.* § 552(a)(6)(A).

107. An agency must comply with a FOIA request by issuing a determination within 20 business days after receipt of the request. *Id.* § 552(a)(6)(A)(i).

108. The determination "must at least inform the requester of the scope of the documents that the agency will produce, as well as the scope of the documents that the agency plans to withhold under any FOIA exemptions." *Citizens for Responsibility & Ethics in Wash. v. Fed. Election Comm'n*, 711 F.3d 180, 186 (D.C. Cir. 2013).

109. An agency may be entitled to one ten-day extension of time to respond to a request if it provides written notice to the requester explaining "unusual circumstances" exist that warrant additional time. 5 U.S.C. § 552(a)(6)(B).

110. An agency must immediately notify the requester of its determination whether to comply with a request, and the reasons for it, and of the right of such person to appeal an adverse determination. *Id.* § 552(a)(6)(A)(i). Further, an agency shall make available a FOIA public liaison to aid the requestor in limiting the scope of the request so that it may be processed within the statutory time limit. *Id.* § 552(a)(6)(B)(ii).

111. An agency's failure to comply with any timing requirements is deemed constructive denial and satisfies the requester's requirement to exhaust administrative remedies. *Id.* § 552(a)(6)(C)(i).

112. A FOIA requester who exhausts administrative remedies may petition the court for injunctive and declaratory relief from the agency's continued withholding of public records. *Id.* § 552(a)(4)(B).

II. FOIA Factual Background

113. On April 25, 2018, California sent the Request by mail and via electronic submission to HHS.

114. By email and letter, on May 10, 2018, HHS confirmed receipt of the Request, which it had received on April 25, 2018. HHS assigned it Request Number 2018-00934-FOIA-OS. In its letter, HHS stated that it "may utilize a 10 working day extension to process your request, as permitted pursuant to the FOIA" if one of two "unusual and exceptional circumstances" applied.

115. In addition, the letter stated that HHS had "initiated a search to locate records falling within the scope of your request. If our searching units advise us that you have requested a voluminous amount of records that require extensive search and examination, my staff will contact you shortly to discuss your willingness to modify your request."

116. With regard to the fee waiver, the letter stated that HHS was "not addressing your request for a fee waiver at this time."

117. The letter further provided that any questions regarding the status of the Request should be directed to the HHS FOIA office.

118. On June 6, 2018, California reached out to the assigned HHS FOIA Public Liaison to discuss the status of the Request as suggested in the May 10, 2018 letter. California received no

response. California reached out to the HHS FOIA Public Liaison again on June 12, 2018, noting that California had also called the number located on the May 10, 2018 letter and reached a voicemail box that was full and no longer accepting messages. On June 19, 2018, California again emailed the HHS FOIA Public Liaison, noting that California had reached someone at the designated HHS phone number; however, California was told that all status requests should be made via email to the HHS FOIA Public Liaison.

119. On June 26, 2018, California sent its fourth request for a status update. The HHS FOIA Liaison responded that "HHS FOIA has not received any responsive records from the program office tasked to search for responsive records pertaining to your request." She stated that she has "reached out once again to those offices (the Office for Civil Rights and the Immediate Office of the Secretary) to ascertain when their records search will be completed." (*See* Exhibit D.) In response, California asked for clarification as to whether its request was placed in the "simple" or complex" queue pursuant to 45 C.F.R. § 5.24(e). California sent a follow-up email on July 16, 2018, requesting an update and received no response.

120. Then on February 15, 2019, California provided a duplicate copy of the FOIA request and follow up correspondence at a meeting with OMB which was also attended by representatives of OCR.

121. As of the date of this filing, HHS has not objected to the Request, provided any detailed information regarding specific disclosure of the records sought, nor produced any responsive documents in response to California's April 25, 2018 Request.

122. Under FOIA, HHS was required to have provided California with a determination on the scope of the documents it would produce and the exemptions it would claim within 20 working days of receiving the request. 5 U.S.C. § 552(a)(6)(A)(i). At no point has HHS explicitly extended the 20-day time, nor has it provided details of any "unusual circumstances." *Id.* § 552(a)(6)(B). Under the statute, HHS could only extend the 20-day time period to 10 additional working days (for a total of 30 days) or else "make available its FOIA Public Liaison" "[t]o aid the requestor" in "limit[ing] the scope of the request." *Id.* § 552(a)(6)(B)(i)-(ii).

123. The 30-day period expired on May 30, 2018. HHS has never provided to California the determination required by statute, nor provided any documents, claimed any exemptions, or provided any reasonably segregable portions of records. The FOIA Public Liaison has failed to respond to California's communications to discuss processing of its Request in a timely manner.

124. Where Defendants have failed to provide any substantive responses to the Request within the statutory timeframe, they have constructively denied the Request. As such, California has exhausted its administrative remedies. *Id.* § 552(a)(6)(C)(i).

125. Because HHS failed to provide California with the determination required in the statutory timeframe, and has failed to respond to California's communications to discuss limiting the scope of its Request, FOIA prevents HHS from assessing search fees on California for records responsive to the Request. *Id.* § 552(a)(4)(A)(viii).

126. Because of HHS's violations of FOIA, California has been required to expend resources to prosecute this action.

FIRST CAUSE OF ACTION

(Violation of APA; 5 U.S.C. § 706—Contrary to Law)

127. Paragraphs 1 through 126 are realleged and incorporated herein by reference.

128. The Rule, constitutes "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court." 5 U.S.C. §§ 551(4), (13), 704.

129. The APA requires courts to "hold unlawful and set aside" agency action that is "not in accordance with law." 5 U.S.C. § 706(2)(A).

130. The Rule is not in accordance with the law because it expands statutory definitions and conscience laws by allowing an overly broad range of individuals and entities to refuse to provide virtually any lawful healthcare service or coverage for any reason, not just due to religious and moral objections. In this way, the Rule goes far beyond what is permitted by the Weldon, Church, and Coats-Snowe Amendments, and other statutes the Rule purports to implement or enforce.

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1 131. The Rule also conflicts with several other federal statutes, including Title VII of the
2 Civil Rights Act of the 1964, Title X of the Public Health Services Act and the nondirective
3 counseling requirement, and the Emergency Medical Treatment & Labor Act.
4 132. The Rule also conflicts with Section 1554 of the ACA, which forbids the HHS
5 Secretary from promulgating "any regulation" that:
6 creates any unreasonable barriers to the ability of individuals to obtain appropriate
7 medical care; (2) impedes timely access to health care services; (3) interferes with
communications regarding a full range of treatment options between the patient and
8 provider; (4) restricts the ability of health care providers to provide full disclosure of
all relevant information to patients making health care decisions; [or] (5) violates the
9 principles of informed consent and the ethical standards of health care professionals.
10 42 U.S.C. § 18114. The Rule violates this provision by creating unreasonable barriers to medical
11 care, including admittedly to patients in rural communities, among others.
12 132. The Rule further conflicts with Section 1557 of the ACA, which states that an
13 "individual shall not . . . be excluded from participation in, be denied the benefits of, or be
14 subjected to discrimination under, any health program or activity" on the basis of sex. 42 U.S.C.
15 § 18116; 20 U.S.C. § 1681.
16 133. Defendants' reversal of their interpretation of the Weldon Amendment as it relates to
17 California's abortion health plan coverage requirement is also unsupported by any legal authority,
18 and is based on a distortion of existing law. Defendants' unsupported reversal creates
19 uncertainties for the future of the State's entire healthcare system, from state programs, to
20 hospitals, to patients.
21 134. Defendants' violation causes ongoing harm to California and its residents and
22 threatens much greater harm should massive amounts of federal funding to the State be revoked.
23 135. By promulgating the Rule, Defendants have acted contrary to law. In doing so,
24 Defendants have taken action in violation of the APA. The Rule is therefore invalid and should
25 be set aside as arbitrary and capricious under 5 U.S.C. § 706(2)(A).
26 **SECOND CAUSE OF ACTION**
27 **(Violation of APA; 5 U.S.C. § 706—Exceeded Statutory Authority)**
28 136. Paragraphs 1 through 135 are realleged and incorporated herein by reference.

1 137. HHS is an agency under the APA. 5 U.S.C. § 551(1).
2 138. The APA requires courts to "hold unlawful and set aside" agency action that is "in
3 excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C.
4 § 706(2)(C). The Rule is in excess of statutory jurisdiction, authority, and limitations in several
5 respects.
6 139. HHS previously acknowledged that "[n]o statutory provision requires the
7 promulgation of rules to implement the requirements of the Church Amendments, Public Health
8 Service (PHS) Act Sec. 245, and the Weldon Amendment. 74 Fed. Reg. 10,207, 10209 (March
9 10, 2009).
10 140. Nevertheless, Defendants have acted in excess of statutory authority by granting
11 themselves broad powers to expand statutory definitions in these and other federal laws, including
12 in direct contravention to statutory text, and by granting themselves broad enforcement powers
13 unmoored from any statutory scheme. *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986)
14 ("[A]n agency literally has no power to act . . . unless and until Congress confers power upon
15 it.").
16 141. By promulgating this new Rule, Defendants have taken action in violation of the
17 APA. The Rule is therefore invalid and should be set aside as arbitrary and capricious under 5
18 U.S.C. § 706(2)(A).
19 **THIRD CAUSE OF ACTION**
20 **(Violation of APA; 5 U.S.C. § 706—Arbitrary, Capricious, and Abuse of Discretion)**
21 142. Paragraphs 1 through 141 are realleged and incorporated herein by reference.
22 143. The Rule constitutes "[a]gency action made reviewable by statute and final agency
23 action for which there is no other adequate remedy in a court." 5 U.S.C. §§ 551(4), (13), 704.
24 144. The APA requires courts to "hold unlawful and set aside" agency action that is
25 "arbitrary," "capricious," or an "abuse of discretion." 5 U.S.C. § 706(2)(A). In this case, the
26 Rule is arbitrary and capricious for several reasons.
27 145. Defendants offer no reasoned explanation for misconstruing and straining well-
28 established statutory language and definitions in federal conscience laws. Without substantial

justification, Defendants have created limitless categories of individuals, entities, and circumstances under which medical information and care can be refused, and also createdconflicts with other federal laws, including the ACA, Title VII of the Civil Rights Act of the 1964, Title X of the Public Health Services Act and the nondirective counseling requirement, and the Emergency Medical Treatment & Labor Act.

146. Defendants offer no reasoned explanation for Defendants' reversal of their interpretation of the Weldon Amendment as it relates to California's abortion health plan coverage requirement. Defendants provide no reasonable justification for now ignoring previous constitutional concerns cited by OCR in its June 21, 2016 letter that may result in the widespread termination of federal funding to California, or California's substantial reliance interest on Defendants' prior interpretation.

147. The Rule is also arbitrary and capricious because Defendants failed to consider important aspects of the problem that were raised by California and others in public comments, including patient harms, particularly to vulnerable patients, including women, LGBTQ individuals, rural patients, and other vulnerable populations.

148. In promulgating the Rule, Defendants have offered ill-reasoned analysis for their decision, which runs counter to the evidence in the administrative record, is based on outdated data, and rests on speculative conclusions. Such speculative conclusions include the unsubstantiated conclusion that the Rule will result in an increase in the number of providers and better patient care because greater enforcement of federal conscience laws will cause more providers to enter and stay in the field , and patients will benefit from more open and honest communications with providers.

149. The Rule is also arbitrary and capricious because it disregards consequential costs of compliance—including the costs to patients and regulated entities such as the State—and is based on a flawed cost-benefit analysis because it relies on unsubstantiated and speculative benefits such as purported increases in the number of providers and better patient care if medical information and care can be broadly denied under the Rule.

1 150. Defendants' violation causes ongoing harm to California and its residents and
2 threatens to inflict much greater harm by withdrawing or withholding massive amounts of federal
3 funding to the State.
4 151. By promulgating the Rule, without a proper factual or legal basis, Defendants have
5 acted arbitrarily and capriciously, have abused their discretion, have otherwise acted not in
6 accordance with law, and have taken unconstitutional and unlawful action in violation of the
7 APA.
8 152. For these reasons, the Rule is unlawful and should be set aside as arbitrary and
9 capricious under 5 U.S.C. § 706(2)(A).
10 **FOURTH CAUSE OF ACTION**
11 **(Violation of the Spending Clause - Coerciveness)**
12 153. Paragraphs 1 through 152 are realleged and incorporated herein by reference.
13 154. While the federal government may "create incentives for states to act in accordance
14 with federal policies," it may not use its Spending Clause powers to coerce States to accept those
15 policy changes without running afoul of our system of federalism. *NFIB*, 567 U.S. 519, 577-78.
16 155. Thus, when conditions on the receipt of federal funds takes the form of threats to
17 terminate significant independent grants, "the conditions are properly viewed as a means of
18 pressuring the States to accept policy changes." *Id*. at 580.
19 156. The Rule violates the Spending Clause because it crosses the line from pressure to
20 compulsion. It leaves the State with no practical alternative but to surrender and comply with the
21 Rule or risk the loss of a substantial portion of the State's budget.
22 157. The Rule is so severe that it forces the State and its entities adopt the Defendants'
23 regulatory scheme and forego enforcement of its state laws and the exercise of its police powers,
24 or risk the loss of billions of dollars in federal funds, including funds for Medicaid, and
25 educational and labor programs.
26 158. The Rule is thus tantamount to "a gun to the head." *NFIB*, 567 U.S. 519, 581. If
27 California opts out of complying with the Rule (or even "[i]f OCR determines that there is a
28 failure to comply") 84 Fed. Reg. 23170, 23271 (May 21, 2019), California "would stand to lose

not a relatively small percentage" of its existing federal funding, but billions of dollars of critical funding for its healthcare, education, and labor programs. *NFIB*, 567 U.S. at 581.

159. As such, the Rule is an unconstitutional abuse of the Spending Clause of the United States Constitution, and is an additional basis to set aside the Rule under the APA.

FIFTH CAUSE OF ACTION

(Violation of the Spending Clause - Vagueness)

160. Paragraphs 1 through 159 are realleged and incorporated herein by reference.

161. The federal government's spending powers are not unlimited, and a condition on the states' receipt of federal funds must be done so unambiguously so as to enable the states to exercise their choice knowingly and cognizant of the consequences of their participation. *Pennhurst State Sch. and Hospital v. Halderman*, 451 U.S. 1, 17 (1981).

162. The Rule cannot be upheld under the Spending Clause because the Rule is vague and does not provide adequate notice of what specific action or conduct, if engaged in, will result in the withholding of federal funds. Because of the Rule's vague and subjective standards, which are based on newly expanded definitions that pay no regard to statutory text, California cannot reasonably anticipate what actions Defendants might deem in violation of the Rule.

163. For example, because the Rule now includes such expansive definitions beyond those long-established by statute—allowing, for example, any medical provider or "health care personnel" to refuse medical care without any information about the patient's medical condition or treatment options, not just on the basis of state and federally protected religious and conscience protections, but also on the basis of "ethical[] or other reasons," and applying to any "action that has a specific, reasonable, and articulable connection to furthering a procedure or a part of a health service program or research activity undertaken by or with another person or entity"—the State cannot make a knowing choice as to whether it would be a violation of the Rule if it takes enforcement action against medical providers or programs that deny care and/or who discriminate against its most vulnerable residents.

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164. Also, the Rule is so broadly and vaguely written that it is nearly impossible to ascertain how California should communicate with its sub-recipients in order to obligate them to comply with the Rule in a manner that effectively protects California's own funding.

165. Terminating California's funding based on the conduct of third parties that California neither controls nor operates would be financially crippling for the State. For example, federal funding for the State and for all counties could be placed at risk based on the alleged violation of a single county under this vague rule.

166. Defendants' reversal of their interpretation of the Weldon Amendment as it relates to California's abortion health plan coverage requirement is also unsupported by any legal authority. This unsupported reversal creates uncertainties as to what additional state laws and policies may also now be deemed a violation of the Rule.

167. And the January 18, 2019 "Notice of Violation" issued against California, although it concluded that further remedial action against California was not warranted, could, under the Rule, be deemed a "determination" that could "inform funding decision-making." 84 Fed. Reg. at 23177, 23262.

168. Yet despite the substantial amounts of funding and critical programs at risk and the evident set up for a direct confrontation between California and the OCR, California cannot reasonably anticipate what actions Defendants might deem a violation of the Rule. The Rule's vague and subjective standards, based on overbroad definitions without regard to statutory definitions and ill-reasoned reversals of prior policy and determinations, invite inconsistent and biased enforcement by Defendants.

169. As such, the Rule is an unconstitutional abuse of the Spending Clause of the United States Constitution, and is an additional basis to set aside the Rule under the APA.

SIXTH CAUSE OF ACTION

(Violation of the Spending Clause – Post-Acceptance Conditions on Federal Funds)

170. Paragraphs 1 through 169 are realleged and incorporated herein by reference.

171. The Rule cannot be upheld under the Spending Clause because the Rule constitutes post-acceptance conditions on federal funds. *Pennhurst*, 451 U.S. 1, 17 ("Though Congress'

power to legislate under the spending power is broad, it does not include surprising participating States with post acceptance or "retroactive" conditions.); *NFIB*, 567 U.S. 519, 584 (a state could hardly anticipate that the federal government's reservation of the right to alter or amend Medicaid included the power to transform the program dramatically).

172. In this case, the Rule dramatically alters the scope of federal conscience laws, California's ability to enforce its own laws (including laws previously found by OCR not to violate federal conscience laws) and compliance requirements, and threatens to withhold massive amounts of federal funding unless California capitulates to the provisions of the new Rule.

173. The Rule was published in the Federal Register on May 21, 2019. The Rule is set to go into effect on July 22, 2019.

174. In fact, even before the Rule was finalized, OCR contacted California to re-open its investigation. See Letter from Roger T. Severino, Dir., Dep't of Health & Human Serv's. Office for Civil Rights, to Xavier Becerra, Att'y. Gen., State of Cal. (Jan. 18, 2019), available at https://www.hhs.gov/sites/default/files/california-notice-of-violation.pdf.

175. As such, the Rule is an unconstitutional abuse of the Spending Clause of the United States Constitution, and is an additional basis to set aside the Rule under the APA.

SEVENTH CAUSE OF ACTION

(Violation of the Spending Clause - Unrelatedness)

176. Paragraphs 1 through 175 are realleged and incorporated herein by reference.

177. The Rule cannot be upheld under the Spending Clause because the Rule is not rationally related to the federal interest in the particular programs that receive federal funds. *See South Dakota v. Dole*, 483 U.S. 203 (1987); *Massachusetts v. United States*, 435 U.S. 444, 461 (1978) (plurality op.) (conditioning federal grants illegitimate if unrelated "to the federal interest in particular national projects or programs").

178. The Rule places various federal grants at risk, including those for Medicaid, HIV prevention, emergency preparedness, education programs, such as those under Individuals with Disabilities Education Act, employment programs, including those under the State

1 Unemployment Insurance Program, and block grants to help low-income parents obtain childcare
2 so they are able to work or go to school.
3 179. But the programs, and so many others, bear no rational relationship between the
4 federal conscience laws Defendants seek to enforce and the federal interest in those programs.
5 180. As such, the Rule is an unconstitutional abuse of the Spending Clause of the United
6 States Constitution, and is an additional basis to set aside the Rule under the APA.

7 **EIGHTH CAUSE OF ACTION**

8 **(First Amendment–Violation of the Establishment Clause)**

9 181. Paragraphs 1 through 180 are realleged and incorporated herein by reference.
10 182. The First Amendment provides that "Congress shall make no law respecting an
11 establishment of religion, or prohibiting the free exercise thereof." U.S. Const., amend. I. "The
12 clearest command of the Establishment Clause is that one religious denomination cannot be
13 officially preferred over another." *Larson v. Valente*, 456 U.S. 228, 244 (1982); *see also*
14 *McCreary County, Kentucky v. ACLU*, 545 U.S. 844, 875 (2005) ("the government may not favor
15 one religion over another, or religion over irreligion").
16 183. Defendants have used their rule-making authority for the primary purpose of
17 advancing and endorsing religious beliefs, and permitting same to be privileged over secular
18 beliefs as a basis for denying medically necessary information, referrals, and services, including
19 emergency healthcare and healthcare guaranteed under federal and state laws.
20 184. By promulgating the Rule, Defendants have also violated the Establishment Clause
21 because the new Rule goes too far in accommodating an employee's religious objections, placing
22 an undue burden on third parties— i.e., patients who seek access to care. *Burwell v. Hobby*
23 *Lobby Stores, Inc*. 134 S.Ct. 2751, 2781 n.37 (2014) (requiring consideration of the burden placed
24 on third parties by a religious accommodation).
25 185. The Rule is not narrowly tailored and ignores the compelling interest of seamless
26 access to healthcare and necessary medical information. This crosses the line from acceptable
27 accommodation to religious endorsement and entanglement.
28

186. As such, the Rule violates the Establishment Clause of the First Amendment of the United States Constitution, and is an additional basis to set aside the Rule under the APA.

NINTH CAUSE OF ACTION

(FOIA)

Claim One (Failure to Conduct Adequate Search)

187. Paragraphs 1 through 186 are realleged and incorporated herein by reference.

188. California has a statutory right to have HHS process its FOIA Request in a manner that complies with FOIA. 5 U.S.C. § 552(a)(3). HHS violated California's rights in this regard when it unlawfully failed to undertake a search that is reasonably calculated to locate all records that are responsive to California's April 25, 2018 Request.

189. Unless enjoined and made subject to a declaration of California's legal rights by this Court, HHS will continue to violate California's rights to receive public records under FOIA.

Claim Two (Failure to Respond to Request Within Statutory Timeframe)

190. Paragraphs 1 through 189 are realleged and incorporated herein by reference.

191. Defendants failed to respond to the Request within the statutorily mandated timeframe, in violation of California's rights under FOIA, including but not limited to 5 U.S.C. § 552(a)(6)(A)(i) and (6)(B). Defendants also effectively failed to make available the FOIA Public Liaison to assist in narrowing the scope of California's Request to justify extending the statutorily-mandated timeline. *Id.* § 552(a)(6)(B)(ii).

192. Unless enjoined and made subject to a declaration of California's legal rights by this Court, HHS will continue to violate California's rights to receive public records under FOIA.

Claim Three (Failure to Disclose Non-Exempt Records)

193. Paragraphs 1 through 192 are realleged and incorporated herein by reference.

194. HHS violated FOIA by refusing to disclose records responsive to California's April 25, 2018 FOIA Request.

195. California has a statutory right to the records it seeks.

196. Unless enjoined and made subject to a declaration of California's legal rights by this Court, HHS will continue to violate California's rights to receive public records under FOIA.

Claim Four (Failure to Provide Reasonably Segregable Portions of Records)

197. Paragraphs 1 through 196 are realleged and incorporated herein by reference.

198. HHS violated FOIA by failing to provide California with reasonably segregable portions of records (after deletion of portions lawfully exempt under FOIA) that are responsive to California's April 25, 2018 FOIA Request, as required by 5 U.S.C. § 552(b).

199. Unless enjoined and made subject to a declaration of California's legal rights by this Court, HHS will continue to violate California's rights to receive reasonably segregable portions of records (after deletion of portions lawfully exempt under FOIA).

PRAYER FOR RELIEF

WHEREFORE, the State of California, by and through Attorney General Xavier Becerra, respectfully requests that this Court:

With regard to the Rule,

1. Issue a declaratory judgment that the Rule is arbitrary and capricious, not in accordance with law, and Defendants acted in excess of statutory authority in promulgating the Rule;

2. Issue an order vacating and setting aside the Rule in accordance with the APA;

3. Issue a declaratory judgment that the Rule violates the Spending Clause;

4. Issue a declaratory judgment that the Rule violates the Establishment Clause;

5. Issue an order enjoining Defendants from withholding, denying, suspending, and/or terminating federal funding from California in connection with the unlawful Rule, or otherwise unlawfully;

6. Issue a preliminary injunction prohibiting the implementation of the Rule;

7. Issue permanent injunction prohibiting the implementation of the Rule;

8. Award California costs, expenses, and reasonable attorneys' fees; and

9. Grant such other relief as the Court deems just and proper.

/ / /.

/ / /

/ / /

1 With regard to the FOIA claims,

2 1. Order HHS to conduct searches that are reasonably calculated to locate all records
3 responsive to California's April 25, 2018 FOIA Request, with the cut-off date for such searches
4 being the date the searches are conducted, and to provide California, by a date certain, with all
5 responsive records and reasonably segregable portions of responsive records sought;

6 2. Declare that HHS's failure to make a timely determination regarding California's
7 April 25, 2018 Request, as alleged above, is unlawful under FOIA, 5 U.S.C. § 552(a)(6)(A)(i) and
8 (6)(B);

9 3. Declare that HHS's failure to search for and disclose to California all records that are
10 responsive to California's Request, as alleged above, is unlawful under FOIA, 5 U.S.C.
11 § 552(a)(3);

12 4. Declare that HHS's failure to provide California with reasonably segregable portions
13 of records (after deletion of portions lawfully exempt under FOIA) that are responsive to
14 California's Request, as alleged above, is unlawful under FOIA, 5 U.S.C. § 552(b);

15 5. Award California its reasonable litigation costs and attorney fees pursuant to 5 U.S.C.
16 § 552(a)(4)(E).

17 6. Grant such other relief as the Court may deem just and proper.

18 Dated: May 21, 2019

Respectfully submitted,

19 XAVIER BECERRA
20 Attorney General of California
MICHAEL NEWMAN
21 Senior Assistant Attorney General
KATHLEEN BOERGERS
22 Supervising Deputy Attorney General

23 */s/ Neli N. Palma*

24

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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

CITY AND COUNTY OF SAN FRANCISCO, Plaintiff, vs. ALEX M. AZAR II, et al., Defendants.	No. C 19-02405 WHA *Related to* No. C 19-02769 WHA No. C 19-02916 WHA
STATE OF CALIFORNIA, by and through ATTORNEY GENERAL XAVIER BECERRA, Plaintiff, vs. ALEX M. AZAR, et al., Defendants.	**PLAINTIFFS' APPENDIX IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**
COUNTY OF SANTA CLARA et al,, Plaintiffs, vs. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.	Date: October 30, 2019 Time: 8:00 AM Dept: 12 Judge: The Honorable William H. Alsup Trial Date: None Set Action Filed: 5/21/2019

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Plaintiffs hereby submit the attached Appendix in support of their motion for summary judgment and in support of their opposition to Defendants' motion for summary judgment.

Dated: September 9, 2019

Respectfully Submitted,

XAVIER BECERRA
Attorney General of California
KATHLEEN BOERGERS
Supervising Deputy Attorney General

/s/ Neli Palma

NELI PALMA
KARLI EISENBERG
STEPHANIE YU
Deputy Attorneys General
Attorneys for Plaintiff State of California, by and through Attorney General Xavier Becerra

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT[1]
		Entity Comment Letters
1.	000140635-000140648	A Better Balance: The Work & Family Legal Center
2.	000147746-000147766	ACLU
3.	000054610-000054622	ACLU of Alabama
4.	000139483-000139494	ACLU of Florida
5.	000160890-000160902	ACLU Foundation of California
6.	000160716-000160727	ACLU of Colorado
7.	000057412-000057423	ACLU of Massachusetts
8.	000068069-000068079	ACLU of Michigan
9.	000058269-000058279	ACLU of Minnesota
10.	000138016-000138027	ACLU of New Mexico
11.	000056876-000056888	ACLU of South Dakota
12.	000035258-000035259	American Academy of Family Physicians
13.	000066627-000066628	American Academy of PAs
14.	000140460-000140477	American Academy of Pediatrics
15.	000133694-000133703	American Atheists
16.	000147981-000147985	American College of Emergency Physicians
17.	000139749-000139751	American College of Obstetricians and Gynecologists
18.	000137623-000137626	American Dental Education Association
19.	000030264	American Health Care Association/National Center for Assisted Living
20.	000067413-000067416	American Hospital Association

[1] The documents listed in the Appendix are drawn from the flash drives, submitted to the Court on July 23, 2019. *See* Dkt. No. 74.

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EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
21.	000139587-000139593	American Medical Association
22.	000056915-000056922	American Nurses Association and American Academy of Nursing
23.	000140452-000140454	American Pharmacists Association
24.	000028893-000028895	American Physical Therapy Association
25.	000147725-000147728	American Psychiatric Association
26.	000140575-000140578	American Psychological Association
27.	000058398-000058399	American Speech-Language-Hearing Association
28.	000147999-000148006	Americans United for Separation of Church and State
29.	000147890-000147892	Anne Arundel Medical Center
30.	000071679-000071683	Anti-Defamation League
31.	000071138-000071143	Association of American Medical Colleges
32.	000147963-000147965	Association of Women's Health, Obstetric and Neonatal Nurses
33.	000068369-000068373	Aurora Health Care
34.	000057077-000057078	Bend the Arc Jewish Action
35.	000147859-000147860	BJC HealthCare
36.	000140265-000140277	Blue Cross Blue Shield Association
37.	000139287-000139293	Boston Medical Center
38.	000137905-000137910	California Attorney General
39.	000140350-000140356	California Department of Insurance
40.	000057541-000057543	California LGBT Health and Human Services Network
41.	000151666-000151674	California Medical Association
42.	000135124-000135126	California Pan-Ethnic Health Network
43.	000147867-000147868	California Primary Care Association
44.	000135824-000135840	Callen-Lorde

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
45.	000160639-000160653	Center for American Progress
46.	000135634-000135638	Center for Health and Gender Equity (CHANGE)
47.	000191027-000191033	Center for Inquiry
48.	000140694-000140701	Center for Medicare Advocacy
49.	000160801-000160828	Center for Reproductive Rights
50.	000148049-000148054	Center on Halsted
51.	000139397-000139401	Child Welfare League of America
52.	000138033-000138034	Christiana Care Health System
53.	000032771-000032772	City of Miami Beach
54.	000140484-000140489	City of New York
55.	000149090-000149098	Colorado Coalition for the Homeless
56.	000139925-000139929	Colorado Consumer Health Initiative
57.	000140332-000140335	Commonwealth of Pennsylvania Departments of Aging, Health, Human Services, Drug and Alcohol Programs, and Insurance
58.	000138088-000138099	Community Catalyst
59.	000135191-000135199	Compassion & Choices
60.	000160775-000160778	Consortium for Citizens with Disabilities Rights Task Force
61.	000071569-000071576	Consumer Health First
62.	000140209-000140214	Consumers for Affordable Health Care
63.	000055806-000055813	County of Santa Clara
64.	000139817-000139819	DignityUSA

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EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
65.	000011509-000011513	Disability Rights Education and Defense Fund (DREDF)
66.	000160542-000160547	Duke Law School - Health Justice Clinic & NC AIDS Action Network
67.	000137943-000137945	EmblemHealth
68.	000160924-000160929	Empire Justice Center
69.	000071187-000071188	Esperanza Health Centers
70.	000055454-000055463	Every Child By Two
71.	000139245-000139253	Family Equality Council
72.	000011504-000011505	Family Voices
73.	000134957-000134959	Federal AIDS Policy Partnership
74.	000063125-000063131	Feminist Majority Foundation
75.	000139476-000139480	Forward Montana
76.	000140547-000140548	Freedom From Religion Foundation
77.	000139354-000139358	GLBTQ Legal Advocates & Defenders
78.	000160566-000160573	GLMA: Health Professionals Advancing LGBT Equality
79.	000147824-000147828	Greater New York Hospital Association (GNYHA)
80.	000067142-000067147	Guttmacher Institute
81.	000071476-000071481	Health Care For All
82.	000134957-000134959	HIV Health Care Access Working Group
83.	000139259-000139262	HIV Medicine Association
84.	000071673	Howard Brown Health
85.	000140153-000140159	Human Rights Campaign
86.	000147969-000147978	Human Rights Watch
87.	000161178-000161186	Institute for Policy Integrity at New York University School of Law
88.	000160934-000160935	Interfaith Voices for Reproductive Justice

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
89.	000140011-000140027	International Women's Health Coalition
90.	000140493-000140497	Jackson County Democrats (JCD) LGBTQ Caucus
91.	000138145-000138149	Jacobs Institute of Women's Health
92.	000070952	Jewish Healthcare Foundation
93.	000140047	Jewish Women International
94.	000148161-000148167	Justice in Aging
95.	000161476-000161495	Lambda Legal
96.	000071624-000071626	Latino Coalition for a Healthy California
97.	000135393-000135395	LeadingAge
98.	000148789-000148799	Legal Voice
99.	000135769-000135772	LGBT Community Advisory Board, Washington, DC
100.	000071750-000071755	Lesbian Health Initiative (LHI)-Houston
101.	000147871-000147873	Massachusetts Health & Hospital Association
102.	000071698-000071699	Massachusetts Law Reform Institute
103.	000064200-000064201	Massachusetts Medical Society
104.	000161033-000161039	Medicare Rights Center
105.	000160169-000160461	MomsRising
106.	000139301-000139305	Montana Women Vote
107.	000068066-000068067	Maine Primary Care Association
108.	000148008-000148010	Muslim Advocates
109.	000057600-000057607	National Association of Chain Drug Stores
110.	000139217-000139228	NARAL Pro-Choice America

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
111.	000148028-000148039	NARAL Pro-Choice Maryland
112.	000067994-000068004	National Abortion Federation
113.	000135610-000135612	National Academy of Elder Law Attorneys
114.	000148014-000148025	National Asian Pacific American Women's Forum
115.	000068426-000068451	National Association of Councils on Developmental Disabilities
116.	000138013-000138014	National Association of County and City Health Officials
117.	000140586-000140587	National Association of Pediatric Nurse Practitioners
118.	000065891-000065892	National Association of Social Work
119.	000134728-000134750	National Center for Lesbian Rights
120.	000148096-000148120	National Center for Transgender Equality
121.	000147915-000147919	National Coalition for LGBT Health
122.	000138161-000138163	National Coalition of STD Directors
123.	000147879-000147881	National Community Pharmacists Association
124.	000140183-000140192	National Council of Jewish Women
125.	000057082-000057093	National Council of Jewish Women New York
126.	000066295-000066296	National Council on Aging
127.	000147849-000147850	National Education Association
128.	000138102-000138112	National Family Planning & Reproductive Health Association
129.	000057126-000057127	National Health Care for the Homeless Council
130.	000139858-000139885	National Health Law Program
131.	000148056-000148062	National Immigration Law Center
132.	000160586-000160588	National Indian Health Board
133.	000057519-000057531	National Institute for Reproductive Health (NIRH)
134.	000160475-000160492	National Latina Institute for Reproductive Health

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
135.	000149690-000149695	National LGBTQ Task Force
136.	000140594-000140597	National Organization for Women
137.	000148177-000148189	National Partnership for Women & Families
138.	000149141-000149156	National Women's Law Center
139.	000137857-000137862	New Voices for Reproductive Justice
140.	000140484-000140489	New York City
141.	000137574-000137587	New York Civil Liberties Union
142.	000140552-000140572	NMAC (formerly, the National Minority AIDS Council)
143.	000139547-000139553	North Carolina Justice Center
144.	000161452-000161462	Northwest Health Law Advocates (NoHLA)
145.	000137611-000137612	Ohio Hospital Association
146.	000059389-000059393	One Colorado Education Fund
147.	000139366-000139377	One Voice to Save Choice
148.	000055622-000055628	Oregon Foundation for Reproductive Health
149.	0000011483-00011487	Our Family Coalition
150.	000149000-000149005	PAI (Champions of Global Reproductive Rights)
151.	000138006-000138010	PCMA (Pharmaceutical Care Management Association)
152.	000070927-000070934	People For the American Way
153.	000148138-000148152	Physicians for Reproductive Health
154.	000160751-000160771	Planned Parenthood Federation of America
155.	000147730-000147734	Power to Decide

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
156.	000071638-000071642	PROMO Fund
157.	000159777-000159781	Public Health Law Watch and Public Health Law Center
158.	000137758-000137767	Public Rights/Private Conscience Project
159.	000066545-000066556	Raising Women's Voices for the Health Care We Need
160.	000067827-000067829	Religious Action Center of Reform Judaism
161.	000133980-000133983	SAGE (Advocacy & Services for LGBT Elders)
162.	000134791-000134793	San Francisco Department of Public Health
163.	000161316-000161342	Sargent Shriver National Center on Poverty Law
164.	000139176-000139177	SisterLove, Inc.
165.	000027575-000027579	Southern Arizona Gender Alliance
166.	000051276-000051290	SPAN Parent Advocacy Network/Family Voices NJ
167.	000070993-000070995	Texas Hospital Association
168.	000157239-000157259	The Alliance: State Advocates for Women's Rights & Gender Equality
169.	000147952-000147955	The Disability Coalition of New Mexico
170.	000140685-000140692	The Fenway Institute at Fenway Health
171.	000160951-000160963	The Leadership Conference on Civil and Human Rights Health Care Task Force
172.	000071648-000071650	The Movement Advancement Project
173.	000148072-000148076	The New York State LGBT Health & Human Services Network
174.	000140339-000140340	The Patients Rights Action Fund
175.	000140395-000140400	The Trevor Project
176.	000160782-000160786	Transgender Law Center
177.	000140507-000140513	URGE: Unite for Reproductive & Gender Equity
178.	000067173-000067175	Washington State Department of Health

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
179.	000135450-000135459	Whitman-Walker Health
180.	000161198-000161295	Williams Institute
181.	000066037-000066047	Wisconsin Alliance for Women's Health
182.	000067865-000067869	Wisconsin Hospital Association
183.	000140325-000140329	Wisconsin Medical Society
184.	000147907-000147913	Women's Health and Family Planning Association of Texas
185.	000068289-000068299	WV FREE

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
Individual Comment Letters		
186.	000000106	Lesbian parent concerned about her children's care
187.	000006649	Transwoman in Indiana who already lives in fear of "trans panic"
188.	000006914	Mother of gay son who "has to face discrimination every day of his life. . . . Please reconsider this regulation."
189.	000007300	"My daughter is transgender and if her physicians were discriminatory, shed [sic] still be stuck in a body that killed her slowly every day."
190.	000007577	Parent of LGBTQ daughter who has a right to healthcare
191.	000008532	Parent of gay daughter concerned about discrimination
192.	000008890	Mother of transgender man
193.	000009247	Transgender person who has had good access but fears for others
194.	000009506	"I deserve as much right to healthcare as any cisgender citizen of this nation"
195.	000010053	Queer woman has been uncomfortable sharing sexual history and worries about being denied birth control
196.	000010211	Mom of transgender son fearing for ER care
197.	000010219	Has friend who's genetically XXY (intersex) and transgender
198.	000010236	Son has suffered discrimination since coming out and has suffered from suicidal ideation
199.	000010251	Woman upset that she, her wife, and their son fear losing healthcare

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
200.	000010274	Worried about access in a sparsely populated area
201.	000010325	Faced discrimination by Seventh Day Adventist hospitals
202.	000011367	Transgender woman who has witnessed horror stories and speaks to med students on transgender access
203.	000011371	"Transgender female who is not going to let them take anything away from me"
204.	000012066	Man whose partner was initially denied parental status at an urgent care center
205.	000012912	Transgender woman and healthcare economist on increased healthcare costs
206.	000012996	Gay man who is a healthcare administrator and rejects discrimination
207.	000016236	Parent of child who struggled before transitioning
208.	000016449	Daughter not allowed to see same-sex partner in hospital in FL
209.	000022614	"I as a part of glbtq am opposed to the refusal of healthcare because of race, religion, sex preference, trans gendered."
210.	000022945	Parents of non-binary child who deserves medical care
211.	000024796	Illinois resident fears being kept alive by doctors
212.	000025913	Grandmother of two transgender kids
213.	000027777	Parent of transgender child who has been subject to "horrific treatment"
214.	000028521	Person whose transgender teenager was discriminated against in ER
215.	000029190	Physician who cares for transgender youth
216.	000029393	Transgender person who fears refusal of care
217.	000029717	Gay individual who needs infusion treatments and fears denial of care

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
218.	000029955	Father of gay son concerned about discrimination
219.	000030586	"My daughter is transgender and her life is already difficult"
220.	000030768	Woman fears denial of access to birth control
221.	000030882	Woman concerned that she and her wife can go to any doctor
222.	000033830	Parent of gay son upset about discrimination
223.	000035302	Transgender individual who was refused service in town and had to drive 2 hours
224.	000035408	Lives in rural area and worries about access
225.	000052491	Transgender man who could be denied access to care
226.	000054575	Transgender woman denied breast-augmentation surgery in DC
227.	000054588	Mother of LGBTQ adult also concerned about hostile work environment in medical field
228.	000054594	"My daughter deserves treatment"
229.	000055272	Transgender individual who could be denied care
230.	000055280	Queer woman and partner whose desire to build a family may be harmed
231.	000055322	Person with transgender child
232.	000055326	Gay minister living with AIDS fears denial of service
233.	000055347	"Because I am gay and live in a rural area, my son (who is not gay) and I have been refused healthcare by our local clinic."
234.	000056864	Transgender individual who requires hormones; denial of care would be a "death sentence"
235.	000056996	Employee of organization that provides medical care for transgender individuals, many who have been afraid of seeking care
236.	000057188	Person with transgender child

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
237.	000057215	Lives in rural area and worries about access
238.	000057309	Gay man who has been shamed from PrEP treatment
239.	000057477	Queer woman rejecting discrimination
240.	000057785	Has transgender daughter, do not take away healthcare
241.	000057844	Transgender man who fears being unable to travel to visit family due to lack of emergency care
242.	000057855	Gay man and healthcare professional rejects discrimination
243.	000059058	Lesbian and Catholic fearing for access
244.	000065789	"My son is transgender and it scares me to think that his health could suffer, legally, because of this new rule."
245.	000066141	Court-appointed special advocate for foster youth fighting for transgender healthcare
246.	000066168	Rural area, was delayed when wanting to know about abortion
247.	000066293	Queer teenager does not look forward to being denied proper care
248.	000066464	Gender-diverse person with chronic illnesses who has been discriminated against
249.	000066474	Trans woman who has experienced "lower class treatment"
250.	000066529	Wants LGBT son to be able to receive care
251.	000066537	Parent of lesbian and sibling of gay man who should not be discriminated against
252.	000066557	Gender affirmation surgery is hard to obtain. "I experience a lot of shaming associated with healthcare discrimination."
253.	000066574	"Active duty, transgender, Airman stationed on Okinawa" who had difficulty getting care
254.	000066595	Father of deceased LGBTQ son

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
255.	000066734	Trans man who needs gynecological care
256.	000066808	Member of Portland's LGBT community who fears for loved ones who get in an accident
257.	000066850	Fears for transgender sister who could be denied care
258.	000066993	Lives in rural area
259.	000067037	Providers are heteronormative and ignorant about queer health issues
260.	000067068 - 000067069	Transgender individual fearing discrimination and listing research and statistics
261.	000067073	Gay individual who does not hide the fact but fears discrimination as a result
262.	000067094	Closeted trans man; fear prevents getting medical care
263.	000067095	Queer woman has struggled even with well-intentioned doctors
264.	000067149	Woman fears denial of abortion or family planning services
265.	000067154	Transgender woman refused gender confirmation surgery in PA
266.	000067434	“As a woman and a queer person, I should not be discriminated against because of my identity.”
267.	000067206	Fears for care for partner and herself, especially if they start a family
268.	000067233	Transgender man who fears denial care for even a broken arm
269.	000067262	Transgender woman who almost died due to denial of care
270.	000067273	Queer person already faces discrimination
271.	000067290	Queer woman who thinks refusal of care is “cruel and inhuman”
272.	000067291	Queer woman afraid of bigotry in healthcare
273.	000067439	Bisexual individual has received supportive care but witnesses discrimination as an EMT

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
274.	000067473	Rabbi who has worked with people who were denied access to care or to visit partners
275.	000067486	Transgender and queer person who has faced obstacles
276.	000067518	Queer woman who has had doctors make assumptions and ask offensive questions
277.	000067534	Trans and gender queer individual who has received biased care
278.	000067542	Queer woman who hasn't experienced healthcare discrimination but fears it
279.	000067655	Nonbinary person who has already experienced small instances of discrimination
280.	000067778	Physician who has heard from transgender patients about poor care; also concerned about gender queer daughter
281.	000067786	Transgender patient who had to fight to get medical records updated
282.	000067845	Queer woman has faced discrimination
283.	000071280	Queer woman and partner of trans man who has to evade invasive questions
284.	000071330	Grandmother because in viro fertilization allowed her daughter and wife to have kids
285.	000071412	Lost a transgender friend because a doctor refused to "waste" a donor kidney
286.	000071454	Gay man concerned about discrimination for himself and friends and family
287.	000071528	Queer woman needs healthcare to stay intact
288.	000071588	Pansexual individual says no one should be refused care
289.	000071643	Spouse of woman who died from MS fears removal of dignity from the dying
290.	000134033	"This legislation affects me personally as I am transgender."

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
291.	000134055	Queer person has "refrained from being honest" with doctor to receive care
292.	000134077	Discrimination affects her transgender daughter
293.	000134121	"As a transgender person, getting adequate and holistic healthcare is already extremely difficult."
294.	000134191	"As a queer person I search for doctors who will treat me with respect. Please do not make this harder for me then it already is."
295.	000134290	10-year-old son is transgender, fear for care in emergency
296.	000134482	77-year-old fears doctors who believe people should suffer before dying
297.	000134515	Person's son is navigating his sexual identity and deserves the same right to services
298.	000134770	Grandmother of transgender individual
299.	000134797	Transgender person who has had difficulties getting routine care
300.	000134816	Mother of transgender adult child
301.	000134857	Bisexual woman hasn't faced discrimination but fears refusal of care based on who she loves
302.	000134880	Fortunate to have transgender doctor, rare in rural CO
303.	000134884	Queer woman with diabetes and depression fearing access to understanding providers
304.	000135797	Same-sex partner "lucky" to be able to visit spouse after giving birth
305.	000135903	Gay doctor who cares for LGBTQ patients and fears for them and himself
306.	000135973-000136474	Compilation of comments from NCTE
307.	000137569	"You cannot permit a medical provider the right to refuse service because I am gay."

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
308.	000137730	Parent of trans son already facing discrimination
309.	000139149	Dropped from insurance when husband transitioned
310.	000139364	Teacher with transgender students and friends
311.	000139941	LGBTQ individual thinks the rule would give murderers better healthcare than LGBTQ individuals
312.	000139951-000139952	Queer woman and HIV-advocacy attorney objects to allowing discrimination
313.	000140241	"As a trans woman, I am deeply disappointed in your lack of dedication to serve all Americans equally."
314.	000148925	"We're a same gender family with a gay son. We've had to seek out health care practitioners who are LGBT friendly."
315.	000148937	Transgender person who avoids seeing the doctor, was previously discriminated against when identifying as lesbian
316.	000148944	Black queer person already faces racial discrimination
317.	000148965	Queer person trying to start a family fears discrimination for self or future children
318.	000148983	Has pastored individuals who were discriminated against
319.	000149039	Individual with intersexed and transgender wife who already have to travel for care
320.	000149044	Mother of lesbian daughter and gay son concerned about appropriate health care
321.	000149049	Queer patient who has relied on antidiscrimination laws
322.	000149055	"Do I not deserve health care because I'm trans?"
323.	000149114	Transgender person who has experienced hostile healthcare workers
324.	000149158	"I am a transgender female and my procedures and medications are important to my health."

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
325.	000149166	"As an LGBTQ person, my rights could be at stake with this proposed rule."
326.	000149167	Gay nurse who has seen discrimination affecting care
327.	000149699	Trans person who has had healthcare providers "turn cold" when finding out patient is trans
328.	000150714	Trans individual who was not treated after NP disparaged
329.	000151241	Individual with queer and transgender friends who return from medical care in tears or delay treatment
330.	000152179	Queer person with chronic pain needs compassionate comprehensive care
331.	000152692	Student fears hormone replacement therapy will be inaccessible after graduation
332.	000154205	Person with transgender grandchild
333.	000155213	Post-op trans who has been dead-named and "viewed" by med students
334.	000160468	"As a transgender person, I should not be afraid to seek medical care because I may be turned away simply because of my sex at birth."
335.	000160536	Parent of trans teen worried about the impact on medical care
336.	000160540	Trans person wants doctors not to discriminate
337.	000160561	Trans person saying that carers shouldn't be able to deny care
338.	000160574	Gay man already struggles to find healthcare
339.	000160632	Queer individual who fears being turned away
340.	000160694	Parent worried about visitation rights for son's committed partner
341.	000160780	Transgender woman with limited healthcare options in rural OR
342.	000160846	Nurse with transgender son

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
343.	000160865	Lesbian former NP who treated transgender and non-binary patients
344.	000160887	Transgender individual with autoimmune condition, dismissed by hematologist
345.	000160908	Transgender individual who is frequently misgendered and has experienced discrimination
346.	000160911	"I was denied care by over 50 doctors because I am transgender and then I had to drive 4 hours to get the needed care."
347.	000160921	"My son is gay, and as his proud mother I worry that he will not Be treated fairly or treated at all."
348.	000160965	"I am transgender. I have had occasions to be treated by doctors as though my trans-ness is contagious."
349.	000160989	"Discriminating impacts my son. This is not equality."
350.	000161005	"As a Christian who is LGBT, my life or quality of life (and that of my family) should not depend on the personal Religious beliefs of a medical professional."
351.	000161013	Gay male who has been refused medical treatment and visitation
352.	000161014	Bisexual and non-binary individual who reports discriminatory treatment
353.	000161019	Gay individual with chronic disease and few health insurance options
354.	000161020 - 000161021	Transgender individual writing about problems accessing care
355.	000161031	Queer woman shouldn't have to watch her words when receiving healthcare
356.	000161041	Disabled veteran living in rural area
357.	000161044	"Military spouse who happens to be transgender"
358.	000161045	Individual with transgender friends and students

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EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
359.	000161062	LGBT woman with family history of ovarian cancer fears denial of a hysterectomy or other care
360.	000161064	Transgender man with two life-threatening illnesses
361.	000161168	"I've been refused treatment before for no other reasons than being transgender."
362.	000161173	"I do not expect either my daughter or her daughter, or her wife to be given anything less than the highest standard of care when they are sick."
363.	000161175	Friend was not treated by paramedics after hemorrhage from transition surgery
364.	000161187	Transgender man who does not want to be "scared to go to the doctor"
365.	000161190	Transgender person could be "left to die on the road by emergency workers"
366.	000161296	"My transgender son's LIFE depends upon ongoing health care"
367.	000161307	Gay man remembers HIV stigma and fears additional discrimination
368.	000161312	Transmale person who has been discriminated against
369.	000161346	Parent of gay son concerned about discrimination
370.	000161369	"I am trans and have already had an incredibly difficult time finding a doctor who will see me. These rules will make that even worse.
371.	000161373	Transgender individual who had trouble finding a doctor even in San Francisco
372.	000161392	Parent of gay daughter who should have the same right to care as her twin sister
373.	000161396	Parent of gay daughter and healthcare worker who has never refused treatment
374.	000171131 - 000171630	Compilation of comments from Planned Parenthood

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
		Other Excerpts from the Record
375.	000537549 - 000537560	Armand H. Matheny Antommaria, *Adjudicating rights or analyzing interests: ethicists' role in the debate over conscience in clinical practice*, Theor. Med. Bioeth. 29:201-212 (2008)
376.	000537563 - 000537577	Lisa H. Harris *et al.*, *Obstetrician-Gynecologists' Objections to an Willingness to Help Patients Obtain and Abortion*, Obstet. Gynecol. 118(4): 905-912 (October 2011)
377.	000537892 - 000537893	Douglas B. White & Baruch Brody, *Would Accommodating Some Conscientious Objections by Physicians Promote Quality in Medical Care?*, JAMA, Vol. 305, No. 17 (May 4, 2011)
378.	000537894 - 000537900	Josh Hyatt, *Recognizing Moral Disengagement and Its Impact on Patient Safety*, J. of Nursing Reg., Vol. 7, Issue 4 (Jan. 2017)
379.	000537901 - 000537923	Joan McCarthy & Chris Gastmans, *Moral distress: A review of the argument based nursing ethics literature*, Nursing Ethics, Vol. 22(I), 131-152 (2015)
380.	000537924 - 000537931	Farr A. Curlin, *et al.*, Religion, Conscience, and Controversial Clinic Practice, N. Engl. J. Med., 356:593-600 (2017)
381.	000538029 - 000538045	Christy A. Rentmeester, *Moral Damage to Health Care Professionals and Trainees: Legalism and Other Consequences for Patients and Colleagues, Journal of Medicine and Philosophy*, J. Med. & Philosophy, 33: 27-43 (2008)
382.	000538046 - 000538051	Kathleen M. Morrell and Wendy Chavkin, *Conscientious Objection to Abortion and Reproductive Healthcare: A Review of Recent Literature and Implications for Adolescents*, Curr. Opin. Obstet. Gynecol. 27:333-338 (2015)
383.	000538052 - 000538075	Emmanuel Scheppers, *et al.*, Potential Barriers to the Use of Health Services Among Ethnic Minorities: A Review, Family Practice 23: 325-348 (2006)
384.	000538670 – 000538674	Michael P. Combs *et al.*, *Conscientious refusal to refer: findings from a national physician survey*, J. Med. Ethics 37:397-401 (2011)
385.	000538675 - 000538708	*Conscientious objection to the provision of reproductive health care*, Ed. Wendy Chavkin, Supp. to Int'l J. Gynecology & Obstetrics 123 Supp. 3
386.	000538709 - 000538727	Stephen J. Genuis and Chris Lipp, Review Article: *Ethical Diversity and the Role of Conscience in Clinical Medicine*, Int'l J. Family Medicine (2013)
387.	000538733 - 000538740	Fariba Borhani *et al.*, *The relationship between moral distress, professional stress, and intent to stay in nursing profession*, J. Med. Ethics & History of Med. 7:4 (2014)
388.	000538792 - 000538810	Fallon Chipidza *et* al., *Impact of the Doctor-Patient Relationship*, Prim. Care Companion CNS Discord. 2015; 17(5)
389.	000538816 - 000538821	Ezekiel Emmanuel *et al.*, *Euthanasia and Physician-Assisted Suicide: attitudes and experiences of oncology patients, oncologists, and the public*, The Lancet 347, 9018 (Jun. 29, 1996)

EXHIBIT	AR NUMBER	DESCRIPTION OF DOCUMENT
390.	000548516 - 000548598	Hill, et al., Reproductive Health Care in Catholic-Owned Hospitals, NBER Working Paper No. 23768 (2017)
391.	000548505 - 000548515	Thorne, et al., *Reproductive Health Care in Catholic Facilities: A Scoping Review*, Obstet. Gynecol. 2019;133:105–15
392.	000548500 - 000548504	Lori R. Freedman, *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008)
393.	000548434 - 000548435	Julie D. Cantor, M.D., J.D., *Conscientious Objection Gone Awry—Restoring Selfless Professionalism in Medicine*, 360 New England J. Med. 1484–85 (April 9, 2009)
394.	000541576 - 000541577	OMB Meeting Notes with Alliance Defending Freedom
395.	000541578 – 000541580	OMB Meeting Notes with Alliance Defending Freedom
396.	000546807 - 000546811	Letter from OCR Director to Complainants (June 21, 2016)
397.	000546783 - 000546794	Letter from Roger T. Severino (OCR) to Xavier Becerra (Jan. 18, 2019)
398.	000548420 - 000548433	Letters from Michelle Rouillard (DMHC) to Seven Insurers Re: Limitations or Exclusions of Abortion Services (Aug. 22, 2014)
399.	000537821 - 000537828	FY 2017 HHS Awards to the State of California, Pivot Table
400.	000537807 - 000537820	FY 2017 HHS Awards to Counties
401.	000537758 - 000537801	FY 2016 HHS Awards to Junior Colleges, Colleges, and Universities
402.	000541228 - 000541233	Notes from Listening Session with California Attorney General, Oregon Attorney General, CDHHS, CDHCS (Feb. 15, 2019)
403.	000537609 - 000537613	Christian Medical Association and Freedom2Care poll data
404.	000548707 - 000548710	Kellyanne Conway Memorandum re "Key Findings on Conscience Rights Polling" (April 8, 2009)
405.	000058342 - 000058346	National Women's Law Center Fact Sheet

CERTIFICATE OF SERVICE

Case Name: **State of California v. Alex M. Azar, et al.** No. **3:19-cv-02769-WHA**

I hereby certify that on September 9, 2019, I electronically filed the following documents with the Clerk of the Court by using the CM/ECF system:

PLAINTIFFS' APPENDIX IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

I certify that **all** participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

I declare under penalty of perjury under the laws of the State of California the foregoing is true and correct and that this declaration was executed on September 9, 2019, at Sacramento, California.

Ashley Harrison	/s/ Ashley Harrison
Declarant	Signature

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Exhibit 5

March 27, 2018

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

Submitted electronically

Re: Proposed New 45 CFR Part 88 Regarding Refusals of Medical Care

The ACLU of Northern California, the ACLU of Southern California, and the ACLU of San Diego and Imperial Counties (collectively "ACLU of California") submit these comments on the proposed rule published at 83 FR 3880 (January 28, 2018), RIN 0945-ZA03, with the title "Ensuring that the Department of Health and Human Services [the "Department"] Does Not Fund or Administer Programs or Activities that Violate Conscience and Associated Anti-Discrimination Laws" (the "Proposed Rule" or "Rule").

The ACLU of California is a collaboration of the three California-based ACLU affiliates with more than 300,000 members and supporters, working to protect and advance the civil rights and civil liberties of all Californians. The ACLU of California has a long history of vigorously defending religious liberty. We are equally vigilant in our efforts to safeguard reproductive rights and to end discrimination against those who have historically been excluded or diminished by more powerful actors in society, including in health care settings. The ACLU of California is thus particularly well-positioned to comment on the Proposed Rule and the serious concerns it raises about access to reproductive and other health care, based on the religious or other beliefs of institutions or individual providers. We steadfastly protect the right to religious freedom. But that right does not include a right to harm others as this Proposed Rule contemplates.

Without any regulatory authority, the Department has proposed a rule that vastly expands narrow statutory sections in ways Congress never intended, in a manner unsupportable by the terms of the statutes, and in a way that upsets the careful balance struck by other federal laws, all in an effort to grant health care providers unprecedented license to refuse to provide care and information to patients. In so doing, the Proposed Rule does not mention, much less grapple with, the consequences of refusals to provide full information and necessary health care to patients. The denials that the Rule proposes to protect will have significant consequences for individuals in terms of their health and well-being, in addition to financial costs. And, because the Proposed Rule is tied to entities that receive federal funding, those consequences will fall most heavily on poor and low-income people who must rely on government-supported programs

and institutions for their care and who will have few, if any, other options if they are denied appropriate care. The Proposed Rule amounts to a license to discriminate, made all the worse because the federal purse will be used to further that discrimination.

The Proposed Rule is not only extremely detrimental to patient health, it is also entirely unnecessary. Individual providers' religious and moral beliefs are already strongly protected by federal law that, among other things, forbids religious discrimination and requires employers to provide reasonable accommodation of an employee's religious objections.

Because the Proposed Rule harms patient health, encourages discrimination against patients, and exceeds the Department's rulemaking authority, it should be withdrawn. If the Department refuses to do so, it must, at a minimum, revise the Proposed Rule so that it aligns with the statutory provisions it purports to implement, makes clear that it is not intended to conflict with or preempt other state or federal laws that protect and expand access to health care, and mitigates the Rule's harm to patients' health and well-being.

1. The Proposed Rule Ignores Its Impact on Patients' Health and Invites Harms That Will Disproportionately Fall on Women and Marginalized Populations

The Proposed Rule, cloaked in the language of non-discrimination, tramples on fundamental civil rights principles to protect those who discriminate rather than those who are discriminated against. In so doing, the Department wholly ignores harm to people seeking health care, thereby abandoning its mission to "protect the health and well-being of all Americans." *See* HHS, https://www.hhs.gov/about/index.html.

But this failure to address the obvious consequences of giving federally subsidized providers *carte blanche* to decide whom to treat or not treat based on religious or moral convictions—or indeed, based on any reasoning or none at all[1]—does not mean the harm does not exist. In fact, the harms would be substantial. For example, the Proposed Rule:

- Appears to provide immunities for health care institutions that receive federal funding and professionals who work in federally funded programs to refuse to provide complete information to patients about their condition and treatment options;
- Purports to create new "exemptions," so that patients who rely on federally subsidized health care programs, such as Title X, may be unable to obtain services those programs are required by law to provide;
- Causes confusion about whether hospitals can prevent staff from providing emergency care to pregnant women who are suffering miscarriages or otherwise need emergency abortion care; and

[1] Although the Notice of Proposed Rulemaking highlights religious freedom and rights of conscience, a number of the referenced statutes—and the proposed expansions of those in the Rule—do not turn on the existence of any religious or moral justification. The Proposed Rule would empower not only those acting based on conscience, but others acting, for example, out of bare animus toward a patient's desired care or any aspect of their identity.

- Invites health care providers to discriminate against individuals based on who they are, for example, by refusing to provide otherwise available services to a patient for the sole reason that the patient is transgender.

These harms would fall most heavily on historically disadvantaged groups and those with limited economic resources. As the ACLU's own cases and requests for assistance reflect, women, LGBT (lesbian, gay, bisexual and transgender) individuals, people of color, immigrants, young people, people with disabilities, and members of other groups who continue to struggle for equal rights are those who most often experience refusals of care. Likewise, poor and low-income people, and people living in rural communities, will also suffer acutely under the Proposed Rule. They are more likely to rely on health care that is in some manner tied to federal funding, and less likely to have other options at their disposal if they are denied access to care or information. All of these communities already suffer health disparities and discrimination, which could be sanctioned and exacerbated by the Rule. Because it will limit access to health care, harm patients' outcomes, and undermine the central, public health mission of the Department, the Proposed Rule should be withdrawn.

2. The Department Lacks the Authority to Issue the Proposed Rule

The Proposed Rule references the Church Amendments, 42 U.S.C. § 300a-7, the Coats-Snowe Amendment, 42 U.S.C. § 238n, the Weldon Amendment, Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, Tit. V, § 507(d), and other similar "protections" or "exemptions," *see* 83 FR 3880, that sometimes allow, under narrow circumstances, health care professionals to avoid providing certain medical procedures or that limit the actions that may be taken against them if they refuse to provide care (collectively, the "Refusal Statutes"). The Preamble to the Rule focuses most extensively on the Church, Coats, and Weldon Amendments (the "Amendments"), and the Rule itself purports to establish extraordinarily expansive new substantive requirements, compliance steps, and enforcement authority under them.

But the Department does not possess *any* legislative rulemaking powers under those Amendments and wholly lacks the authority to promulgate the Proposed Rule as it applies to them. None of those Amendments includes, or references, any explicit delegation of regulatory authority. *Compare, e.g.*, 42 U.S.C. § 2000d-1 (expressly directing all relevant federal agencies to issue "rules, regulations, or orders of general applicability" to achieve the objectives of Title VI). Nor does any implicit delegation of legislative rulemaking authority exist for these provisions. For this reason alone, the Department cannot properly proceed to adopt the Proposed Rule or any similar variation of it.

3. The Proposed Rule Impermissibly Expands the Narrow Referenced Statutes and Does So In Ways That Ignore The Statutes' Limited Terms and Purposes

Even if the Department had the necessary rulemaking authority (which it does not), the Proposed Rule's virtually unbounded definition of certain terms and expansions of the Refusal Statutes' reach would broaden the Refusal Statutes beyond reason and recognition, create conflict with federal law, and lead to denials of appropriate care to patients. While we do not

attempt to catalogue each way in which the Proposed Rule impermissibly expands the Refusal Statutes, a few examples follow.

A. Assist in the Performance

For example, Subsection (c)(1) of the Church Amendments prohibits recipients of certain federal funds from engaging in employment discrimination against health care providers who have objected to performing or "assist[ing] in the performance of" an abortion or sterilization. 42 U.S.C. § 300a-7(c)(1). Under the Proposed Rule, however, the Department defines "assist in the performance" of an abortion or sterilization to include not only assistance *in the performance* of those actual procedures – the ordinary meaning of the phrase – but also to participation in any other activity with "an articulable connection to a procedure[.]" 83 FD 8892, 3923. Through this expanded definition, the Department explicitly aims to include activities beyond "direct involvement with a procedure" and to provide "broad protection"—despite the fact that the statutory references are limited to "assistance in the performance of" an abortion or sterilization procedure itself. 83 FR 3892. *cf. e.g.*, 42 U.S.C. § 300a-7(c)(1).

This means, for example, that simply admitting a patient to a health care facility, filing her chart, transporting her from one part of the facility to another, or even taking her temperature could conceivably be considered "assist[ing] in the performance" of an abortion or sterilization, as any of those activities could have an "articulable connection" to the procedure. As described more fully below, the Proposed Rule could even be cited by health care providers who withhold basic information from patients seeking information about abortion or sterilization on the grounds that "assist[ing] in the performance" of a procedure "includes but is not limited to counseling, referral, training, and other arrangements for the procedure." 83 FR 3892, 3923.

But the term "assist in the performance" simply does not have the virtually limitless meaning the Department proposes ascribing to it. The Department has no basis for declaring that Congress meant anything beyond actually "assist[ing] in the performance of" the specified procedure—given that it used that phrasing, 42 U.S.C. §§ 300a-7(c)(1)—and instead meant any activity with any connection that can be articulated, regardless of how attenuated the claimed connection, how distant in time, or how non-procedure-specific the activity.

B. Referral or Refer for

Others of the Refusal Statutes provide limited protections to certain health care entities and individuals that refuse to, among other things, "refer for" abortions. For those statutes, the Proposed Rule expands "referral or refer for" beyond recognition, by proposing to define a referral as "the provision of *any* information … by any method … pertaining to a health care service, activity, or procedure … that could provide *any assistance* in a person obtaining, assisting, … financing, or performing" it, where the entity (including a person) doing so "sincerely understands" the service, activity, or procedure to be a "possible outcome[.]" 83 FR 3894-95 (emphasis added), 3924. This wholesale re-definition of the concept of "referral" could have dire consequences for patients. For example, a hospital that prohibits its doctors from even discussing abortion as a treatment option for certain serious medical conditions could attempt to claim that the Rule protects this withholding of critical information because the hospital

"sincerely understands" the provision of this information to the patient may provide some assistance to the patient in obtaining an abortion.

Providing a green light for the refusal to provide information that patients need to make informed decisions about their medical care not only violates basic medical ethics, but also far exceeds Congress's language and intent. A referral—as used in common parlance, the underlying statutes, and the government's own websites—has a far more limited meaning than providing *any* information that *could* provide *any assistance whatsoever* to a person who may ultimately decide to obtain, assist, finance, or perform a given procedure sometime in the future. The meaning of "referral or refer for" in the health care context is to *direct* a patient elsewhere for care. *See* Merriam-Webster, https//www.merriam-webster.com/dictionary/referral ("referral" is "the process of directing or redirecting (as a medical case or a patient) to an appropriate specialist or agency for definitive treatment"); U.S. Centers for Medicare & Medicaid Services, https://www.healthcare.gov/glossary/referral/ ("referral" is "a written order from your primary care doctor for you to see a specialist or get certain medical services").

C. Discriminate or Discrimination

These expansive definitions are all the more troubling given the Proposed Rule's definition of "discrimination," which purports to provide unlimited immunity for institutions that receive some federal funds to deny abortion care, to block coverage for such care, or to stop patients' access to information, no matter what the patients' circumstances or the mandates of state or federal law. Likewise, the definition appears aimed at providing immunity for employees who refuse to perform central parts of their job, regardless of the impact on the ability of a health care entity to provide appropriate care to its patients. This expansion of "discrimination" would apparently treat virtually any adverse action – including government enforcement of a patient non-discrimination or access-to-care law – against a health care facility or individual as *per se* discrimination. But "discrimination" does not mean any negative action, and instead requires an assessment of context and justification, with the claimant showing unequal treatment on prohibited grounds under the operative circumstances. The Proposed Rule abandons, for example, the nuanced and balanced approach required by Title VII, and also ignores other federal laws, state laws, and providers' ethical obligations to their patients. *See infra* Parts 4-6.

D. Other Expansions of the Scope of the Refusal Statutes

The Proposed Rule not only distorts the definitions of words in the statutes, but also alters the statutes' substantive provisions in other ways to attempt to expand the ability of individuals and entities to deny care in contravention of legal and ethical requirements and to the severe detriment of patients. Again, these comments do not attempt to exhaustively catalogue all of the unauthorized expansions but instead provide a few illustrative examples.

For example, Congress enacted Subsection (d) of the Church Amendment in 1974 as part of Public Law 93-348, a law that addressed biomedical and behavioral research, and appended that new Subsection (d) to the pre-existing subsections of Church from 1973, which all are codified within 42 U.S.C. § 300a-7: the "Sterilization or Abortion" section within the code

subchapter that relates to "Population Research and Voluntary Family Planning Programs." Despite this explicit context for Subsection (d), and Congress's intent that it apply narrowly, however, the Proposed Rule attempts to import into this Subsection an unduly broad definition of "health service program," along with the expansive definitions discussed above, to purportedly transform it into a much more general prohibition that would apply to any programs or services administered by the Department, and that would assertedly prevent any entity that receives federal funding through those programs or services from requiring individuals to perform or assist in the performance of actions contrary to their religious beliefs or moral convictions. *See* 83 FR 3894, 3906, 3925. This erroneous expansion of Church (d), as described in this attempted rule-making, could prevent health care institutions from ensuring that their employees provide appropriate care and information. It would purportedly prevent institutions taking action against members of their workforce who refuse to provide any information or care that they "sincerely understand" may have an "articulable connection" to some eventual procedure to which they object—no matter what medical ethics, their job requirements, Title VII, or laws directly protecting patient access to care may require.

The Rule similarly attempts to expand the Coats Amendment beyond its limited provisions, which apply to certain "governmental activities regarding training and licensing of physicians," 42 U.S.C. § 238n (quoting title), to apply *regardless* of context. Thus, rather than being confined to residency training programs as Congress intended, the Proposed Rule purports to give all manner of health care entities, including insurance companies and hospitals, a broad right to refuse to provide abortion and abortion-related care. In addition, the Rule's expansion of the terms "referral" and "make arrangements for" extends the Coats Amendment to shield any conduct that would provide "any information … by any method … that could provide *any assistance* in a person obtaining, assisting, … financing, or performing" an abortion or that "render[s] aid to anyone else reasonably likely" to make an abortion referral. 83 FR 3894-95 (emphasis added), 3924. This expansive interpretation not only goes far beyond congressional intent and the terms of the statute, it also could have extremely detrimental effects on patient health. For example, it would apparently shield, against any state or federal government penalties, a women's health center that required any obstetrician-gynecologist practicing there who diagnosed a pregnant patient as having a serious uterine health condition to refuse to provide her with even the name of an appropriate specialist, because that specialist "is reasonably likely" to provide the patient with information about abortion.

Similarly, as written, the Weldon Amendment is no more than a bar on particular appropriated funds flowing to a "Federal agency or program, or State or local government," if any of those government institutions discriminate on the basis that a health care entity does not provide, pay for, provide coverage of, or refer for abortion. Pub. L. No. 115-31, Div. H, Tit. V, § 507(d)(1). Yet again, however, the Proposed Rule attempts to vastly increase its reach by (i) expanding the scope of the federal funding streams to which the Weldon Amendment prohibition reaches and (ii) binding "any entity" that receives such funding—not just the government entities listed in the Amendment—to its proscriptions. 83 FR 3925. These unauthorized expansions, combined with the expansive definitions discussed *supra*, can lead to broad and harmful denials of care. For example, under this unduly expansive interpretation of Weldon, an organization that refuses to discuss the option of abortion with people who discover they are pregnant may claim a right to participate in the Title X program, despite the fact that both federal law and medical

ethics require that Title X patients be provided with counseling about all of their options. *See, e.g.*, 42 C.F.R. § 59.5(a)(5).

The Department should withdraw the Rule to prevent it from impeding health care and harming patients. But if it does not do so, each of the definitions must be clarified and revert to the terms' proper meaning, and each of the substantive requirements should track only those provisions actually found in the Refusal Statutes themselves.

4. The Rule Undermines Legal and Ethical Requirements of Fully Informed Consent

The Proposed Rule appears to allow institutional and individual health care providers to manipulate and distort provider-patient communications and deprive patients of critical health care information about their condition and treatment options. While the Proposed Rule's Preamble suggests the Rule will improve physician-patient communication because it will purportedly "assist patients in seeking counselors and other health-care providers who share their deepest held convictions," 83 FR 3916-17, the notion that empowering health care providers to deny care to and withhold information from some patients is somehow necessary to enable other patients to identify like-minded providers strains credulity: Patients are already free to inquire about their providers' views, and patients' own expressions of faith and decisions based on that faith must already be honored. *Cf. id.* Allowing *providers* to decide what information to share– or not share—with patients, regardless of the patient's needs or the requirements of informed consent and professional ethics would gravely harm trust and open communication in health care, rather than aiding it.

As the American Medical Association's Code of Medical Ethics ("AMA Code") explains, the relationship between patient and physician "gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own self-interest[.]" AMA Code § 1.1.1. Even in instances where a provider's beliefs are opposed to a particular course of action, the provider must "[u]phold standards of informed consent and inform the patient about all relevant options for treatment, including options to which the physician morally objects." *Id.* § 1.1.7(e).

Acknowledging the right of every patient to receive basic information necessary to competently make decisions about their own health, California law requires that patients receive full and complete information about the health care services available. Withholding this vital information from patients violates fundamental legal and ethical principles, deprives patients of the ability to make informed decisions, and leads to negligent care.

By erroneously expanding the meaning of "assist in the performance of," "refer for" and "make arrangements for," as described above, the Proposed Rule purports to allow health care providers to refuse to provide basic information to patients in ways that were never contemplated by the underlying statutes. As described above, these broad definitions may be used to immunize the denial of basic information about a patient's condition as well as their treatment options.

If the Department moves forward with the Proposed Rule, it should, among other necessary changes, modify it to make clear that it does not subvert basic principles of medical ethics and does not protect withholding information from a patient about her condition or treatment options.

5. By Failing to Acknowledge Other Federal Laws, the Proposed Rule Will Lead to Confusion, Denials for Care, and Harm to Patients

A. Title VII

The Proposed Rule is not only unauthorized and harmful to patients, it is also unnecessary to accommodate individual workers—federal law already amply protects individuals' religious freedom in the workplace. For more than four decades, Title VII has required employers to make reasonable accommodations for current and prospective employers' religious beliefs so long as doing so does not pose an "undue hardship" to the employer. 42 U.S.C. §§ 2000e(j), 2000e-(2)(a); *Trans World Airlines, Inc. v. Hardison*, 432 U.S. 63, 84 (1977); EEOC Guidelines, 29 C.F.R. § 1605.2(e)(1).[2] Thus, Title VII—while protecting freedom of religion—establishes an essential balance. It recognizes that an employer cannot subject an employee to less favorable treatment because of that individual's religion and that generally an employer must accommodate an employee's religious practices. However, it does not require accommodation when the employee objects to performing core job functions, particularly when those objections harm patients, depart from the standard of care, or otherwise constitute an undue hardship. *Id.* This careful balance between the needs of employees, patients, and employers is critical to ensuring that religious beliefs are respected while at the same time health care employers are able to provide quality health care to their patients.

Despite this long-standing balance and the lack of any evidence that Congress intended the Refusal Statutes to disrupt it, the Proposed Rule does not even mention these basic federal legal standards or the need to ensure patient needs are met. Instead, by presenting a seemingly unqualified definition of what constitutes "discrimination," 83 FR 3892-93, 3923-24, and expansive refusal rights, the Department appears to attempt to provide complete immunity for religious refusals in the workplace, no matter how significantly those refusals undermine patient care, informed consent, or the essential work of institutions established for the purpose of promoting health. Indeed, the Rule is explicit in seeking not simply a "level playing field" and reasonable accommodation, but rather an unlimited ability for individuals to "be[] free not to act contrary to one's beliefs," regardless of the harm it causes others and without any repercussions. *Id.* Such an interpretation could have a drastic impact on the nation's safety-net providers' ability to provide high quality care by requiring, for example, a family planning provider to hire a counselor to provide pregnancy options counseling even if the counselor refuses to comply with ethical and legal obligations to inform patients of the availability of abortion. If the Department does not withdraw the entire Rule, therefore, it should explicitly limit its reach and make clear that Title VII provides the governing standard for employment situations.

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[2] Religion for purposes of Title VII includes not only theistic beliefs, but also non-theistic "moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views." Equal Employment Opportunity Commission ("EEOC") Guidelines, 29 C.F.R. §1605.1.

B. EMTALA

The Proposed Rule also puts patients at risk by ignoring the federal Emergency Medical Treatment and Labor Act ("EMTALA") and hospitals' obligations to care for patients in an emergency. As Congress has recognized, a refusal to treat patients facing an emergency puts their health and, in some cases, their lives at serious risk. Through EMTALA, Congress has required hospitals with an emergency room to provide stabilizing treatment to any individual experiencing an emergency medical condition or to provide a medically beneficial transfer. 42 U.S.C. § 1395dd(a)-(c).

The Refusal Statutes do not override the requirements of EMTALA or similar state laws, like California's, that require health care providers to provide abortion care to a woman facing an emergency. *See, e.g.*, *California v. U.S.*, Civ. No. 05-00328, 2008 WL 744840, at *4 (N.D. Cal. March 18, 2008) (rejecting notion "[t]hat enforcing [a state law requiring emergency departments to provide emergency care] or the EMTALA to require medical treatment for emergency medical conditions would be considered 'discrimination' under the Weldon Amendment if the required medical treatment was abortion related services").

It is particularly troubling, therefore, to have the Department use attempts to require hospitals to comply with their obligations under EMTALA in its Preamble as *justification* for expanding the Refusal Statutes. 83 FR 3888-89. For example, the Preamble discusses the case brought by the ACLU on behalf of Tamesha Means who at 18 weeks of pregnancy began to miscarry and sought care, not once but three times, at her local hospital. 83 FR 3888-89. Despite the fact that she was bleeding, in severe pain, and had developed a serious infection, the hospital repeatedly sent her away and never told her that her health was at risk and that having an abortion was the safest course for her. *See* Health Care Denied 9-10 (May 2016), *available at* https://www.aclu.org/report/report-health-care-denied?redirect=report/health-care-denied. But the ethical imperative is the opposite: "In an emergency in which referral is not possible or might negatively affect a patient's physical or mental health, providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections." 83 FR 3888 (quoting American Congress of Obstetricians and Gynecologists ("ACOG") Committee Opinion No. 365) (reaffirmed 2016).

The Proposed Rule suggests that hospitals like the one who put Ms. Means's health at risk should be given a free pass. Yet doing so would not only violate EMTALA, but also other legal, professional, and ethical principles governing access to health care in this country. For that reason, if not withdrawn in its entirety, the Proposed Rule should, at minimum, clarify that it does not disturb health care providers' obligations to provide appropriate care in an emergency.

C. Section 1557

The Proposed Rule also puts patients at risk by ignoring the federal Patient Protection and Affordable Care Act ("ACA"), which explicitly confers on patients the right to receive nondiscriminatory health care in any health program or activity that receives federal funding. 42 U.S.C. § 18116. Incorporating the prohibited grounds for discrimination described in other

federal civil rights laws, the ACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability. *Id.* at § 18116(a).

The Refusal Statutes must be read to coexist with the statutory nondiscrimination requirements of the ACA and similar state nondiscrimination laws such as California's clear statutory prohibitions on gender identity, gender expression, and sexual orientation discrimination. If a nondiscrimination requirement has any meaning in the healthcare context, it must mean that a patient cannot be refused care simply because of her race, color, national origin, sex, age, or disability. And as courts have recognized, the prohibition on sex discrimination under the federal civil rights statutes should be interpreted to prohibit discrimination against transgender people. *See Whitaker by Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1049-50 (7th Cir. 2017) (discrimination against transgender students violates Title IX, which is the basis for the ACA's prohibition on sex discrimination); *see also EEOC v. R.G. & G.R. Funeral Homes, Inc.*, 2018 WL 1177669 at *5-12 (6th Cir. Mar. 7, 2018) (Title VII). Notwithstanding these protections, as well as explicit statutory protections from discrimination based on gender identity and sexual orientation in many states (as discussed below), the Proposed Rule invites providers to discriminate against LGBT patients, particularly transgender people.

6. The Rule Also Appears Aimed at Pre-Empting State Laws That Expand Access to Health Care or Otherwise Immunizing Violations of State Law

The Proposed Rule creates even more concern with regard to its intended effect on state law. The Preamble devotes extensive discussion to "Recently Enacted State and Local Government Health Care Laws" that have triggered some litigation, much of it here in California, by "conscientious objectors," 83 FR 3888, characterizing those disputes as part of the rationale for the Rule. Although the Department states it "has not opined on or judged the legal merits of any of the" catalogued state and local laws, it uses these laws "to illustrate the need for clarity" concerning the Refusal Statutes that are the subject of the Proposed Rule. 83 FR 3889.

The Preamble's "Recently Enacted State and Local Government Health Care Laws" references several California laws, without explaining how the Rule's requirements interact with those or other state and local laws (nor does it provide any statutory authority on which those requirements rest under federal law, as discussed above). The Rule's expansion of definitions, covered entities, and enforcement mechanisms appears to impermissibly invite institutions and individuals to violate state law, and to attempt somehow to inhibit states from enforcing their own laws that require institutions to provide care, coverage, or even just information. The Proposed Rule also includes a troubling preemption provision, which specifies only that state and local laws that are "equally or more protective of religious freedom" should be saved from preemption, 83 FR 3931, and ignores the importance of maintaining the protection of other state laws, such as laws mandating non-discrimination in the provision of health care or requiring that state funding be available for certain procedures.

Thus, the Proposed Regulation and its unclear relationship to state and local laws puts at potential risk several vital California laws that safeguard patients from substandard health care and ensure patients' health, well-being, access, and choice, including but not limited to state laws

that mandate minimum educational requirements for licensed medical professionals, medically necessary services in emergency situations, that managed care health plans cover abortion as basic health care under the Knox-Keene Act, and that patients be informed when they are not offered all of their medical options. Such laws demonstrate California's concerted commitment to patients' health.

The ACLU Foundation of California has a strong history protecting patients' access to necessary medical services. Rebecca Chamorro, for example, decided, in consultation with her doctor, that she would have a tubal ligation following her scheduled C-section, which is the standard of care. Despite the clear health and cost benefits to performing one procedure rather than two separate procedures, the hospital refused her doctor's request to perform the procedure. Consequently, Ms. Chamorro endured additional stress, health risks, and costs, with no benefits to her, her baby, or even her doctor. Similarly, Evan Minton, a transgender man who was scheduled to receive a hysterectomy from his doctor, received notice that the hysterectomy was canceled on the eve of procedure when the hospital learned his gender identity. The Proposed Rule cites Ms. Chamorro's and Mr. Minton's cases as the type of harm the Rule seeks to address, confirming that the Rule facilitates and encourages blatant discrimination, with no regard for a patient's needs.

The Rule, if it survives in any fashion, should clarify that it creates no new preemption of state or local laws. That is because any preemption must be limited to that which already existed, if any, by virtue of the extremely limited, pre-existing Refusal Statutes. These regulations cannot create some new gutting of state and local mandates.

7. The Rule Would Violate the Establishment Clause Because It Forces Unwilling Third Parties to Bear Serious Harms From Others' Religious Exercise

The Proposed Rule imposes the significant harms on patients identified above in service of institutional and individual religious objectors. It purports to mandate that their religious choices take precedence over providing medical information and health care to patients. But the First Amendment forbids government action that favors the free exercise of religion to the point of forcing unwilling third parties to bear the burdens and costs of someone else's faith. As the Supreme Court has emphasized, "[t]he principle that government may accommodate the free exercise of religion does not supersede the fundamental limitation imposed by the Establishment Clause." *Lee v. Weisman*, 505 U.S. 577, 587 (1992); *accord Bd. of Educ. of Kiryas Joel Village School Dist. v. Grumet*, 512 U.S. 687, 706 (1994) ("accommodation is not a principle without limits").

Because the Rule attempts to license serious patient harms in the name of shielding others' religious conduct, it is incompatible with our longstanding constitutional commitment to separation of church and state. *See Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 708-10 (1985) (rejecting, as Establishment Clause violation, law that freed religious workers from Sabbath duties, because the law imposed substantial harms on other employees); *see also Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 14, 18 n.8 (1989) (plurality opinion) (invalidating sales tax exemption for religious periodicals, in part because the exemption "burden[e]d nonbeneficiaries

markedly" by increasing their tax bills). The Department should withdraw the Rule to avoid its violation of the Establishment Clause.

8. The Rule Unnecessarily Expands Compliance Tools, Without Clear Due Process Protections, and Risks Overzealous Enforcement That Would Harm Patient Care

Finally, the Department provides no evidence that existing enforcement mechanisms are insufficient to educate providers, investigate and conduct compliance reviews, and address any meritorious complaints under the Refusal Statutes. Yet the Department itself, in a woefully inadequate and low estimation, concedes that at least hundreds of millions of dollars will be spent by health care providers to attempt to comply with the new requirements the Proposed Rule purports to create. Moreover, the Rule proposes ongoing reporting requirements for five years after any investigation of a complaint or compliance review, regardless of its outcome; purports to empower the Department to revoke federal funding before any opportunity for voluntary compliance occurs; allows punishment of grantees for acts, no matter how independent, of sub-recipients; and lacks clarity as to any procedural protections that a grantee may have in contesting enforcement actions. If the entire Rule is not withdrawn, its enforcement powers and obligations should be substantially scaled back, and full due process protections should clearly be identified and provided if any funding impact is threatened, *see, e.g.*, 45 C.F.R. §§ 80.8-80.10 (Title VI due process protections).

The Rule contemplates an enormous outlay of funds to implement a complex, extreme compliance scheme that will only serve to divert funds away from the provision of high-quality health care to those who need it most.

* * *

For all these reasons, the Department should withdraw the Proposed Rule. If it fails to do so, it must substantially modify the Proposed Rule so as, at a minimum, not to exceed the terms of and congressional intent behind the underlying statutes.

Sincerely,

Aditi Fruitwala
ACLU Foundation of Southern California

Melissa Goodman
ACLU Foundation of Southern California

Elizabeth Gill
ACLU Foundation of Northern California

David Loy
ACLU Foundation of San Diego
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Exhibit 7

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March 23, 2018

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

Submitted electronically

Re: ACLUM Comments on Proposed New 45 CFR Part 88 Regarding Refusals of Medical Care

The American Civil Liberties Union of Massachusetts (ACLUM) submits these comments on the proposed rule published at 83 FR 3880 (January 28, 2018), RIN 0945-ZA03, with the title "Ensuring that the Department of Health and Human Services [the "Department"] Does Not Fund or Administer Programs or Activities that Violate Conscience and Associated Anti-Discrimination Laws" (the "Proposed Rule" or "Rule").

ACLUM, an affiliate of the national American Civil Liberties Union (ACLU) with more than 80,000 members, is a statewide nonprofit membership organization dedicated to defending and preserving the individual rights and liberties guaranteed by the U.S. Constitution and Bill of Rights as well as the Massachusetts Declaration of Rights. ACLUM has a long history of vigorously defending religious liberty. We are equally vigilant in our efforts to safeguard reproductive rights and to end discrimination against those who have historically been excluded or diminished by more powerful actors in society, including in health care settings. ACLUM is thus particularly well-positioned to comment on the Proposed Rule and the serious concerns it raises about access to reproductive and other health care, based on the religious or other beliefs of institutions or individual providers. We steadfastly protect the right to religious freedom. But that right does not include a right to harm others as this Proposed Rule contemplates.

Without any regulatory authority, the Department has proposed a rule that vastly expands narrow statutory sections in ways Congress never intended, in a manner unsupportable by the terms of the statutes, and in a way that upsets the careful balance struck by other federal laws, all in an effort to grant health care providers unprecedented license to refuse to provide care and information to patients. In so doing, the Proposed Rule does not mention, much less grapple with, the consequences of refusals to provide full information and necessary health care to patients. The denials that the Rule proposes to protect will have significant consequences for individuals in terms of their health and well-being, in addition to financial costs. And, because the Proposed Rule is tied to entities that receive federal funding, those consequences will fall most heavily on poor and low-income people who must rely on government-supported programs and institutions for their care and who will have few, if any, other options if they are denied appropriate care. The Proposed Rule amounts to a license to discriminate, made all the worse because the federal purse will be used to further that discrimination.

The Proposed Rule is not only extremely detrimental to patient health, it is also entirely unnecessary. Individual providers' religious and moral beliefs are already strongly protected by federal law that, among other things, forbids religious discrimination and requires employers to provide reasonable accommodation of an employee's religious objections.

Because the Proposed Rule harms patient health, encourages discrimination against patients, and exceeds the Department's rulemaking authority, it should be withdrawn. If the Department refuses to do so, it must, at a minimum, revise the Proposed Rule so that it aligns with the statutory provisions it purports to implement, makes clear that it is not intended to conflict with or preempt other state or federal laws that protect and expand access to health care, and mitigates the Rule's harm to patients' health and well-being.

1. The Proposed Rule Ignores Its Impact on Patients' Health and Invites Harms That Will Disproportionately Fall on Women and Marginalized Populations

The Proposed Rule seeks to immunize refusals of health care, yet utterly fails to consider the harmful impact it would have on patients' health. But this failure to address the obvious consequences of giving federally subsidized providers *carte blanche* to decide whom to treat or not treat based on religious or moral convictions—or indeed, based on any reasoning or none at all[1]—does not mean the harm does not exist. In fact, the harms would be substantial. For example, the Proposed Rule:

- Appears to provide immunities for health care institutions that receive federal funding and professionals who work in federally funded programs to refuse to provide complete information to patients about their condition and treatment options;

- Purports to create new "exemptions," so that patients who rely on federally subsidized health care programs, such as Title X, may be unable to obtain services those programs are required by law to provide;

- Causes confusion about whether hospitals can prevent staff from providing emergency care to pregnant women who are suffering miscarriages or otherwise need emergency abortion care; and

- Invites health care providers to discriminate against individuals based on who they are, for example, by refusing to provide otherwise available services to a patient for the sole reason that the patient is transgender.

These harms would fall most heavily on historically disadvantaged groups and those with limited economic resources. As the ACLU's own cases and requests for assistance reflect, women, LGBT (lesbian, gay,

[1] Although the Notice of Proposed Rulemaking highlights religious freedom and rights of conscience, a number of the referenced statutes—and the proposed expansions of those in the Rule—do not turn on the existence of any religious or moral justification. The Proposed Rule would empower not only those acting based on conscience, but others acting, for example, out of bare animus toward a patient's desired care or any aspect of their identity.

bisexual and transgender) individuals, people of color, immigrants, young people, and members of other groups who continue to struggle for equal rights are those who most often experience refusals of care. Likewise, poor and low-income people will also suffer acutely under the Proposed Rule. They are more likely to rely on health care that is in some manner tied to federal funding, and less likely to have other options at their disposal if they are denied access to care or information. Because it will limit access to health care, harm patients' outcomes, and undermine the central, public health mission of the Department, the Proposed Rule should be withdrawn.

2. The Department Lacks the Authority to Issue the Proposed Rule

The Proposed Rule references the Church Amendments, 42 U.S.C. § 300a-7, the Coats-Snowe Amendment, 42 U.S.C. § 238n, the Weldon Amendment, Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, Tit. V, § 507(d), and other similar "protections" or "exemptions," *see* 83 FR 3880, that sometimes allow, under narrow circumstances, health care professionals to avoid providing certain medical procedures or that limit the actions that may be taken against them if they refuse to provide care (collectively, the "Refusal Statutes"). The Preamble to the Rule focuses most extensively on the Church, Coats, and Weldon Amendments (the "Amendments"), and the Rule itself purports to establish extraordinarily expansive new substantive requirements, compliance steps, and enforcement authority under them.

But the Department does not possess *any* legislative rulemaking powers under those Amendments and wholly lacks the authority to promulgate the Proposed Rule as it applies to them. None of those Amendments includes, or references, any explicit delegation of regulatory authority. *Compare, e.g.,* 42 U.S.C. § 2000d-1 (expressly directing all relevant federal agencies to issue "rules, regulations, or orders of general applicability" to achieve the objectives of Title VI). Nor does any implicit delegation of legislative rulemaking authority exist for these provisions. For this reason alone, the Department cannot properly proceed to adopt the Proposed Rule or any similar variation of it.

3. The Proposed Rule Impermissibly Expands the Narrow Referenced Statutes and Does So In Ways That Ignore The Statutes' Limited Terms and Purposes

Even if the Department had the necessary rulemaking authority (which it does not), the Proposed Rule's virtually unbounded definition of certain terms and expansions of the Refusal Statutes' reach would broaden the Refusal Statutes beyond reason and recognition, create conflict with federal law, and lead to denials of appropriate care to patients. While we do not attempt to catalogue each way in which the Proposed Rule impermissibly expands the Refusal Statutes, a few examples follow.

A. Assist in the Performance

For example, Subsection (c)(1) of the Church Amendments prohibits recipients of certain federal funds from engaging in employment discrimination against health care providers who have objected to performing or "assist[ing] in the performance of" an abortion or sterilization. 42 U.S.C. § 300a-7(c)(1). Under the Proposed Rule, however, the Department defines "assist in the performance" of an abortion or sterilization to include not only assistance *in the performance* of those actual procedures – the ordinary meaning of the phrase – but

also to participation in any other activity with "an articulable connection to a procedure[.]" 83 FD 8892, 3923. Through this expanded definition, the Department explicitly aims to include activities beyond "direct involvement with a procedure" and to provide "broad protection"—despite the fact that the statutory references are limited to "assistance in the performance of" an abortion or sterilization procedure itself. 83 FR 3892.; *cf. e.g.,* 42 U.S.C. § 300a-7(c)(1).

This means, for example, that simply admitting a patient to a health care facility, filing her chart, transporting her from one part of the facility to another, or even taking her temperature could conceivably be considered "assist[ing] in the performance" of an abortion or sterilization, as any of those activities could have an "articulable connection" to the procedure. As described more fully below, the Proposed Rule could even be cited by health care providers who withhold basic information from patients seeking information about abortion or sterilization on the grounds that "assist[ing] in the performance" of a procedure "includes but is not limited to counseling, referral, training, and other arrangements for the procedure." 83 FR 3892, 3923.

But the term "assist in the performance" simply does not have the virtually limitless meaning the Department proposes ascribing to it. The Department has no basis for declaring that Congress meant anything beyond actually "assist[ing] in the performance of" the specified procedure—given that it used that phrasing, 42 U.S.C. §§ 300a-7(c)(1)—and instead meant any activity with any connection that can be articulated, regardless of how attenuated the claimed connection, how distant in time, or how non-procedure-specific the activity.

B. <u>Referral or Refer for</u>

Others of the Refusal Statutes provide limited protections to certain health care entities and individuals that refuse to, among other things, "refer for" abortions. For those statutes , the Proposed Rule expands "referral or refer for" beyond recognition, by proposing to define a referral as "the provision of *any* information … by any method … pertaining to a health care service, activity, or procedure … that could provide *any assistance* in a person obtaining, assisting, … financing, or performing" it, where the entity (including a person) doing so "sincerely understands" the service, activity, or procedure to be a "possible outcome[.]" 83 FR 3894-95 (emphasis added), 3924. This wholesale re-definition of the concept of "referral" could have dire consequences for patients. For example, a hospital that prohibits its doctors from even discussing abortion as a treatment option for certain serious medical conditions could attempt to claim that the Rule protects this withholding of critical information because the hospital "sincerely understands" the provision of this information to the patient may provide some assistance to the patient in obtaining an abortion.

Providing a green light for the refusal to provide information that patients need to make informed decisions about their medical care not only violates basic medical ethics, but also far exceeds Congress's language and intent. A referral—as used in common parlance and the underlying statutes—has a far more limited meaning than providing *any* information that *could* provide *any assistance whatsoever* to a person who may ultimately decide to obtain, assist, finance, or perform a given procedure sometime in the future. The meaning of "referral or refer for" in the health care context is to *direct* a patient elsewhere for care. *See* Merriam-Webster, https//www.merriam-webster.com/dictionary/referral ("referral" is "the process of

directing or redirecting (as a medical case or a patient) to an appropriate specialist or agency for definitive treatment").

C. Discriminate or Discrimination

These expansive definitions are all the more troubling given the Proposed Rule's definition of "discrimination," which purports to provide unlimited immunity for institutions that receive some federal funds to deny abortion care, to block coverage for such care, or to stop patients' access to information, no matter what the patients' circumstances or the mandates of state or federal law. Likewise, the definition appears aimed at providing immunity for employees who refuse to perform central parts of their job, regardless of the impact on the ability of a health care entity to provide appropriate care to its patients. This expansion of "discrimination" would apparently treat virtually any adverse action – including government enforcement of a patient non-discrimination or access-to-care law – against a health care facility or individual as *per se* discrimination. But "discrimination" does not mean any negative action, and instead requires an assessment of context and justification, with the claimant showing unequal treatment on prohibited grounds under the operative circumstances. The Proposed Rule abandons, for example, the nuanced and balanced approach required by Title VII, and also ignores other federal laws, state laws, and providers' ethical obligations to their patients. *See infra* Parts 4-6.

D. Other Expansions of the Scope of the Refusal Statutes

The Proposed Rule not only distorts the definitions of words in the statutes, but also alters the statutes' substantive provisions in other ways to attempt to expand the ability of individuals and entities to deny care in contravention of legal and ethical requirements and to the severe detriment of patients. Again, these comments do not attempt to exhaustively catalogue all of the unauthorized expansions but instead provide a few illustrative examples.

For example, Congress enacted Subsection (d) of the Church Amendment in 1974 as part of Public Law 93-348, a law that addressed biomedical and behavioral research, and appended that new Subsection (d) to the pre-existing subsections of Church from 1973, which all are codified within 42 U.S.C. § 300a-7: the "Sterilization or Abortion" section within the code subchapter that relates to "Population Research and Voluntary Family Planning Programs." Despite this explicit context for Subsection (d), and Congress' intent that it apply narrowly, however, the Proposed Rule attempts to import into this Subsection an unduly broad definition of "health service program," along with the expansive definitions discussed above, to purportedly transform it into a much more general prohibition that would apply to any programs or services administered by the Department, and that would assertedly prevent any entity that receives federal funding through those programs or services from requiring individuals to perform or assist in the performance of actions contrary to their religious beliefs or moral convictions. *See* 83 FR 3894, 3906, 3925. This erroneous expansion of Church (d), as described in this attempted rule-making, could prevent health care institutions from ensuring that their employees provide appropriate care and information. It would purportedly prevent institutions taking action against members of their workforce who refuse to provide any information or care that they "sincerely understand" may have an "articulable connection" to some eventual procedure to which they object—no

matter what medical ethics, their job requirements, Title VII or laws directly protecting patient access to care may require.

The Rule similarly attempts to expand the Coats Amendment beyond its limited provisions, which apply to certain "governmental activities regarding training and licensing of physicians," 42 U.S.C. § 238n (quoting title), to apply *regardless* of context. Thus, rather than being confined to residency training programs as Congress intended, the Proposed Rule purports to give all manner of health care entities, including insurance companies and hospitals, a broad right to refuse to provide abortion and abortion-related care. In addition, the Rule's expansion of the terms "referral" and "make arrangements for" extends the Coats Amendment to shield any conduct that would provide "any information … by any method … that could provide *any assistance* in a person obtaining, assisting, … financing, or performing" an abortion or that "render[s] aid to anyone else reasonably likely" to make an abortion referral. 83 FR 3894-95 (emphasis added), 3924. This expansive interpretation not only goes far beyond congressional intent and the terms of the statute, it also could have extremely detrimental effects on patient health. For example, it would apparently shield, against any state or federal government penalties, a women's health center that required any obstetrician-gynecologist practicing there who diagnosed a pregnant patient as having a serious uterine health condition to refuse to provide her with even the name of an appropriate specialist, because that specialist "is reasonably likely" to provide the patient with information about abortion.

Similarly, as written, the Weldon Amendment is no more than a bar on particular appropriated funds flowing to a "Federal agency or program, or State or local government," if any of those government institutions discriminate on the basis that a health care entity does not provide, pay for, provide coverage of, or refer for abortion. Pub. L. No. 115-31, Div. H, Tit. V, § 507(d)(1). Yet again, however, the Proposed Rule attempts to vastly increase its reach by (i) expanding the scope of the federal funding streams to which the Weldon Amendment prohibition reaches and (ii) binding "any entity" that receives such funding—not just the government entities listed in the Amendment—to its proscriptions. 83 FR 3925. These unauthorized expansions, combined with the expansive definitions discussed *supra,* can lead to broad and harmful denials of care. For example, under this unduly expansive interpretation of Weldon, an organization that refuses to discuss the option of abortion with people who discover they are pregnant may claim a right to participate in the Title X program, despite the fact that both federal law and medical ethics require that Title X patients be provided with counseling about all of their options. *See, e.g.,* 42 C.F.R. § 59.5(a)(5).

The Department should withdraw the Rule to prevent it from impeding health care and harming patients. But if it does not do so, each of the definitions must be clarified and revert to the terms' proper meaning, and each of the substantive requirements should track only those provisions actually found in the Refusal Statutes themselves.

4. The Rule Undermines Legal and Ethical Requirements of Fully Informed Consent

The Proposed Rule appears to allow institutional and individual health care providers to manipulate and distort provider-patient communications and deprive patients of critical health care information about their condition and treatment options. While the Proposed Rule's Preamble suggests the Rule will improve

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physician-patient communication because it will purportedly "assist patients in seeking counselors and other health-care providers who share their deepest held convictions," 83 FR 3916-17, the notion that empowering health care providers to deny care to and withhold information from some patients is somehow necessary to enable other patients to identify like-minded providers strains credulity: Patients are already free to inquire about their providers' views and patients' own expressions of faith and decisions based on that faith must already be honored. *Cf. id.* Allowing *providers* to decide what information to share– or not share—with patients, regardless of the patient's needs or the requirements of informed consent and professional ethics would gravely harm trust and open communication in health care, rather than aiding it.

As the American Medical Association's Code of Medical Ethics ("AMA Code") explains, the relationship between patient and physician "gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own self-interest[.]" AMA Code § 1.1.1. Even in instances where a provider's beliefs are opposed to a particular course of action, the provider must "[u]phold standards of informed consent and inform the patient about all relevant options for treatment, including options to which the physician morally objects." *Id.* § 1.1.7(e).

By erroneously expanding the meaning of "assist in the performance of," "refer for" and "make arrangements for," as described above, however, the Proposed Rule purports to allow health care providers to refuse to provide basic information to patients in ways that were never contemplated by the underlying statutes. As described above, these broad definitions may be used to immunize the denial of basic information about a patient's condition as well as her treatment options.

Withholding this vital information from patients violates fundamental legal and ethical principles, deprives patients of the ability to make informed decisions, and leads to negligent care. If the Department moves forward with the Proposed Rule, it should, among other necessary changes, modify it to make clear that it does not subvert basic principles of medical ethics and does not protect withholding information from a patient about her condition or treatment options.

5. By Failing to Acknowledge Other Federal Laws, the Proposed Rule Will Lead to Confusion, Denials for Care, and Harm to Patients

A. Title VII

The Proposed Rule is not only unauthorized and harmful to patients, it is also unnecessary to accommodate individual workers—federal law already amply protects individuals' religious freedom in the workplace. For more than four decades, Title VII has required employers to make reasonable accommodations for current and prospective employers' religious beliefs so long as doing so does not pose an "undue hardship" to the employer. 42 U.S.C. §§ 2000e(j), 2000e-(2)(a); *Trans World Airlines, Inc. v. Hardison*, 432 U.S. 63, 84 (1977); EEOC Guidelines, 29 C.F.R. § 1605.2(e)(1).[2] Thus, Title VII—while protecting freedom of religion—establishes an essential balance. It recognizes that an employer cannot subject an employee to less favorable

[2] Religion for purposes of Title VII includes not only theistic beliefs, but also non-theistic "moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views." Equal Employment Opportunity Commission ("EEOC") Guidelines, 29 C.F.R. §1605.1.

treatment because of that individual's religion and that generally an employer must accommodate an employee's religious practices. However, it does not require accommodation when the employee objects to performing core job functions, particularly when those objections harm patients, depart from the standard of care, or otherwise constitute an undue hardship. *Id.* This careful balance between the needs of employees, patients, and employers is critical to ensuring that religious beliefs are respected while at the same time health care employers are able to provide quality health care to their patients.

Despite this long-standing balance and the lack of any evidence that Congress intended the Refusal Statutes to disrupt it, the Proposed Rule does not even mention these basic federal legal standards or the need to ensure patient needs are met. Instead, by presenting a seemingly unqualified definition of what constitutes "discrimination," 83 FR 3892-93, 3923-24, and expansive refusal rights, the Department appears to attempt to provide complete immunity for religious refusals in the workplace, no matter how significantly those refusals undermine patient care, informed consent, or the essential work of institutions established for the purpose of promoting health. Indeed, the Rule is explicit in seeking not simply a "level playing field" and reasonable accommodation, but rather an unlimited ability for individuals to "be[] free not to act contrary to one's beliefs," regardless of the harm it causes others and without any repercussions. *Id.* Such an interpretation could have a drastic impact on the nation's safety-net providers' ability to provide high quality care by requiring, for example, a family planning provider to hire a counselor to provide pregnancy options counseling even if the counselor refuses to comply with ethical and legal obligations to inform patients of the availability of abortion. If the Department does not withdraw the entire Rule, therefore, it should explicitly limit its reach and make clear that Title VII provides the governing standard for employment situations.

B. EMTALA

The Proposed Rule also puts patients at risk by ignoring the federal Emergency Medical Treatment and Labor Act ("EMTALA") and hospitals' obligations to care for patients in an emergency. As Congress has recognized, a refusal to treat patients facing an emergency puts their health and, in some cases, their lives at serious risk. Through EMTALA, Congress has required hospitals with an emergency room to provide stabilizing treatment to any individual experiencing an emergency medical condition or to provide a medically beneficial transfer. 42 U.S.C. § 1395dd(a)-(c).

The Refusal Statutes do not override the requirements of EMTALA or similar state laws that require health care providers to provide abortion care to a woman facing an emergency. *See, e.g.*, *California v. U.S.*, Civ. No. 05-00328, 2008 WL 744840, at *4 (N.D. Cal. March 18, 2008) (rejecting notion "[t]hat enforcing [a state law requiring emergency departments to provide emergency care] or the EMTALA to require medical treatment for emergency medical conditions would be considered 'discrimination' under the Weldon Amendment if the required medical treatment was abortion related services").

It is particularly troubling, therefore, to have the Department use attempts to require hospitals to comply with their obligations under EMTALA in its Preamble as *justification* for expanding the Refusal Statutes. 83 FR 3888-89. For example, the Preamble discusses the case brought by the ACLU on behalf of Tamesha Means who at 18 weeks of pregnancy began to miscarry and sought care, not once but three times, at her local hospital. 83

FR 3888-89. Despite the fact that she was bleeding, in severe pain, and had developed a serious infection, the hospital repeatedly sent her away and never told her that her health was at risk and that having an abortion was the safest course for her. *See* Health Care Denied 9-10 (May 2016), *available at* https://www.aclu.org/report/report-health-care-denied?redirect=report/health-care-denied. But the ethical imperative is the opposite: "In an emergency in which referral is not possible or might negatively affect a patient's physical or mental health, providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections." 83 FR 3888 (quoting American Congress of Obstetricians and Gynecologists ("ACOG") Committee Opinion No. 365) (reaffirmed 2016).

The Proposed Rule suggests that hospitals like the one who put Ms. Means' health at risk should be given a free pass. Yet doing so would not only violate EMTALA, but also other legal, professional, and ethical principles governing access to health care in this country. For that reason, if not withdrawn in its entirety, the Proposed Rule should, at minimum, clarify that it does not disturb health care providers' obligations to provide appropriate care in an emergency.

C. Section 1557

The Proposed Rule also puts patients at risk by ignoring the federal Patient Protection and Affordable Care Act ("ACA"), which explicitly confers on patients the right to receive nondiscriminatory health care in any health program or activity that receives federal funding. 42 U.S.C. § 18116. Incorporating the prohibited grounds for discrimination described in other federal civil rights laws, the ACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability. *Id.* at § 18116(a).

The Refusal Statutes must be read to coexist with the statutory nondiscrimination requirements of the ACA and similar state nondiscrimination laws. If a nondiscrimination requirement has any meaning in the healthcare context, it must mean that a patient cannot be refused care simply because of her race, color, national origin, sex, age, or disability. And as courts have recognized, the prohibition on sex discrimination under the federal civil rights statutes should be interpreted to prohibit discrimination against transgender people. *See Whitaker by Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1049-50 (7th Cir. 2017) (discrimination against transgender students violates Title IX, which is the basis for the ACA's prohibition on sex discrimination);); *see also EEOC v. R.G. & G.R. Funeral Homes, Inc.*, 2018 WL 1177669 at *5-12 (6th Cir. Mar. 7, 2018) (Title VII). Notwithstanding these protections, as well as explicit statutory protections from discrimination based on gender identity and sexual orientation in Massachusetts (as discussed below), the Proposed Rule invites providers to discriminate against LGBT patients, particularly transgender people.

6. The Rule Also Appears Aimed at Pre-Empting State Laws That Expand Access to Health Care or Otherwise Immunizing Violations of State Law

The Proposed Rule creates even more concern with regard to its intended effect on state law. The Preamble devotes extensive discussion to "Recently Enacted State and Local health Government Health Care Laws" that have triggered some litigation by "conscientious objectors," 83 FR 3888, characterizing those disputes as part of the rationale for the Rule. Although the Department states it "has not opined on or judged the

legal merits of any of the" catalogued state and local laws, it uses these laws "to illustrate the need for clarity" concerning the Refusal Statutes that are the subject of the Proposed Rule. 83 FR 3889.

But no clarity, only more questions ensue, because the Proposed Rule does not explain how its requirements interact with state and local law (nor does it provide any statutory authority on which those requirements rest under federal law, as discussed above). The Rule's expansion of definitions, covered entities, and enforcement mechanisms appears to impermissibly invite institutions and individuals to violate state law, and to attempt somehow to inhibit states from enforcing their own laws that require institutions to provide care, coverage, or even just information. The Proposed Rule also includes a troubling preemption provision, which specifies only that state and local laws that are "equally or more protective of religious freedom" should be saved from preemption, 83 FR 3931, and ignores the importance of maintaining the protection of other state laws, such as laws mandating non-discrimination in the provision of health care or requiring that state funding be available for certain procedures.

Thus, the Proposed Regulation's treatment of state and local laws calls into question its intersection with the protections embodied in Massachusetts' public accommodation law and employment discrimination law, both of which prohibit discrimination on the basis of gender identity. *See, e.g.,* M.G.L c. 272 § 98 ("Whoever makes any distinction, discrimination or restriction on account of . . . gender identity . . . relative to the admission of any person to, or his treatment in any place of public accommodation . . . shall be punished. All persons shall have the right to the full and equal accommodations, advantages, facilities and privileges of any place of public accommodation . . . "); M.G.L. c. 151B § 4 ("It shall be an unlawful practice [f]or an employer, by himself or his agent, because of the . . . gender identity . . .of any individual to refuse to hire or employ or to bar or to discharge from employment such individual or to discriminate against such individual in compensation or in terms, conditions or privileges of employment . . ."). Indeed, the Proposed Regulations appear to encourage the exact discrimination these laws were designed to prevent. As Governor Charlie Baker emphasized while signing the public accommodation's law, "no one should be discriminated against in Massachusetts because of their gender identity."[3]

As a result, the Rule, if it survives in any fashion, should clarify that it creates no new preemption of state or local laws. That is because any preemption must be limited to that which already existed, if any, by virtue of the extremely limited, pre-existing Refusal Statutes. These regulations cannot create some new gutting of state and local mandates.

7. The Rule Would Violate the Establishment Clause Because It Forces Unwilling Third Parties to Bear Serious Harms From Others' Religious Exercise

The Proposed Rule imposes the significant harms on patients identified above in service of institutional and individual religious objectors. It purports to mandate that their religious choices take precedence over providing medical information and health care to patients. But the First Amendment forbids government action that favors the free exercise of religion to the point of forcing unwilling third parties to bear the burdens and costs of someone else's faith. As the Supreme Court has emphasized, "[t]he principle that

[3] http://www.bostonglobe.com/metro/2016/07/08/baker-signs-transgender-bill/xvWZhgReudbWc8XdFBflkM/story.html?event=event12

government may accommodate the free exercise of religion does not supersede the fundamental limitation imposed by the Establishment Clause." *Lee v. Weisman*, 505 U.S. 577, 587 (1992); *accord Bd. of Educ. of Kiryas Joel Village School Dist. v. Grumet*, 512 U.S. 687, 706 (1994) ("accommodation is not a principle without limits").

Because the Rule attempts to license serious patient harms in the name of shielding others' religious conduct, it is incompatible with our longstanding constitutional commitment to separation of church and state. *See Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 708-10 (1985) (rejecting, as Establishment Clause violation, law that freed religious workers from Sabbath duties, because the law imposed substantial harms on other employees); *see also Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 14, 18 n.8 (1989) (plurality opinion) (invalidating sales tax exemption for religious periodicals, in part because the exemption "burden[e]d nonbeneficiaries markedly" by increasing their tax bills). The Department should withdraw the Rule to avoid its violation of the Establishment Clause.

8. The Rule Unnecessarily Expands Compliance Tools, Without Clear Due Process Protections, and Risks Overzealous Enforcement That Would Harm Patient Care

Finally, the Department provides no evidence that existing enforcement mechanisms are insufficient to educate providers, investigate and conduct compliance reviews, and address any meritorious complaints under the Refusal Statutes. Yet the Department itself, in a woefully inadequate and low estimation, concedes that at least hundreds of millions of dollars will be spent by health care providers to attempt to comply with the new requirements the Proposed Rule purports to create. Moreover, the Rule proposes ongoing reporting requirements for five years after any investigation of a complaint or compliance review, regardless of its outcome; purports to empower the Department to revoke federal funding before any opportunity for voluntary compliance occurs; allows punishment of grantees for acts, no matter how independent, of sub-recipients; and lacks clarity as to any procedural protections that a grantee may have in contesting enforcement actions. If the entire Rule is not withdrawn, its enforcement powers and obligations should be substantially scaled back, and full due process protections should clearly be identified and provided if any funding impact is threatened, *see, e.g.,* 45 C.F.R. §§ 80.8-80.10 (Title VI due process protections).

The Rule contemplates an enormous outlay of funds to implement a complex, extreme compliance scheme that will only serve to divert funds away from the provision of high-quality health care to those who need it most.

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For all these reasons, the Department should withdraw the Proposed Rule. If it fails to do so, it must substantially modify the Proposed Rule so as, at a minimum, not to exceed the terms of and congressional intent behind the underlying statutes.

Sincerely,

/s/ Jessie J. Rossman

Jessie J. Rossman
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Exhibit 13

March 26, 2018

Alex Azar, Secretary
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

RE: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, RIN: 0945-ZA03 Comments

Dear Secretary Azar:

On behalf of the more than 123,000 PAs (physician assistants) throughout the United States, the American Academy of PAs (AAPA) welcomes the opportunity to submit comments to the Department of Health and Human Services (HHS) regarding the recent creation of the Conscience and Religious Freedom Division, along with the release of a rule to impose additional enforcement mechanisms with regard to federal laws that grant healthcare professionals the right to decline to participate in medical procedures to which they are opposed on moral or religious grounds.

In the proposed rule, the Office for Civil Rights (OCR) seeks to strengthen enforcement of existing statutory conscience protections for healthcare providers to protect them from being coerced into participating in activities that may violate their beliefs. The proposed rule also creates a new Conscience and Religious Freedom Division within OCR.

AAPA's policy, which is contained in its Guidelines for Ethical Conduct for the PA Profession, provides guidance on how PAs should act in situations where they believe their beliefs may be compromised, and how best to manage these beliefs in relation to a PA's obligation to provide the best possible care to their patients.

AAPA is concerned that the proposal's effort to broaden the scope of conscience objection regulations and to increase related enforcement efforts could have a negative impact on access to healthcare for patients, especially those who are most vulnerable and those who may live in rural or underserved areas. AAPA is also concerned new paperwork requirements related to "Assurance and Certification of Compliance" could be excessively burdensome to healthcare providers.

PA Practice

PAs are medical professionals who manage the full scope of patient care, often serving patients with multiple comorbidities. They conduct physical exams, order and interpret tests, diagnose and treat illnesses, develop and manage treatment plans, prescribe medications, assist in surgery, and counsel

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patients on preventative healthcare, and often serve as a patient's principal healthcare professional. PAs are one of three categories of healthcare professionals, including physicians and nurse practitioners, who are authorized by law to provide primary care in the United States. In addition to primary care, PAs practice in a wide range of settings and medical specialties, improving healthcare access and quality.

AAPA Policy on Personal Beliefs and Patient Access to Care

The foremost value of the PA profession is respect for the health, safety, welfare, and dignity of all human beings, which requires PAs to always act in the best interest of their patients. This concept is the foundation of the patient–PA relationship, and underpins PAs' ethical obligation to see that each of their patients receives appropriate care.

The PA profession's policy on nondiscrimination is as follows: "PAs should not discriminate against classes or categories of patients in the delivery of needed healthcare. Such classes and categories include gender, color, creed, race, religion, age, ethnic or national origin, political beliefs, nature of illness, disability, socioeconomic status, physical stature, body size, gender identity, marital status, or sexual orientation."

Importantly, our policy also holds that, "While PAs are not expected to ignore their own personal values, scientific or ethical standards, or the law, they should not allow their personal beliefs to restrict patient access to care. A PA has an ethical duty to offer each patient the full range of information on relevant options for their healthcare. *If personal moral, religious, or ethical beliefs prevent a PA from offering the full range of treatments available or care the patient desires, the PA has an ethical duty to refer a patient to another qualified provider.*" [Emphasis added.]

AAPA View and Recommendations

AAPA has significant concerns about the proposed regulatory changes because they put the personal beliefs of healthcare providers above each provider's paramount responsibility to ensure that every patient has access to care. We urge the administration to be cognizant of creating new barriers for healthcare for our most vulnerable populations, which would undermine the progress made in addressing medical disparities among these groups. Doing what is best for the patient must continue to be of utmost concern.

In promulgating the final rule and undertaking new initiatives, AAPA urges the department to work with all relevant healthcare provider groups to ensure that any actions are supported by and consistent with best healthcare practices, and that every patient has access to appropriate care.

AAPA looks forward to working with Secretary Azar, HHS and all relevant parties moving forward. Please do not hesitate to contact Tate Heuer, AAPA Vice President, Federal Advocacy, at 571-319-4338 or theuer@aapa.org, with any questions.

Sincerely,

L. Gail Curtis, MPAS, PA-C, DFAAPA
President and Chair of the Board

Exhibit 16

March 27, 2018

Alex Azar
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, SW.
Washington, DC 20201

Re: RIN 0945-ZA03

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Secretary Azar:

On behalf of more than 37,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the draft rule relating to protecting conscience rights in health care, as it affects our practice of emergency medicine and the patients we serve.

While we believe that enforcement of existing federal conscience protections for health care providers is important, we strongly object to this proposed rule and do not believe it should be finalized. As written, it does not reflect nor allow for our moral and legal duty as emergency physicians to treat everyone who comes through our doors. Both by law[1] and by oath, emergency physicians care for all patients seeking emergency medical treatment. Denial of emergency care or delay in providing emergency services on the basis of race, religion, sexual orientation, gender identity, ethnic background, social status, type of illness, or ability to pay, is unethical[2].

ACEP has specific comments on multiple sections of the proposed rule, which are found below.

Application of Proposals in Emergency Situations

As emergency physicians, we are surprised and concerned that the proposed rule does not in any way address how conscience rights of individuals and institutions interact

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[1] 42 U.S. Code § 1395dd - Examination and treatment for emergency medical conditions and women in labor
[2] ACEP Code of Ethics for Emergency Physicians; Approved Jan 2017; https://www.acep.org/clinical---practice-management/code-of-ethics-for-emergency-physicians

with the mandated provision of emergency services. The Emergency Medical Treatment and Labor Act (EMTALA) requires clinicians to screen and stabilize patients who come to the emergency department. Such patients have every right to expect the best possible care and to receive the most appropriate treatment and information about their condition.

Patients with life-threatening injuries or illnesses may not have time to wait to be referred to another physician or other healthcare professional to treat them if the present provider has a moral or religious objection. Likewise, emergency departments operate on tight budgets and do not have the staffing capacity to be able to have additional personnel on hand 24 hours a day, 7 days a week to respond to different types of emergency situations that might arise involving patients with different backgrounds, sexual orientations, gender identities, or religious or cultural beliefs. The proposed rule seems to demand that, in order to meet EMTALA requirements, an emergency department anticipate every possible basis for a religious or moral objection, survey its employees to ascertain on which basis they might object, and staff accordingly. This is an impossible task that jeopardizes the ability to provide care, both for standard emergency room readiness and for emergency preparedness. Emergency departments serve as the safety-net in many communities, providing a place where those who are most vulnerable and those in need of the most immediate attention can receive care. By not addressing the rights and needs of patients undergoing an emergency, the legal obligations of emergency physicians, and the budget and staffing constraints that emergency departments face, this rule has the potential of undermining the critical role that emergency departments play across the country.

Definition of Referrals

Under the proposed rule, health care providers could refuse not only to perform any given health care service, but also to provide patients access to information about or referrals for such services. The Department of Health and Human Services (HHS) defines a referral broadly in the rule as "the provision of any information… by any method… pertaining to a service, activity, or procedure, including related to availability, location, training, information resources, private or public funding or financing, or direction that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity, or procedure, when the entity or health care entity making the referral sincerely understands that particular health care service, activity, or procedure to be a purpose or possible outcome of the referral."

Such a broad definition of referral as referenced under the proposed rule's prohibition could create unintended consequences, such as preventing patients from getting appropriate care now or even in the future. For example, this definition would allow a primary care physician with a moral or religious objection to abortion to deny referring a pregnant woman (who may not have any immediate intentions or desire for an abortion) to a particular obstetrician-gynecologist out of fear that the woman could eventually receive an abortion from that obstetrician-gynecologist, whether at some point in the future of this pregnancy or even for a future pregnancy.

Another situation where this definition could lead to an undesirable outcome for a patient is when a provider has an objection to a patient's end-of-life wishes expressed in an advance directive. Emergency physicians often treat patients with advanced illness, and ACEP strongly believes that providers should respect the wishes of dying patients including those expressed in advance directives. Most States today allow for a conscience objection and the right to refuse to comply with a patient's advance directive, but they all impose

an obligation to inform such patients and, more importantly, to make some level of effort to transfer the patient to another provider or facility that will comply with the patient's wishes. However, under this proposed rule, providers with a religious or moral objection to their patients' end-of-life or advanced care wishes would have no obligation to either treat these patients in accordance with their wishes or refer them to another provider who would. Unfortunately, it is unclear how such State laws would interact with or be impacted by the federal enforcement aspects of this proposed rule, were it to be finalized. What is clear however, is that if this proposed rule is finalized, the patient's wishes could be ignored and the patient ultimately loses.

In all, the proposed rule's far-reaching definition of referral will likely cause confusion about when a referral may or may not be appropriate, thereby increasing the chances that patients do not receive accurate or timely information that may be critical to their overall health and wellbeing. The proposed rule therefore threatens to fundamentally undermine the relationship between providers and patients, who will have no way of knowing which services, information, or referrals they may have been denied, or potentially whether they were even denied medically appropriate and necessary services to begin with. Additionally, given that many insurance plans such as HMOs require referrals before coverage of specialty services, the proposed rule could place patients at financial risk based on the refusal of their primary care physician to provide a referral.

The definition of referral is representative of one of the major, unacceptable flaws in the rule: it does not focus on the needs of patients or our responsibility as providers to treat them. The rule does not mention the rights of patients even once or seek comment on how patients can still be treated if providers have a moral and religious objection to their treatment. It seems to imply that these providers have no responsibility to their patients to make sure they receive the best possible care when they are unable to provide it themselves, and there is no process or guidance in place for these providers to still try to serve their patients. The lack of attention to protecting and serving patients is one of the major reasons we believe that the rule should be withdrawn.

Requirement to Submit Written Assurances and Certifications of Compliance

HHS would require certain recipients of federal funding (including hospitals that provide care to patients under Medicare Part A) to submit annual written assurances and certifications of compliance with the federal health care conscience and associated anti-discrimination laws as a condition of the terms of acceptance of the federal financial assistance or other federal funding from HHS. There are several exceptions from the proposed requirements for written assurance and certification of compliance, including physicians, physician offices, and other health care practitioners participating in Part B of the Medicare program. However, "excepted" providers could become subject to the written certification requirement if they receive HHS funds under a separate agency or program, such as a clinical trial.

ACEP finds the lack of clarity around this requirement extremely concerning, as we believe that it will pose a significant burden on health care professionals including emergency physicians.

First, the rule does not account for all the possible circumstances or arrangements that would potentially force "excepted" physicians to file certifications. For example, some emergency physicians who are participating in Medicare Part B also have joined an accountable care organization (ACO) led by a hospital where they see patients. In many cases, the ACO has entered into a contract with the Centers for Medicare

& Medicaid Services (CMS) to be part of the Medicare Shared Savings Program or a Center for Medicare & Medicaid Innovation (CMMI) ACO model. Since the ACO includes both physicians and a hospital and therefore receives payments from both Parts A and B of Medicare, it is unclear whether emergency physicians who are part of the ACO would lose their exemption status. Numerous other alternative payment models besides ACO models are operated by CMS and involve participation from both hospitals and physicians. HHS should clarify whether physicians who are part of these models would still be exempted from the certification requirement.

Second, it is unclear whether clinicians who treat Medicaid patients are exempt from the requirement. In the rule, HHS includes Medicaid in the list of examples for why some exemptions may be appropriate[3], but does not actually list reimbursement from the program as one of the exceptions. Some of our members may see only patients with Medicaid, so this lack of clarity is of great concern to them.

Third, ACEP is concerned about the cost-burden that this proposal will have on the hospitals, free-standing emergency departments, and emergency physicians who are subject to the requirement. CMS estimates that the assurance and certification requirement alone could cost health care entities nearly $1,000 initially and $900 annually thereafter to sign documents, review policies and procedures, and update policies and procedures and conduct training. This substantial cost is on top of the cost of posting a notice, which is estimated to be $140 per entity. Since emergency physicians by law must provide services to patients regardless of their insurance status, their total reimbursement, if any, rarely covers the full cost of providing the services. By adding more burdensome government mandates that emergency departments must cover out of their own constrained budgets, the proposed rule could potentially jeopardize the financial viability of the emergency care safety net. While we believe the proposed rule should be withdrawn because it is so problematic, in the event the rule is finalized, ACEP requests that at minimum emergency departments, and the physicians and other health care providers that furnish care within them, be exempt from the written assurances and certifications of compliance requirement.

Notice Requirement

The proposed rule requires all health entities to post a notice on their websites and in locations in their organizations where public notices are typically posted. This notice advises people about their rights and the entity's obligation to abide by federal health care conscience and associated anti-discrimination laws. The notice also provides information about how to file a complaint with the Office of Civil Rights within HHS. The rule requires entities to use a prescribed notice, found in "Appendix A" of the rule, but seeks comment on whether to permit entities to draft their own notices.

ACEP objects to this posting requirement. Beyond our concerns with the burden of having to adhere to another government-imposed mandate as discussed above, we also are troubled by the fact that the notice in no way addresses the needs of patients or our responsibilities as providers to treat them. It does not provide any information about the fundamental rights of patients to receive the most accurate information and best available treatment options for their conditions. We therefore have grave concerns about posting the notice as currently drafted.

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[3] On pages 73- 74 of the proposed rule, HHS states "Furthermore, the Department believes that, due primarily to their generally smaller size, several of the excepted categories of recipients of Federal financial assistance or other Federal funds from the Department are less likely to encounter the types of issues sought to be addressed in this regulation. For example, State Medicaid programs are already responsible for ensuring the compliance of their sub-recipients as part of ensuring that the State Medicaid program is operated consistently with applicable nondiscrimination provisions."

It is also unclear whose exact responsibility it is to post the notice(s). Most emergency physicians are employed by a group independent from the hospital that houses the emergency department where they see patients. Therefore, would the hospital's posted notice be sufficient, or would the group that the hospital's emergency physicians are employed by need to also take on this responsibility as a separate entity, with a separate, additional posting in the emergency department?

If so, posting this notice in the emergency department could potentially be considered a violation of EMTALA. EMTALA requires providers to screen and stabilize patients who come to the emergency department. Therefore, notices that could potentially dissuade patients from receiving care that is mandated by Federal law cannot be posted publicly in the emergency department. Since the notice proposed in this rule explicitly states that providers have the right to decline treatment for patients based on their conscience, religious beliefs, or moral convictions, some patients may become concerned that they would not be treated appropriately and decide to leave before they treated— a violation of EMTALA.

In light of the above concerns, ACEP urges the Department to withdraw the proposed rule. We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at jdavis@acep.org.

Sincerely,

Paul D. Kivela, MD, MBA, FACEP
ACEP President

Exhibit 17

Office of the President
Haywood Brown, MD, FACOG

March 27, 2018

VIA ELECTRONIC SUBMISSION

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

Re: RIN 0945-A03; Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Secretary Azar:

The American College of Obstetricians and Gynecologists (ACOG) writes in response to the proposed rule, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" (Proposed Rule), published in the Federal Register on January 26, 2018 by the Department of Health and Human Services (HHS) Office for Civil Rights (OCR).

The creation of the Proposed Rule, coupled with the creation of a new division within OCR – the "Conscience and Religious Freedom Division" – suggests a concerning expansion of OCR's authority in a way that threatens to restrict access for patients seeking medical care and support. We are concerned that the Proposed Rule and new office will encourage some providers and institutions to place their personal beliefs over their patients' medical needs, a move that can have real-world, potentially life-and-death consequences for patients. ACOG opposes this expansion and calls on HHS and OCR to immediately withdraw the Proposed Rule.

ACOG believes that respect for an individual's conscience is important in the practice of medicine, and recognizes that physicians may find that providing indicated care could present a conflict of conscience. ACOG is committed to ensuring all women have unhindered access to health care and opposes all forms of discrimination.[i]

As outlined in the American Medical Association's Code of Medical Ethics, responsibility to the patient is paramount for all physicians. ACOG holds that providers with moral or religious objections should ensure that processes are in place to protect access to and maintain a continuity of care for all patients. If health care providers feel that they cannot provide the standard services that patients request or require, they should refer patients in a timely

manner to other providers. In an emergency in which referral is not possible or might negatively impact the patient's physical or mental health, providers have an obligation to provide medically indicated and requested care. Conscientious refusals should be limited if they constitute an imposition of religious or moral beliefs on patients, negatively affect a patient's health, are based on scientific misinformation, or create or reinforce racial or socioeconomic inequalities. The Proposed Rule disregards these rigorous standards of care established by the medical community.

The Proposed Rule demonstrates political interference in the patient-physician relationship. Institutions, facilities, and providers must give patients the full range of appropriate medical care to meet each patient's needs as well as relevant information regarding evidence-based options for care, outcomes associated with different interventions, and, in some cases, transfer to a full-service facility. Communication is the foundation of a positive patient-physician relationship and the informed consent process.[ii,iii] By allowing providers to refuse to provide patients with information, the Proposed Rule makes it impossible for patients to make the health care decision that is right for them. All patients should be fully informed of their options.[iv]

ACOG evaluates policies based on the standard of "first, do no harm" to patients, and the result of the Proposed Rule could be just the opposite. Across the country, refusals of care based on personal beliefs have kept women from needed medical care.[v]

The Proposed Rule expands existing conscientious refusal laws by allowing any entity involved in a patient's care to claim a conflict of conscience, from a hospital board of directors to an individual who schedules procedures, and by allowing the refusal of "any lawful health service or activity."[vi] This threatens patients' access to all health care services, including vaccinations and blood transfusions.

ACOG believes that the top priority in any federal rulemaking must be ensuring access to comprehensive, evidence-based health care services. Access to comprehensive reproductive health care services is essential to women's health and well-being.[vii] ACOG urges HHS and OCR to put patients first and withdraw the Proposed Rule.

Sincerely,

Haywood L. Brown, MD, FACOG
President
American College of Obstetricians and Gynecologists

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[i] American College of Obstetricians and Gynecologists. Statement of Policy: Racial Bias. Feb 2017. *Accessed online:* https://www.acog.org/-/media/Statements-of-Policy/Public/StatementofPolicy93RacialBias2017-2.pdf?dmc=1&ts=20180326T1531018088

[ii] Informed consent. ACOG Committee Opinion No. 439. American College of Obstetricians and Gynecologists. Obstet Gynecol 2009; 114:401–8.

[iii] Partnering with patients to improve safety. Committee Opinion No. 490. American College of Obstetricians and Gynecologists. Obstet Gynecol 2011;117:1247–9.

[iv] Effective patient–physician communication. Committee Opinion No. 587. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;123:389–93.

[v] American College of Obstetricians and Gynecologists. Position Statement: Restrictions to Comprehensive Reproductive Health Care. April 2016. *Accessed online:* https://www.acog.org/Clinical-Guidance-and-Publications/Position-Statements/Restrictions-to-Comprehensive-Reproductive-Health-Care

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

[vii] Increasing access to abortion. Committee Opinion No. 613. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;124:1060–5.

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Exhibit 19

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Roger Severino
Director
Office for Civil Rights, Department for Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W. Room 509-F
Washington, DC 20201

RE: RIN 0945-ZA03; Docket HHS-OCR-2018-0002: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Mr. Severino:

The American Health Care Association and National Center for Assisted Living (AHCA/NCAL) is the nation's largest association of long term and post-acute care providers, with more than 13,000 member facilities who provide care to approximately 1.7 million residents and patients every year. Thank you for the opportunity to comment on the Office for Civil Rights' proposed rule intended to protect statutory conscience rights in health care.

AHCA/NCAL has concerns about the increased regulatory burden of this proposed rule for long term and post-acute care providers. Staff, residents, and residents' families from nursing centers, centers providing care for individuals with intellectual or developmental disabilities, and assisted living communities that accept Medicaid already have multiple outlets for reporting complaints or concerns. Furthermore, these are highly regulated sectors. In particular, nursing centers are in the process of implementing myriad new requirements through 2019 and are one of the most highly regulated sectors in the country. These requirements add another regulatory burden that reduces time for providing high quality patient-centered care.

We respectfully request that the Department of Health and Human Services do not apply the proposed regulations to these long term and post-acute care providers. For questions or to discuss these comments further, please contact Lillian Hummel at 202-898-2845

Sincerely,

Lillian Hummel

Lillian Hummel
Senior Director, Policy and Program Integrity

The American Health Care Association and National Center for Assisted Living (AHCA/NCAL) represent more than 12,000 non-profit and proprietary skilled nursing centers, assisted living communities, sub-acute centers and homes for individuals with intellectual and developmental disabilities. By delivering solutions for quality care, AHCA/NCAL aims to improve the lives of the millions of frail, elderly and individuals with disabilities who receive long term or post-acute care in our member facilities each day.

Exhibit 20

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March 26, 2018

Roger Severino
Director, Office for Civil Rights
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 515F
Washington, DC 20201

Re: HHS—OCR—2018—0002, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority; Proposed Rule (Vol. 83, No. 18) Jan. 26, 2018.

Dear Mr. Severino:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinical partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Department of Health and Human Services (HHS) Office for Civil Rights' (OCR) proposed rule regarding certain statutory conscience protections.

Hospitals and health systems are committed to respecting the conscience objections of hospital employees and medical staff. Conscience protections for health care professionals are long-standing and deeply rooted in our health care delivery system. For decades, the AHA and its members have supported policies to accommodate the differing convictions of our employees and medical staff by making provisions for them to decline to participate in delivering services they say they cannot perform in good conscience. Existing federal and state laws protect health care workers who express religious objections related to performing certain procedures.

At the same time, hospitals and health systems have obligations to their patients and are committed to providing the care they need. Existing laws create protections for patients and impose certain obligations on providers to ensure that patients have access to necessary care. Hospitals and health systems value every individual they have the opportunity to serve, and oppose discrimination against patients based on characteristics such as race, religion, national origin, sexual orientation or gender identity.

The intersection of these equally important obligations can present unique challenges. Neither obligation can or should be addressed in a vacuum. OCR's framework for enforcing the conscience protections at issue should account for this intersection of hospitals' obligation to ensure needed care for patients and the obligation to honor conscience objections of employees.

With this as a backdrop, we make the following recommendations.

THE POLICIES, PRACTICES, AND COURT PRECEDENT GOVERNING ENFORCEMENT OF OTHER CIVIL RIGHTS PROTECTIONS SHOULD BE THE MODEL FOR ENFORCEMENT OF THE CONSCIENCE PROTECTIONS AT ISSUE.

OCR observes that the conscience protections at issue are civil rights to be enforced no less than other civil rights protections. The AHA agrees that the conscience protections are among the civil rights of hospital employees and medical staff. They should, therefore, be duly protected.

In keeping with the principle that the conscience protections should be treated akin to other civil rights, the AHA urges OCR to ensure that the enforcement policies and practices applicable to the conscience protections are comparable to the long-standing policies and practices applicable when guaranteeing other civil rights protections for employees and staff. OCR should not invent new, distinct, or additional policies and practices that add unnecessary complexity and burden or prefer conscience protections over other civil rights. Rather, OCR should use existing civil rights frameworks as the model for the conscience protections at issue. This not only would place the conscience protections on a level playing field with other civil rights, but would ensure that the conscience protections are guaranteed through an enforcement framework that already has proven effective in analogous civil rights contexts.

To this end, **OCR should explicitly adopt a reasonable accommodation framework that provides the flexibility for HHS to take into account particular facts and circumstances to determine that a hospital has done all it reasonably could under the circumstances to accommodate conscience objections of employees or medical staff** (*Bruff v. North Miss. Health Servs.*, 244 F.3d 495 (5th Cir. 2001)).

Employment discrimination on the basis of religion is prohibited and employers are required to reasonably accommodate the sincerely held religious beliefs of employees, absent a showing of undue hardship on the employer (*See* 29 C.F.R. § 1605.2). This has been true for over a half century, and this framework has successfully protected employees, including those of hospitals and health systems, from religious discrimination. Analogous reasonable accommodation frameworks also have been successfully employed in other civil rights contexts, such as the Rehabilitation Act of 1973.

This framework has proven successful in the hospital context, in part, because it allows for an assessment of the reasonableness of a requested accommodation in context. The requirement of reasonably accommodating the sincerely held religious beliefs of employees and medical staff, absent a showing of undue hardship, guarantees robust protections for the religious beliefs of hospital employees and medical staff.

Consistent with this framework, a hospital should be responsible for providing *reasonable* conscience-based accommodations and an employee is responsible for providing fair notice of a specific and sincerely held religious or moral objection. A hospital should not be sanctioned for failing to accommodate the moral or religious beliefs of an employee or medical staff where, despite being on notice of his or her right to do so, the individual did not give the hospital advance notice of his or her objection (*Wessling v. Kroger Co.*, 554 F. Supp. 548 (E.D. Mich. 1982) (no Title VII violation when the employee did not give the employer notice of a desire for a religious accommodation)).

Adoption of this framework in the conscience rule would assure hospitals that they may continue with a time-tested way of honoring their responsibilities to ensure access to necessary care for all patients, while effectively protecting the religious and other conscience rights of employees and medical staff. It also would avoid the unnecessary and duplicative administrative burdens for hospitals that imposing an additional and different framework would create.

Hospitals have existing policies, procedures, and best practices. They also have decades of experience with how to meet their responsibility to provide reasonable accommodations. Adopting a parallel framework for the conscience protections would enable hospitals to seamlessly incorporate the conscience rights of employees and medical staff into the existing compliance frameworks. The religious and moral beliefs of hospital employees and medical staff would be protected, while reducing the complexity and burden for hospitals. **OCR should expressly affirm these guiding principles.**

DUE PROCESS PROTECTIONS SHOULD BE EXPLICITLY INCLUDED IN THE REGULATIONS.

The proposed regulations are silent on procedural protections for a recipient of funding before the Department may take an adverse action. OCR should affirmatively recognize the due process rights of recipients of federal funds. The regulations should reinforce those rights with a clear acknowledgement of the procedural protections applicable to any action by the Department that would adversely affect a recipient's continued receipt of, or future eligibility for, federal funding. For example, the Social Security Act controls whether participation in, or receipt of funding from, the Medicare program may be limited or terminated; the Medicare law and regulations control the procedural protections for providers.

As discussed above, there are existing and proven civil rights policies and practices that should apply equally here. In particular, the conscience regulations should expressly adopt the longstanding due process protections for Title VI enforcement. The same protections should apply for challenges to any finding of noncompliance with the conscience protections that OCR may make or any penalty or other adverse action for noncompliance with the conscience protections that OCR may seek to impose.

Additionally, the regulations should be explicit about the grounds for imposing any contemplated sanction and the procedural protections. The proposed regulation lists numerous potential adverse actions available to OCR or the Department without delineating the specific circumstances that must occur before taking any such action. The implication is that they are

available at OCR's or the Department's discretion, without reference to any reasonable standards. The regulation should expressly identify which sanction is applicable under which circumstances. It also should identify the related procedural protections, including notice and hearing rights. This would further the government's interests in not only ensuring fundamental fairness but also avoiding inappropriate disruption of health services that are federally funded.

REGULATORY BURDEN SHOULD BE EASED WHEREVER POSSIBLE.

The proposed requirement that a recipient report reviews, investigations, and complaints to any component of the Department from which it receives funding is burdensome and unnecessary. So, too, is the proposed requirement that a recipient seeking new or renewed funding report reviews, investigations, and complaints from the prior five years. No such requirements apply in other civil rights contexts. Because OCR will know of all such reviews, investigations, and complaints, OCR should instead be the source of this information within the Department. OCR will be the central repository of all such data and can make it readily available to other Departmental components, greatly reducing unnecessary burden on regulated parties.

Additionally, the sweep of these proposed disclosures is problematic. There is no distinction in the proposed treatment of, for example, general compliance reviews (unprompted by any particular concern), rejections of frivolous complaints, findings of compliance, or cases where a sanction is ultimately overturned. With new, renewed, or continuing funding at stake, the proposed reporting requirement risks inappropriately suggesting to the decision-maker that there is a cause for concern when there is in fact none, improperly biasing the decision-making against the recipient. The regulation should not effectively create a presumption of noncompliance. **The proposed reporting requirement should not be finalized.**

We appreciate your consideration of these issues. Please contact me if you have questions or feel free to have a member of your team contact Maureen Mudron, AHA deputy general counsel, at (202) 626-2301 or mmudron@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President

Exhibit 21

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

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March 27, 2018

The Honorable Alex M. Azar, II
Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (RIN 0945-ZA03), 83 Fed. Reg. 3880 (January 26, 2018)

Dear Secretary Azar:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to provide comments to the Department of Health and Human Services (HHS) in response to the Notice of Proposed Rulemaking (Proposed Rule or Proposal) on "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," issued by the Office of Civil Rights (OCR). In its Proposed Rule, OCR proposes to revise existing regulations and create new regulations to interpret and enforce more than 20 federal statutory provisions related to conscience and religious freedom. Under OCR's broad interpretation of these provisions, individuals, health care organizations, and other entities would be allowed to refuse to provide or participate in medical treatment, services, information, and referrals to which they have religious or moral objections. This would include services related to abortion, contraception (including sterilization), vaccination, end-of-life care, mental health, and global health support, and could include health care services provided to patients who are lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ).

For the reasons discussed below, the AMA believes the Proposed Rule would undermine patients' access to medical care and information, impose barriers to physicians' and health care institutions' ability to provide treatment, impede advances in biomedical research, and create confusion and uncertainty among physicians, other health care professionals, and health care institutions about their legal and ethical obligations to treat patients. We are very concerned that the Proposed Rule would legitimize discrimination against vulnerable patients and in fact create a right to refuse to provide certain treatments or services. Given our concerns, we urge HHS to withdraw this Proposal.

The AMA supports conscience protections for physicians and other health professional personnel. We believe that no physician or other professional personnel should be required to perform an act that violates good medical judgment, and no physician, hospital, or hospital personnel should be required to perform any act that violates personally held moral principles. As moral agents in their own right, physicians are informed by and committed to diverse cultural, religious, and philosophical traditions and beliefs. According to the *AMA Code of Medical Ethics*, "physicians should have considerable latitude to practice in accord with well-considered, deeply held beliefs that are central to their self-identities."

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Conscience protections for medical students and residents are also warranted. The AMA supports educating medical students, residents, and young physicians about the need for physicians who provide termination of pregnancy services, the medical and public health importance of access to safe termination of pregnancy, and the medical, ethical, legal, and psychological principles associated with termination of pregnancy, while maintaining that the observation of, attendance at, or any direct or indirect participation in abortion should not be required.

Nonetheless, while we support the legitimate conscience rights of individual health care professionals, the exercise of these rights must be balanced against the fundamental obligations of the medical profession and physicians' paramount responsibility and commitment to serving the needs of their patients. As advocates for our patients, we strongly support patients' access to comprehensive reproductive health care and freedom of communication between physicians and their patients, and oppose government interference in the practice of medicine or the use of health care funding mechanisms to deny established and accepted medical care to any segment of the population.

According to the AMA *Code of Medical Ethics*, physicians' freedom to act according to conscience is not unlimited. Physicians are expected to provide care in emergencies, honor patients' informed decisions to refuse life-sustaining treatment, and respect basic civil liberties and not discriminate against individuals in deciding whether to enter into a professional relationship with a new patient. Physicians have stronger obligations to patients with whom they have a patient-physician relationship, especially one of long standing; when there is imminent risk of foreseeable harm to the patient or delay in access to treatment would significantly adversely affect the patient's physical or emotional well-being; and when the patient is not reasonably able to access needed treatment from another qualified physician. The Code provides guidance to physicians in assessing how and when to act according to the dictates of their conscience. Of key relevance to the Proposed Rule, the *Code* directs physicians to:

- Take care that their actions do not discriminate against or unduly burden individual patients or populations of patients and do not adversely affect patient or public trust.
- Be mindful of the burden their actions may place on fellow professionals.
- Uphold standards of informed consent and inform the patient about all relevant options for treatment, including options to which the physician morally objects.
- In general, physicians should refer a patient to another physician or institution to provide treatment the physician declines to offer. When a deeply held, well-considered personal belief leads a physician also to decline to refer, the physician should offer impartial guidance to patients about how to inform themselves regarding access to desired services.
- Continue to provide other ongoing care for the patient or formally terminate the patient-physician relationship in keeping with ethics guidance.

The ethical responsibilities of physicians are also reflected in the AMA's long-standing policy protecting access to care, especially for vulnerable and underserved populations, and our anti-discrimination policy, which opposes any discrimination based on an individual's sex, sexual orientation, gender identity, race, religion, disability, ethnic origin, national origin or age. We are concerned that the Proposed Rule, by attempting to allow individuals and health care entities who receive federal funding to refuse to provide *any* part of a health service or program based on religious beliefs or moral convictions, will allow discrimination against patients, exacerbate health inequities, and undermine patients' access to care.

We would like to note that no statutory provision requires the promulgation of rules to implement various conscience laws that have been in existence for years. We believe physicians are aware of their legal obligations under these requirements and do not think that the promulgation of this rule is necessary to enforce the conscience provisions under existing law. OCR has failed to provide adequate reasons or a satisfactory explanation for the Proposed Rule as required under the Administrative Procedure Act (APA). As OCR itself acknowledges, between 2008 and November 2016, OCR received 10 complaints alleging violations of federal conscience laws; OCR received an additional 34 similar complaints between November 2016 and January 2018. In comparison, during a similar time period, from fall 2016 to fall 2017, OCR received over 30,000 complaints alleging violations of either HIPAA or civil rights. These numbers demonstrate that the Proposed Rule to enhance enforcement authority over conscience laws is not necessary.

OCR's stated purpose in revising existing regulations is to ensure that persons or entities are not subjected to certain practices or policies that violate conscience, coerce, or discriminate, in violation of federal laws. We believe that several provisions and definitions in the Proposed Rule go beyond this stated purpose and are ambiguous, overly broad, and could lead to differing interpretations, causing unnecessary confusion among health care institutions and professionals, thereby potentially impeding patients' access to needed health care services and information. The Proposed Rule attempts to expand existing refusal of care/right of conscience laws—which already are used to deny patients the care they need—in numerous ways that are directly contrary to the stated purpose of the existing laws. For example, one provision of the Church Amendments allows individuals who work for or with entities receiving grants or contracts for biomedical or behavioral research entities to refuse to participate in "any lawful health services or research activity" based on religious beliefs or moral convictions specifically related to the service or research activity to which they object. But the Proposed Rule attempts to broaden this provision to allow individuals to refuse to perform aspects of their jobs based on a mere reference to a religious or moral belief regardless of whether it relates to the specific biomedical or behavioral service or research activity they are working on. Such an attempted expansion goes beyond what the statute enacted by Congress allows.

We are concerned that the scope of the services and programs that would be covered under the Proposed Rule is broader than allowed by existing law. While OCR claims that it is trying to clarify key terms in existing statutes, it appears that they are actually redefining many terms to expand the meaning and reach of these laws. For example, "health program or activity" is defined in the proposed regulatory text to include "the provision or administration of any health-related services, health service programs and research activities, health-related insurance coverage, health studies, or any other service related to health or wellness whether directly, through payments, grants, contracts, or other instruments, through insurance, or otherwise." Likewise, "health service program" is defined in the proposed regulatory text to include "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded, in whole or in part, by [HHS]." These definitions make clear that OCR intends to interpret these terms to include an activity related <u>in any way</u> to providing medicine, health care, or any other service related to health or wellness, including programs where HHS provides care directly, grant programs such as Title X, programs such as Medicare where HHS provides reimbursement, and health insurance programs where federal funds are used to provide access to health coverage, such as Medicaid and CHIP. The definitions inappropriately expand the scope of the conscience provisions to include virtually any medical treatment or service, biomedical and behavioral research, and health insurance.

Furthermore, the Proposed Rule's new and expanded definitions often exceed, or are not in accordance with, existing definitions contained within the existing laws OCR seeks to enforce. For example, "health care entity" is defined under the Coats and Weldon Amendments to include a limited and specific range of individuals and entities involved in the delivery of health care. However, 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 by including a wide range of individuals, e.g., not just health care professionals, but any personnel, and institutions, including not only health care facilities and insurance plans, but also plan sponsors and state and local governments. This impermissibly expands statutory definitions and will create confusion.

We are also concerned that the proposed rule expands the range of health care institutions and individuals who may refuse to provide services, and broadens the scope of what qualifies as a refusal under the applicable law beyond the actual provision of health care services to information and counseling about health services, as well as referrals. For example, "assist in the performance" is defined as "participating in any program or activity with an articulable connection to a given procedure or service." The definition also states that it includes "counseling, referral, training, and other arrangements for the procedure, health service, or research activity." While "articulable connection" is not further explained, OCR states in the preamble that it seeks to provide broad protection for individuals and that a narrower definition, such as a definition restricted to those activities that constitute direct involvement with a procedure, health service, or research activity, would not provide sufficient protection as intended by Congress.

However, this definition goes well beyond what was intended by Congress. Specifically, 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. The statute does not contain a definition for the phrase "assist in the performance." Senator Church, during debate on the legislation, stated that, "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 to perform what would otherwise be a legal operation." Read in conjunction with the rest of the proposed rule, it is clear this definition is intended to broaden the amendment's scope far beyond what was envisioned when the amendment was enacted. It allows any entity involved in a patient's care—from a hospital board of directors to the receptionist that schedules procedures—to use their personal beliefs to determine a patient's access to care.

In a similar fashion, the proposed definition of "workforce" extends the right to refuse not only to an entity's employees but also to volunteers and trainees. When both of these definitions are viewed together, this language seems to go well beyond those who perform or participate in a particular service to permit, for example, receptionists or schedulers to refuse to schedule or refer patients for medically necessary services or to provide patients with factual information, financing information, and options for medical treatment. It could also mean that individuals who clean or maintain equipment or rooms used in procedures to which they object would have a new right of refusal and would have to be accommodated. We believe this could significantly impact the smooth flow of health care operations for physicians, hospitals, and other health care institutions and could be unworkable in many circumstances.

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The AMA is concerned that the Proposed Rule fails to address the interaction with existing federal and state laws that apply to similar issues, and thus is likely to create uncertainty and confusion about the rights and obligations of physicians, other health care providers, and health care institutions. Most notably, the Proposal is silent on the interplay with Title VII of the Civil Rights Act of 1964 and guidance by the Equal Employment Opportunity Commission, which along with state laws govern religious discrimination in the workplace. Title VII provides an important balance between employers' need to accommodate their employees' religious beliefs and practices—including their refusal to participate in specific health care activities to which they have religious objections—with the needs of the people the employer must serve. Under Title VII, employers have a duty to reasonably accommodate an employee or applicant's religious beliefs or practices, unless doing so places an "undue hardship" on the employer's business. It is unclear under the Proposed Rule if, for example, hospitals would be able to argue that an accommodation to an employee is an undue hardship in providing care. The Proposed Rule also could put hospitals, physician practices, and other health care entities in the impossible position of being forced to hire individuals who intend to refuse to perform essential elements of a job. Under Title VII, such an accommodation most likely would not be required.

Additional concerns exist for physicians with respect to their workforce under this Proposal. The Proposed Rule is unclear about what a physician employer's rights are in the event that an employee alleges discrimination based on moral or religious views when in fact there may be just cause for adverse employment decisions. For example, if a physician declines to hire an individual based on a lack of necessary skill, compensation and/or benefit requests out of the physician's budget, or simply because the individual is not a good fit in the office, but the individual also happens to be opposed to providing care to LGBTQ patients, does the physician open him/herself up to risk of a complaint to OCR? If so, physicians will be forced to substantially increase their documentation related to hiring and other decision-making related to human resources, adding administrative burden to already overworked practices. These considerations must not be overlooked by regulators, as OCR's enforcement mechanisms include the power to terminate federal funding for the practice or health care program implicated.

Adding to a practice's administrative burden is the Proposal's requirement that physicians submit both an assurance and certification of compliance requirements to OCR. Despite its reasoning in the preamble that HHS is "concerned that there is a lack of knowledge" about federal health care conscience and associated anti-discrimination laws, it remains unclear why OCR would require physicians to make two separate attestations of compliance to the same requirements, particularly given the administration's emphasis on reducing administrative burden in virtually every other space in health care. At the very least, OCR should (1) streamline the certification and assurance requirements with those already required on the HHS portal; and (2) expand the current exemptions from such requirements to include physicians participating not only in Medicare Part B, but also in Medicare Part C and Medicaid, as was the case in the 2008 regulation implementing various conscience laws. We reiterate, however, that we believe the overall compliance attestation requirements are unnecessary. If HHS' concern is about lack of awareness of the conscience laws, the AMA stands ready to assist with the agency's educational efforts in place of increased administrative requirements.

The Proposed Rule also seems to set up a conflict between conscience rights and federal, state, and local anti-discrimination laws, as well as policies adopted by employers and other entities and ethical codes of conduct for physicians and other health professionals. These laws, policies, and ethical codes are designed to protect individuals and patients against discrimination on the basis of race, gender, gender

identity, sexual orientation, disability, immigration status, religion, and national origin. It is unclear under the Proposed Rule how these important anti-discrimination laws, policies, and ethical codes will apply in the context of the expanded conscience rights proposed by OCR. The Proposed Rule also fails to account for those providers that have strongly held moral beliefs that motivate them to treat and provide health care to patients, especially abortion, end-of-life care, and transition-related care. For example, the Church Amendment affirmatively protects health care professionals who support or participate in abortion or sterilization services yet there is no acknowledgement of it in the Proposal.

Moreover, the Proposed Rule appears to conflict with, and in fact contradict, OCR's own mission, which states that "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" (emphasis added). In the past, HHS and OCR have played an important role in protecting patient access to care, reducing and eliminating health disparities, and fighting discrimination. There is still much more work to be done in these areas given disparities in racial and gender health outcomes and high rates of discrimination in health care experienced by LGBTQ patients. The Proposed Rule is a step in the wrong direction and will harm patients.

Likewise, the Proposed Rule does not address how conscience rights of individuals and institutions apply when emergency health situations arise. For example, the federal Emergency Medical Treatment and Labor Act (EMTALA) requires hospitals that have a Medicare provider agreement and an emergency room or department to provide an appropriate medical screening to any patient requesting treatment to determine whether an emergency medical condition exists, and to either stabilize the condition or transfer the patient if medically indicated to another facility. Every hospital, including those that are religiously affiliated, is required to comply with EMTALA. By failing to address EMTALA, the Proposed Rule might be interpreted to mean that federal refusal laws are not limited by state or federal legal requirements related to emergency care. This could result in danger to patients' health, particularly in emergencies involving miscarriage management or abortion, or for transgender patients recovering from transition surgery who might have complications, such as infections.

We are also concerned that the Proposed Rule could interfere with numerous existing state laws that protect women's access to comprehensive reproductive health care and other services. For example, the Proposed Rule specifically targets state laws that require many health insurance plans to cover abortion care (e.g., California, New York, and Oregon). OCR overturns previous guidance that was issued by the Obama administration providing that employers sponsoring health insurance plans for their employees were not health care entities with conscience rights; OCR argues that the previous guidance misinterpreted federal law, and, as discussed previously, proposes to add plan sponsors to the definition of health care entities. Likewise, the Proposed Rule could conflict with, and undermine, state laws related to contraceptive coverage. In addition, the Proposed Rule requires entities to certify in writing that they will comply with applicable Federal health care conscience and associated anti-discrimination laws. Under the broad language of the rule, hospitals, insurers, and pharmacies could claim they are being discriminated against if states attempt to enforce laws that require insurance plans that cover other prescription drugs to cover birth control, ensure rape victims get timely access to and information about emergency contraception, ensure that pharmacies provide timely access to birth control, and ensure that

hospital mergers and sales do not deprive patients of needed reproductive health services and other health care services.

In conclusion, the AMA believes that, as currently drafted, the Proposed Rule could seriously undermine patients' access to necessary health services and information, negatively impact federally-funded biomedical research activities, and create confusion and uncertainty among physicians, other health care professionals, and health care institutions about their legal and ethical obligations to treat patients. Given our concerns, we urge HHS to withdraw this proposed rule. If HHS does decide to move forward with a final rule, it should, at the very least, reconcile the rule with existing laws and modify the provisions we have identified to ensure that physicians and other health providers understand their legal rights and obligations.

Sincerely,

James L. Madara, MD

Exhibit 22

March 23, 2018

Office for Civil Rights
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 509F
200 Constitution Avenue, NW
Washington, DC 20210

Attention: Conscience Notice of Proposed Rule Making (NPRM), RIN 0945-ZA03

Submitted electronically to www.regulations.gov

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority
[HHS-OCR-2018-0002; RIN 0945-ZA03]

Dear Sir/Madam:

The American Nurses Association (ANA) and the American Academy of Nursing (AAN) submit the following comments in response to the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) Proposed Rule: *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*. This proposed rule requests comment on a number of provisions contained therein, and ANA and AAN through this comment letter seek to highlight the potential negative and unintended impacts which might follow from the final implementation of such, and offers policy recommendations. ANA is the premier organization representing the interests of the nation's 3.6 million registered nurses (RNs), through its state and constituent member associations, organizational affiliates, and individual members. ANA advances the nursing profession by fostering high standards of nursing practice, promoting a safe and ethical work environment, bolstering the health and wellness of nurses, and advocating on health care issues that affect nurses and the public. AAN serves the public and the nursing profession by advancing health policy and practice through the generation, synthesis, and dissemination of nursing knowledge. The Academy's more than 2,400 fellows are nursing's most accomplished leaders in education, management, practice, and research.

ANA and AAN strongly support the right and prerogative of nurses - and all healthcare workers – to heed their moral and ethical values when making care decisions. However, the primacy of the patient in nursing practice is paramount, and the moral and ethical considerations of the nurse should never, under any circumstance, result in the inability of the patient to receive quality, medically necessary, and compassionate care.

ANA and AAN are concerned that this proposed rule, in strengthening the authority of OCR to enforce statutory conscience rights under the Church Amendments, the Coats-Snowe Amendment, the Weldon Amendment, and other federal statutes, could lead to inordinate discrimination against certain patient populations – namely individuals seeking reproductive

health care services and lesbian, gay, bisexual, transgender, and queer or questioning (LGBTQ) individuals. Proliferation of such discrimination – which in the case of LGBTQ individuals is unlawful under Section 1557 of the Affordable Care Act (ACA) – could result in reduced access to crucial and medically necessary health care services and the further exacerbation of health disparities between these groups and the overall population.

Discrimination in health care settings remains a grave and widespread problem for many vulnerable populations and contributes to a wide range of health disparities. Existing religion-based exemptions already create hardships for many individuals. The mission of HHS is to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, patient care, public health, and social services. This proposed rule fails to ensure that all people have equal access to comprehensive and nondiscriminatory services, and dangerously expands the ability of institutions and entities, including hospitals, pharmacies, doctors, nurses, even receptionists, to use their religious or moral beliefs to discriminate and deny patients health care. All patients deserve universal access to high quality care and we as health care providers must guard against any erosion of civil rights protections in health care that would lead to denied or delayed care.

ANA and AAN believe that HHS should rescind this proposed rule and instead, through OCR, should create a standard for health systems and individual practices to ensure prompt, easy access to critical health care services if an individual provider has a moral or ethical objection to certain health care services; such a standard should build on evidence-based and effective mechanisms to accommodate conscientious objections to services including abortion, sterilization, or assisted suicide as cited in the proposed rule. ANA and AAN also believe that in no instance should a nurse – or any health care provider – refuse to treat a patient based on that patient's individual attributes; such treatment violates one of the central tenets of the professional *Code of Ethics for Nurses*. No patient should ever be deprived of necessary health care services or of compassionate health care; it is incumbent upon HHS to work to create accommodations to that end.

Code of Ethics for Nurses and Moral and Ethical Obligations

The critical importance of the relationship between the patient and the nurse is inherent in the fact that Provision 1 and Provision 2 of the *Code of Ethics for Nurses*[1] deal explicitly with these topics.

Affirming Health through Relationships of Dignity and Respect: *Provision 1 of the Code of Ethics:* states that "The nurse practices with compassion and respect for the inherent dignity, worth, and unique attributes of every person."[2] This includes respect for the human dignity of the patient and the demand that nurses must never behave prejudicially – which is to say, with

[1]American Nurses Association. *Code of Ethics for Nurses with Interpretive Statements*. 2015: Second Edition.
[2]Ibid: Pg. 1.

unjust discrimination. Nurses can and should base patient care on individual attributes, but only in the sense that those individual attributes inform the patient's care plan; nurses must always respect the dignity of such individual attributes.

Health care professionals work within a matrix of legal, institutional, and professional constraints and obligations, and their primary commitment to patients remains the foundational responsibility of health care.[3] *Provision 2* states that "The nurse's primary commitment is to the patient, whether an individual, family, group, community, or population."[4] Provision 2 explicitly establishes the primacy of the patient's interests in health care settings; this principle also situates the nurse-patient relationship within a larger "ethic of care" which encompasses the entire relational nexus in which the nurse and patient are situated, including the patient, the patient's family or close relationships, the nurse, the healthcare team, the institution or agency, and even societal expectations of care."[5]

While the primacy of the patient is not the only consideration when a nurse makes a care decision, it is the consideration which carries by far the most relative weight. Nurses then must base care decisions primarily on patients' needs. If a nurse feels that a moral or ethical consideration prevents him or her from delivering health care services, then the nurse, the full medical team, and/or the practice, institution, health system, or agency, should make an exhaustive and good-faith effort to ensure that the patient easily and promptly receives those health care services. In addition to the provisions contained within this proposed rule, OCR must implement guidelines by which the aforementioned stakeholders must ensure access to essential and quality health care services for all patients.

Considerations for Access to Reproductive Health Care Services

In addition to providing competent, professional and high quality care, there is also an emphasis on providing evidence-informed patient education and support as part of the nursing standard of care. The nursing profession holds sacred the patient's right of autonomy to make informed decisions to direct his or her care, as well as the crucial role that nurses play in supporting the patient. Patient education and advocacy are essential elements of the nursing process. Thus, it is the patients' decisions, regardless of faith or moral convictions, that should guide healthcare providers' care of patients, as articulated in the Code of Ethics for Nurses with Interpretive Statements.

For nurses who have concerns about the provision of specific healthcare services, existing laws and ethical guidelines are more than adequate to protect the rights of health care providers to follow their moral and religious convictions. There already exist effective models to accommodate providers' moral and religious beliefs in training and practice, while striking a

[3]Stahl, Ronit Y. and Emanuel, Ezekiel J. *Physicians, Not Conscripts — Conscientious Objection in Health Care*. The New England Journal of Medicine: 2017 April; 376: 1380-1385.
[4]American Nurses Association. Code *of Ethics for Nurses*: Pgs. 25-26.
[5]Ibid: Pg. 28.

crucial balance with delivering evidence-based, patient-centered care.[6] This proposed rule skews that balance, lowers the bar for care necessary for patients in vulnerable populations, and exposes women who seek reproductive health care to discrimination and harmful delays.[7] Such discrimination is well-documented – one study notes that 24% of women were denied treatment by a health care provider for pregnancy termination.[8] The proposed rule defines "discrimination" for the first time in a way that subverts the language of landmark civil rights statutes to shield those who discriminate, rather than protecting against discrimination.[9]

The proposed rule provides a broad definition of "assist in the performance" of an activity to which an individual can refuse to participate. The definition allows for blanket discrimination by permitting a broad interpretation of not only what type of services that can be refused but also the individuals who can refuse. For example, under this proposed rule, a receptionist can refuse to schedule a patient's pregnancy termination or appointment for contraception consultation. This expansion violates the plain meaning of the existing law and goes against the stated mission of HHS.

Data suggest that health care providers believe that even when they are morally opposed to offering care, they are willing to make referrals and coordinate care according to care coordination standards to ensure adequate, timely and safe care, as well as full information about standard of care and available services, is provided for all patients.[10] Yet, the proposed rule creates a definition of "referral" that allows refusal to provide any information that could help the patient receive the proper care necessary; withholding information or complete care recommendations (e.g., professionals withholding diagnostic or treatment information) is unethical.

International professional associations such as the World Medical Association, as well as national medical and nursing societies and groups such as the American Congress of Obstetricians and Gynecologists and the Royal College of Nursing, Australia, have similarly agreed that the provider's right to conscientiously refuse to provide certain services must be secondary to his or her first duty, which is to the patient.[11] This right to refuse must be bound

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[6]National Women's Law Center. *Trump Administration Proposes Sweeping Rule to Permit Personal Beliefs to Dictate Health Care.* February 16, 2018. Web: https://nwlc.org/resources/trump-administration-proposes-sweeping-rule-to-permit-personal-beliefs-to-dictate-health-care/
[7]Ibid.
[8]Biggs, M. Antonia and John M. Neuhaus and Diana G. Foster. *Mental Health Diagnoses 3 Years After Receiving or Being Denied an Abortion in the United States.* The American Journal of Public Health: 2015 December; 105(12): 2557-2563.
[9]National Women's Law Center. *Trump Administration Proposes Sweeping Rule to Permit Personal Beliefs to Dictate Health Care.*
[10]Harris, LH et al. *Obstetrician-gynecologists' objections to and willingness to help patients obtain an abortion.* Obstetrics and Gynecology: 2011 October; 118(4): 905-912.
[11]Chavkin, W. et al. *Conscientious objection and refusal to provide reproductive healthcare: a White Paper examining prevalence, health consequences, and policy responses.* The International Journal of Gynaecology and Obstetrics: 2013 December; 123 Supplement 3: S41-56.

by obligations to ensure that the patient's autonomous rights to information and services are not infringed upon.[12]

Considerations for the Protection of LGBTQ Access to Health Care Services

LGBTQ populations experience a significant rate of discrimination in health care settings, and also experience negative health outcomes compared with the overall population. The reasons for this are complex and varied, but many stem from a pattern of societal stigma and discrimination[13] exacerbated by the historical designation of homosexuality as a mental disorder[14], the onset of the HIV/AIDS epidemic[15], religious prejudice with respect to homosexuality[16], and government policy such as *Don't Ask, Don't Tell*.[17] Indeed, the current administration filed a brief in federal court with the U.S. Court of Appeals for the 2nd Circuit in the case of *Zarda v. Altitude Express* arguing that sex discrimination provisions under Title VII of the 1964 Civil Rights Act do not protect employees from discrimination based on sexual orientation.[18]

HHS in May 2016 issued a rule to implement Section 1557 of the ACA, which clarifies that discrimination based on sex stereotyping and gender identity is impermissible sex discrimination under the law.[19] The current administration has failed to defend this regulation in federal court in the case of *Franciscan Alliance v. Burwell* (a different federal court recently ruled that Section 1557 *ipso facto* provides for the rule's aforementioned protections);[20] this seems to point to a preferential pattern of treatment in favor of religious conscience objections over the civil rights of LGBTQ populations despite consistent federal court opinions to the contrary.

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[12] Ibid.

[13] U.S. Centers for Disease Control and Prevention. *Gay and Bisexual Men's Health: Stigma and Discrimination.* February 29, 2016. Web: https://www.cdc.gov/msmhealth/stigma-and-discrimination.htm

[14] Burton, Neel. *When Homosexuality Stopped Being a Mental Disorder.* Psychology Today (Blog). September 18, 2015. Web: https://www.psychologytoday.com/blog/hide-and-seek/201509/when-homosexuality-stopped-being-mental-disorder

[15] Barnes, David M. and Meyer, Ilan H. *Religious Affiliation, Internalized Homophobia, and Mental Health in Lesbians, Gay Men, and Bisexuals.* American Journal of Orthopsychiatry: 2012 October; 82(4): 505-515.

[16] DeCarlo, Pamela and Ekstrand, Maria. *How does stigma affect HIV prevention and treatment*? University of California, San Francisco: October 2016. Web: https://prevention.ucsf.edu/library/stigma

[17] U.S. Department of Defense. *Don't Ask, Don't Tell Is Repealed.* September 2011. Web: http://archive.defense.gov/home/features/2010/0610_dadt/

[18] Feuer, Alan and Weiser, Benjamin. *Civil Rights Act Protects Gay Workers, Appeals Court Rules.* The New York Times: February 26, 2018. Web: https://www.nytimes.com/2018/02/26/nyregion/gender-discrimination-civil-rights-lawsuit-zarda.html

[19] Gruberg, Sharita and Bewkes, Frank J. *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial.* Center for American Progress: March 7, 2018: Pg. 1. Web: https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/

[20] Ibid: Pg. 2.

OCR is responsible for accepting and investigating such complaints under Section 1557; the Center for American Progress in 2018 conducted an independent analysis of such complaints from May 2010 to January 2017 and found the following breakdown of complaint issues:[21]

- Denied care because of gender identity – non-transition related (24.3%)
- Misgendering or other derogatory language (18.9%)
- Denied insurance coverage for transition care (13.2%)
- Provider denied transition care (10.8%)
- Inadequate care because of gender identity (10.8%)
- Other discrimination based on sexual orientation (8.1%)
- Denied insurance coverage because of gender identity – non-transition-related (5.4%)
- Denied care because of sexual orientation or HIV status (5.4%)
- Inadequate care because of sexual orientation (2.7%)

It is worth noting that the number of Section 1557 complaints during this 7-year period (34) is comparable to the number of health care conscience complaints (44) during the 10-year period cited in the proposed rule. This comparison not only highlights the balance that must be struck between these two types of complaints, but also raises the question as to how such discrimination translates to actual health outcomes.

Negative health outcomes that disproportionately impact LGTBQ individuals include: increased instances of mood and anxiety disorders and depression, and an elevated risk for suicidal ideation and attempts; higher rates of smoking, alcohol use, and substance use; higher instances of stigma, discrimination, and violence; less frequent use of preventive health services; and increased levels of homelessness among LGBTQ youth.[22] Men who have sex with men (MSM) and transgender women also experience significantly higher rates of HIV/AIDS infections, complications, and deaths; this burden falls particularly heavily on young, African-American MSM and transgender women. As evidenced in the Section 1557 complaints above, this disease burden is itself known to contribute to discrimination against LGBTQ individuals. Transgender individuals also face particularly severe discrimination in health care settings: 33% of transgender patients say that a health care provider turned them away because of being transgender.[23]

As noted in the "*Code of Ethics for Nurses and Moral and Ethical Obligations*" section of this comment letter, nurses are obligated to respect the human dignity of all patients and to ensure that all patients receive quality, medically necessary, and compassionate care that is timely and safe. The health disparities highlighted in this section demonstrate the negative outcomes

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[21] Ibid: Pg. 5.
[22] U.S. Institute of Medicine Committee on Lesbian, Gay, Bisexual, and Transgender Health Issues and Research Gaps and Opportunities. *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding.* Washington, DC: National Academies Press; 2011.
[23] James, Sandy E. et al. *The Report of the U.S. Transgender Survey.* 2016: 96-97. Web: www.ustranssurvey.org/report

associated with failure to provide such care. The civil rights of LGBTQ individuals – including the accessibility of quality health care services for LGBTQ individuals – should be protected in a manner consistent with the statutory conscience rights of health care workers under this proposed rule; the protection of such conscience rights should never impede the ability of LGBTQ individuals to access health care services.

Policy Recommendations and Conclusion

ANA and AAN do not wish to diminish the role of moral and ethical considerations in patient care. In fact, the *Code of Ethics for Nurses* acknowledges both implicitly and explicitly that such considerations play critical roles when it comes to a patient's care plan. ANA and AAN do, however, reiterate the primacy of the patient in nursing care; ensuring that all patients are able to access quality, medically necessary, and compassionate care is paramount to nursing practice. ANA and AAN also acknowledge the dual roles that OCR plays with respect to simultaneously enforcing the ACA's Section 1557 provisions and the statutory conscience rights provisions referenced in the proposed rule, including those under the Church Amendments, the Coats-Snowe Amendment, and the Weldon Amendment.

To this end, ANA and AAN believe that in order to accommodate both priorities, OCR should implement guidelines for individual providers, practices, agencies, health systems, and institutions to accommodate both employees and patients. Namely, these guidelines must ensure that if any of the aforementioned stakeholders has a moral or ethical objection to providing certain health care services, they must have in place an organized plan by which the patient – without creating or exacerbating inequities - is able to easily access the quality, affordable, compassionate, and comprehensive health care that they need. Such guidelines reflect the primacy of the patient while at the same time recognizing that various federal statutes protect the conscience rights of health care workers. HHS and OCR must also work with stakeholders to implement existing, evidence-based models that facilitate a standard of care that integrates timely care coordination when health care providers or their employers exhibit a moral or ethical objection to providing certain health care services; such models must also protect the ability of the patient to access evidence-informed care and must not expose women and other marginalized populations to discrimination.

ANA and AAN also reiterate in no uncertain terms that nurses (or any other health care provider) cannot cite conscience rights protections as a reason for refusing to treat certain patient populations, including women seeking reproductive health care and LGBTQ populations. Such refusals go far beyond the provisions of any of the federal statutes cited in the proposed rule, a fact again borne out consistently in federal court opinions. As noted above, the nurse's primary concern is the patient's care. To provide inequitable care for an individual, or to refuse to provide that care entirely, would demonstrate unjust discrimination toward that patient. Such care (or lack thereof) directly contradicts one of the central tenets of nursing practice, violates federal law – including Section 1557 of the ACA – and leads to negative health outcomes and population health disparities.

March 23, 2018
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ANA and AAN believe that this proposed rule should be rescinded and that HHS should develop a standard for accommodation for conscientious objection to certain services which in no way limits the ability of the patient to receive timely, affordable, quality, and compassionate care. This proposed rule is restrictive with respect to ensuring such care. Given the current administration's track record when it comes to defending religious objections at the expense of individual rights, it seems to follow that this proposed rule would represent a significant lurch toward such defense in the health care field. This is unacceptable; in health care practice, patients come first, and HHS must make every attempt to strike an equitable balance between conscientious objections and patients' inalienable rights.

ANA and AAN welcome an opportunity to further discuss the issue of statutory conscience rights protections for health care workers. If you have questions, please contact Liz Stokes, Director, Center for Ethics and Human Rights (liz.stokes@ana.org) or Mary Beth Bresch White, Director, Health Policy (marybreschwhite@ana.org).

Sincerely,

Pamela F. Cipriano, PhD, RN, NEA-BC, FAAN
President
American Nurses Association

Karen S. Cox, PhD, RN, FACHE, FAAN
President
American Academy of Nursing

cc: Debbie Hatmaker, PhD, RN, FAAN, Interim Chief Executive Officer, American Nurses Assoc.
Cheryl G. Sullivan, MSES, Chief Executive Officer, American Academy of Nursing

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Exhibit 29

2001 Medical Parkway
Annapolis, Md. 21401
443-481-1000
askAAMC.org

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 Anne Arundel Medical Center (AAMC) in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26. AAMC is a health system based in Annapolis, Maryland. Our health system includes Maryland's third busiest hospital, five outpatient pavilions, a 40-bed substance use and mental health treatment facility, and a medical group with more than 55 locations throughout our service area. Last fiscal year (FY 2017), AAMC saw 26,300 inpatient admissions and did more than 920,000 office visits. We have more than 4,700 employees and 1,100 members of Medical Staff.

Notably, AAMC was recently recognized by the Human Rights Campaign's Healthcare Equality Index as a "2018 LGBTQ Healthcare Equality Top Performer." We are proud that AAMC fosters a culture and environment that is welcoming, fair, and open to all patients, regardless of sexual orientation or gender identity.

Providing quality, consistent patient care is a priority for AAMC. Both federal and state laws already protect individual health care employees from discrimination on the basis of their religious beliefs. These protections are meaningful and familiar to health care providers that have navigated these personnel obligations alongside our commitment to providing seamless, respectful healthcare to patients. The proposed regulation creates a complex, burdensome notice and reporting process for organizations and hospitals that is not only unnecessary, but also threatens to undermine the continuity of patient care at our facility.

These are our concerns:

1. **The proposed regulation attempts to inappropriately broaden religious exemptions in a way that would deny patients medically necessary or lifesaving care.**

Hospitals and healthcare organizations are in the business of providing healthcare services and information to our patients and communities. The broad and undefined nature of the proposed regulation prioritizes individual providers' beliefs over life-saving patient care and threatens to prevent the provision of services to patients in need. The lack of definition, structure, and guidelines will leave healthcare providers without standards and structures to guide the provision of necessary care to the most vulnerable populations, especially lesbian, gay, bisexual, and transgender (LGBT) people and women.

The scope of the regulation and the health care workers it applies to may make it impossible for some providers to offer certain treatments or to see certain patients. The proposed regulation purports to extend the interpretation of existing statutory exemptions far beyond the current standards. Under the proposed regulation a provider could be seen as empowered to refuse to provide any health care service or information for a religious or moral reason – capturing Pre-Exposure Prophylaxis (PrEP), infertility care, hormone therapy and other non-surgical gender transition-related services, and possibly even HIV treatment under the auspices of "any" service.

2. **The proposed regulation conflicts with Title VII and fails to inform hospitals of the boundaries of the regulation when the exemption may cause an undue hardship on the hospital.**

Title VII requires employers to reasonably accommodate the sincerely-held religious beliefs, observances, and practices of its applicants and employees, when requested, unless the accommodation would impose an undue hardship on business operations. This is defined as more than a de minimis cost. The proposed regulation fails to mention Title VII and the balancing of employee rights and provider hardships. Hospitals and health organizations are at a loss as to how to reconcile the proposed regulation and Title VII given the dearth of litigation on the subject and the lack of explanation in the proposed regulation. The Equal Employment Opportunity Commission (EEOC) addressed this problematic intersection in its public comment in response to the 2008 regulation that had the substantively identical legal problem, noting that "Introducing another standard under the Provider Conscience Regulation for some workplace discrimination and accommodation complaints would disrupt this judicially-approved balance and raise challenging questions about the proper scope of workplace accommodation for religious, moral or ethical beliefs." In this public comment the EEOC concluded that, "Title VII should continue to provide the legal standards for deciding all workplace religious accommodation complaints. HHS's mandate to protect the conscience rights of health care professionals could be met through coordination between EEOC and HHS's Office for Civil Rights, which have had a process for coordinating religious discrimination complaints under Title VII for over 25 years." We agree with the EEOC.

3. **The proposed regulation lacks safeguards to ensure patients would receive emergency care as required by federal law (EMTALA) and ethical standards.**

The proposed regulation is dangerously silent in regards to ensuring patient wellbeing. The lack of consideration of patients' rights is evidenced by the fact that the proposed regulation contains no provision to ensure that patients receive legally available, 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.

The proposed regulation also fails to address potential conflicts with emergency care requirements. Under the Emergency Medical Treatment and Active Labor Act (EMTALA), a hospital receiving government funds and providing emergency services is required also to provide medical screening and stabilizing treatment to a patient who has an emergency medical condition (including severe pain or labor). However, the proposed regulation contains a blanket right of refusal for physicians, with no discussion of their duties under EMTALA or how conflicts should be resolved.

AAMC's EMTALA policy states, "All patients to whom this Policy applies shall receive an initial screening examination by Qualified Medical Personnel and appropriate treatment within the capabilities of Anne Arundel Medical Center without regard to age, race, color, religion, national origin, sex, sexual orientation, ability to pay, payer, physical or mental condition or handicap." Similar language exists in other AAMC policies, including our Patient Rights and discrimination policies.

Conclusion

Simply put, this proposed regulation is bad policy and will hurt our patients and communities. Hospitals and health systems exist to treat patients and provide them with access to the information they need for treatment. Entities that serve patients must be committed to respecting both the values of health care workers and the patients and the communities they serve in a way that allows for the delivery of care. The sweeping exemption and its undefined boundaries of the proposed regulation will have a chilling effect on the provision of life saving and medically necessary healthcare.

Sincerely,

Maulik

Maulik Joshi, DrPH
Executive Vice President, Integrated Care Delivery and Chief Operating Officer
Anne Arundel Medical Center
2000 Medical Parkway
Annapolis, MD 21401

Exhibit 31

Association of
American Medical Colleges
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400
www.aamc.org

Via Electronic Submission *(www.regulations.gov)*

March 26, 2018

Roger Severino
Director, Office of Civil Rights
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Protecting Statutory Conscience Rights in Health Care, HHS (HHS-OCR-2018-0002)

Dear Mr. Severino:

The Association of American Medical Colleges (AAMC or Association) welcomes the opportunity to comment on the Department of Health and Human Services (HHS' or the Agency's) proposed rule titled *Protecting Statutory Conscience Rights in Health Care, HHS*, 83 *Fed. Reg.* 3880 (January 26, 2018).

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Our members are all 151 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, we serve the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences. As will be described in detail below, should the rule be finalized as proposed, it will result in harm to patients, undermine standards of medical professionalism, and raise serious concerns regarding individuals' rights that are protected by other federal and state laws. **Therefore, we urge the Department to withdraw the proposed regulation.**

The Needs of Patients Should Be Put First

Ethical and moral issues within the context of health care are among the most challenging that we face. They require a careful balance between the rights of the health care professional to avoid behavior that violates his/her moral or ethical code, and the rights of a patient to receive lawful health care services that are safe and medically appropriate. In some circumstances, it is difficult to maintain this balance. When that happens, the health and the rights of the patient, who is in the more vulnerable position, must be given precedence. Those who choose the profession of medicine are taught repeatedly during their medical school and residency training that, in the end, their duty to care for the patient must come first, before self. For example, the American Medical Association *Principles of Medical Ethics* state, "A physician shall, while caring for a patient, regard responsibility to the patient as paramount." This does not mean that a physician or other health care provider must act in violation of his or her own moral code,

but it does mean that a physician has the duty to provide information and to refer the patient to other caregivers without judgment.[1]

Julie Cantor wrote about the need for a balance towards professionalism in her article, "Conscientious Objection Gone Awry – Restoring Selfless Professionalism in Medicine" (New England Journal of Medicine, April 9, 2009), which is cited in this proposed rule instead as evidence of rampant discrimination against those who wish to practice women's health. Rather than promote discrimination against health care professionals, Dr. Cantor calls on those who "freely choose their field" to evaluate their beliefs in relation to their specialties and whether they are able to provide all legal options for care. "As gatekeepers to medicine, physicians and other health care providers have an obligation to choose specialties that are not moral minefields for them. ... Conscience is a burden that belongs to that individual professional; patients should not have to shoulder it."

There Is No Demonstrable Need for the Proposed Rule

As we stated when we commented on the original 2008 Federal Health Care Conscience Rule, no individual or entity in this country has the option to pick and choose the laws to which he/she will adhere. Every health care provider and entity already has the obligation to comply with all applicable federal laws. The Department has offered little evidence that this has not been the case. The Office of Civil Rights has received just forty-four complaints since it was designated with authority to enforce the Church, Coats-Snow, and Weldon Amendments. The paucity of complaints does not provide compelling evidence of a need for the expansion of OCR's authority, or the need for changes in the current regulations.

Accreditation Organizations Require Medical Students and Residents to Be Taught to Respond to the Many Health Care Needs of a Diverse Patient Population and Respect a Medical Student or Resident's Decision to Not Receive Training in Abortions

Starting with undergraduate medical education and continuing through residency training, physicians are taught that they will be practicing medicine in a multi-cultural, multi-ethnic world in which patients and their families hold diverse viewpoints on many complex ethical issues that affect health care. Their education also occurs in an atmosphere that acknowledges that as health care providers, physicians themselves bring a diversity of religious and moral views on health care issues to their work. Such disparate views are examined during the educational process during a physician's initial training and throughout the individual's professional development.

Belying the concern that medical schools and training program are discriminating against medical students and residents for their religious views are the accreditation requirements of the Liaison Committee for Medical Education (LCME), which accredits all US medical education programs leading to the MD degree, and the Accreditation Council for Graduate Medical Education (ACGME), which accredits residency programs that seek to attract a wide variety of individuals into medicine. Both organizations have standards that are designed to ensure that the education of physicians provides an environment that embraces diversity of views and values for both health care providers and patients. For instance, the LCME requires that "[t]he selection of individual [medical] students must not be influenced by any political or financial factors."

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[1] American Medical Association Council on Ethical & Judicial Affairs, "Code of Medical Ethics Opinion 1.1.7" https://www.ama-assn.org/delivering-care/physician-exercise-conscience

Additional requirements include the following:

> A medical school does not discriminate on the basis of age, creed, gender identity, national origin, race, sex, or sexual orientation.
>
> A medical school ensures that the learning environment of its medical education program is conducive to the ongoing development of explicit and appropriate professional behaviors in its medical students, faculty, and staff at all locations and is one in which all individuals are treated with respect. The medical school and its clinical affiliates share the responsibility for periodic evaluation of the learning environment in order to identify positive and negative influences on the maintenance of professional standards, develop and conduct appropriate strategies to enhance positive and mitigate negative influences, and identify and promptly correct violations of professional standards.
>
> A medical school develops effective written policies that address violations of the code, has effective mechanisms in place for a prompt response to any complaints, and supports educational activities aimed at preventing inappropriate behavior. Mechanisms for reporting violations of the code of professional conduct are understood by medical students, including visiting medical students, and ensure that any violations can be registered and investigated without fear of retaliation. (Standards, Publications, & Notification Forms. LCME. lcme.org/publications. Accessed March 2018).

Further, the LCME's June 2017 Rules of Procedure regarding medical school accreditation state that:

> Medical education programs are reviewed solely to determine compliance with LCME accreditation standards. LCME accreditation standards and their related elements are stated in terms that respect the diversity of mission of U.S. medical schools, including religious missions.

The LCME also recognizes the need for medical students to learn how to care for a diverse patient population. For example,

> The faculty of a medical school ensure that the medical curriculum provides opportunities for medical students to learn to recognize and appropriately address gender and cultural biases in themselves, in others, and in the health care delivery process. The medical curriculum includes instruction regarding the following:
>
> - The manner in which people of diverse cultures and belief systems perceive health and illness and respond to various symptoms, diseases, and treatments
> - The basic principles of culturally competent health care
> - The recognition and development of solutions for health care disparities
> - The importance of meeting the health care needs of medically underserved populations
> - The development of core professional attributes (e.g., altruism, accountability) needed to provide effective care in a multidimensional and diverse society

Similarly, the ACGME states that:

> Residents are expected to demonstrate sensitivity and responsiveness to a diverse patient population, including but not limited to diversity in gender, age, culture, race, religion, disabilities, and sexual orientation.

> Clinical learning environments (CLEs) need to ensure that their residents and fellows learn to recognize health care disparities and strive for optimal outcomes for all patients, especially those in potentially vulnerable populations. As front-line caregivers, residents and fellows are a valuable resource for formulating strategies on these matters. They can assist the CLEs in addressing not only low-income populations, but also those that experience differences in access or outcome based on gender, race, ethnicity, sexual orientation, health literacy, primary language, disability, geography, and other factors.
>
> The diverse, often vulnerable, patient populations served by CLEs also provide an important opportunity for teaching residents and fellows to be respectful of patients' cultural differences and beliefs, and the social determinants of health.
>
> In considering patient outcomes, it is important to note that patients at risk for disparities are likely to require differences in care that are tailored to their specific needs—based not only on their biological differences, but also on other social determinants of health (e.g., personal social support networks, economic factors, cultural factors, safe housing, local food markets, etc.).

The ACGME's Common Program Requirements state that "Programs must provide a professional, respectful, and civil environment that is free from mistreatment, abuse, or coercion of students, residents, faculty and staff. Programs, in partnership with their Sponsoring Institutions, should have a process for education of residents and faculty regarding unprofessional behavior and a confidential process for reporting, investigating, and addressing such concerns. (Standard VI.B.6)

In regard to women's healthcare, both accrediting organizations are clear that a program cannot require training in abortion procedures. The ACGME's Program requirements specific to obstetrics and gynecology state "Residents who have a religious or moral objection may opt-out and must not be required to participate in training in or performing induced abortions." The profession of medicine seeks to embrace within its ranks individuals from diverse racial/ethnic, cultural, religious and socioeconomic backgrounds. Such diversity of backgrounds helps to ensure that physicians will understand and be sympathetic to the traditions, values, and beliefs of their patients and provide competent care.

The Proposed Rule Is Overly Expansive In Its Reach and Is Incongruous with Medical Professionalism

The proposed rule is overly expansive, allowing physicians and others to avoid engaging in any activity "with an articulable connection" to the objectionable procedure, "include[ing] counseling, referral, training, and other arrangements for the procedure." It then proposes a definition of referral that expands the general understanding of referral to include "the provision of <u>*any*</u> information…when the entity or health care entity making the referral sincerely understands that particular health care service, activity, or procedure to be a purpose or *possible outcome of the referral*." (emphasis added). The refusal of a physician or other health care professional to provide a patient with information, or to give a patient a referral to a provider where the desired care is available, risks limiting the patient's access to health care. Allowing health care professionals to engage in behavior that could harm patients is incongruous with the standards of medical professionalism that are the core of a physician's education and the practice of medicine.

Similarly, the proposed regulation would interpret the term "assist in the performance" to include "any activity with an articulable connection to a procedure, health service, or research activity[.]" The proposed regulation states that this definition is intended to be broad, and not limited to direct involvement with a procedure, health service, or research activity. For example, this broader definition could apply to an employee whose task is to clean a room where a particular procedure took place. Such a

broad view is unnecessary particularly since the employee has the option to seek employment elsewhere while the patient may have only one place where he/she can receive care.

The Proposed Rule Will Do Harm to Lower Income Americans, Racial and Ethnic Minorities, the LGBTQ Community, and Patients in Rural Areas

The proposed rule would allow physicians and others to avoid engaging in any activity "with an articulable connection" to the objectionable procedure, "includ[ing] counseling, referral, training, and other arrangements for the procedure." This broad reach will create or exacerbate inequities in health care access for Americans whose access may already be limited due to their geographic residence or financial means. For rural- and frontier-dwelling Americans who reside in a health professional shortage area, access to certain services might functionally cease to exist as a result of this proposed rule: seeking care in distant locales might be too burdensome or expensive. This holds, too, for lower income Americans who lack the financial means to seek out care for procedures when their primary physicians decline to provide services.

Racial and ethnic minority women have reported experiencing race-based discrimination when receiving family planning care.[2] The proposed rule may exacerbate this problem and the consequences that follow for women and their children. Research has associated unintended pregnancy with several adverse maternal and child health outcomes, such as delayed prenatal care, tobacco and alcohol use during pregnancy, delivery of low birthweight babies[3], and poor maternal mental health.[4] These negative health outcomes are more prevalent in racial and ethnic minority communities likely would worsen under the proposed rule.

For the lesbian, gay, bisexual, transgender, and queer (LGBTQ) communities, the proposed rule may further exacerbate heath care access disparities. It is well documented that LGBTQ Americans currently experience discrimination in health care settings, erecting a barrier to accessing health care services.[5] This proposed rule would codify what many within and beyond the LGBTQ communities will view as state-sanctioned discrimination, and allow providers to refuse care or appropriate referrals solely on the basis of their patients' sexual orientation or gender identity. This stands in stark opposition to OCR's stated goal to "protect fundamental rights of nondiscrimination."

The Proposed Rule Adds Burdensome Requirements That Have No Commensurate Benefit

The Department and this Administration have undertaken major efforts to reduce regulatory burden, such as "Reducing Regulation and Controlling Regulatory Costs" (Executive Order 13771, issued January 30, 2017), "Enforcing the Regulatory Reform Agenda" (Executive Order 13777, issued February 24, 2017), the Centers for Medicare & Medicaid's "Patient over Paperwork" initiative (launched October 2017, in an effort to reduce unnecessary burden), and several Requests for Information regarding administrative burden. The burden associated with complying with the proposed rule runs counter to this goal. Moreover, the investment in resources that would be required for a large teaching health care system to

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[2] Thorburn S, Bogart LM. "African American women and family planning services: perceptions of discrimination." *Women Health*. 2005;42(1):23–39.

[3] Institute of Medicine (US) Committee on Unintended Pregnancy; Brown SS, Eisenberg L, editors. "The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families. National Academies Press (US); 1995. 3, *Consequences of Unintended Pregnancy*. Available from: https://www.ncbi.nlm.nih.gov/books/NBK232137/

[4] Herd P et al., "The implications of unintended pregnancies for mental health in later life," *American Journal of Public Health*, 2016, 106(3):421–429.

[5] Cahill, S. "LGBT Experiences with Health Care," *Health Affairs* Vol. 36, No.4. 2017. Available from: https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.0277

ensure compliance and monitoring of all of the proposed requirements would be even more onerous and reduce funds available for the core missions of teaching, patient care, and research.

The Department proposes to modify existing civil rights clearance forms (or develop similar forms in the future), and notes that it might require submission of these documents annually and incorporate by reference in all other applications submitted that year. The receipt of any federal funds already requires the compliance with all federal laws and regulations; assurances and attestations to compliance are routine. OCR has not made clear why there is a need for additional assurance and certification.

The Department also proposes notice requirements, which includes notice on the funding recipient's website, in prominent and conspicuous physical locations where other notices to the public and notices to the recipient's workforce are customarily posted. The notice is to be posted by April 26, 2018, or for new recipients, within 90 days of becoming a recipient. Even if the rule is finalized by April 26, and no changes are made in the notice requirement, it is unreasonable to expect current recipients to comply by that date.

The rule also proposes that if a sub-recipient is found to have violated federal health care conscience and associated anti-discrimination laws, the recipients "shall be subject to the imposition of funding restrictions and other appropriate remedies." Requiring the imposition of funding restrictions should be dependent on the facts and circumstances of a particular case; however, by using the word "shall" there seems to be no discretion in whether this penalty is appropriate. If the rule is finalized, the AAMC asks that OCR clearly make the penalty optional by using "may" instead of "shall."

The AAMC strongly urges the Department to withdraw the proposed rule. Alternatively, the rule should be re-proposed and narrowed in scope to, at a minimum, appropriately balance the needs of patients with the needs of health care providers who have freely chosen their profession.

If you would like additional information, please contact Ivy Baer, Senior Director and Regulatory Counsel, at 202-828-0499 or ibaer@aamc.org.

Sincerely,

Janis M. Orlowski MD

Janis M. Orlowski, MD MACP
Chief, Health Care Affairs

Exhibit 32

March 27, 2018

The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) opposes the Department of Health and Human Services proposed rule, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, which seeks to permit discrimination by providers in all aspects of health care without adequately protecting patients from discrimination in accessing health care services. This proposed rule is not necessary to protect the rights of providers. The existing rule issued in 2011 adequately protects the conscience of providers and patients.

As a membership organization of nurses dedicated to improving and promoting the health of women and newborns and strengthening the nursing profession, AWHONN asserts that nurses have the professional responsibility to provide nonjudgmental nursing care to all patients, either directly or through appropriate and timely referrals. However, AWHONN recognizes that some nurses may have religious or moral objections to participating in certain reproductive health care services, research, or associated activities. Therefore, AWHONN supports the existing protections afforded under federal law for a nurse who refuses to assist in performing any health care procedure to which the nurse has a moral or religious objection so long as the nurse has given appropriate notice to his or her employer.

AWHONN considers access to affordable and acceptable health care services a basic human right. With regard to the nurse's role in meeting the health care needs of patients, AWHONN advocates that nurses adhere to the following principles:

- Nurses should not abandon a patient, nor should they refuse to care for someone based on personal preference, prejudice, or bias.
- Nurses have the professional responsibility to provide impartial care and help ensure patient safety in emergency situations and not withdraw care until alternate care is available, regardless of the nurses' personal beliefs.
- At the time of employment, nurses are professionally obligated to inform their employers of any values or beliefs that may interfere with essential job functions. Nurses should ideally practice in settings in which they are less likely to be asked to assist in care or procedures that conflict with their religious or moral beliefs.

By permitting providers to refuse to refer patients based on the provider's religious beliefs or moral convictions, the proposed rule carries severe consequences for patients, making it difficult for many individuals to access the care they need.

The proposed rule will undermine critical federal health programs delivered through the Title X Family Grants. The Proposed Rule would seemingly allow health care entities to receive grants and contracts under Title X, while refusing to provide key services required by those programs.[1] For instance, Congress

[1] *See* Rule *supra* note 1, at 180-181, 183. *See also Title X Family Planning*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (2018), https://www.hhs.gov/opa/title-x-family-planning/index.html; *Title X an Introduction to the Nation's*

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has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling[2] and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.[3] Under the Proposed Rule, the Department would seemingly allow entities to apply for and receive federal funds while exempting them from the core legal and programmatic duties upon which such funds are generally conditioned.[4] The Proposed Rule creates uncertainty about whether Title X grantees may ensure that the sub recipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. Such actions are particularly concerning in the context of federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for low-income populations.[5] When it comes to Title X, the Proposed Rule would not only sanction conduct at odds with pre-existing legal requirements, but could also undermine the program's fundamental objectives. Every year millions of low-income, including under-insured, and uninsured individuals, rely on Title X clinics to access services they otherwise might not be able to afford.[6]

The Proposed Rule will carry severe consequences for providers and undermine the provider-patient relationship. AWHONN asserts that any woman's reproductive health care decisions are best made by the informed woman in consultation with her health care provider. AWHONN believes these personal and private decisions are best made within a health care system whose providers respect the woman's right to make her own decisions according to her personal values and preferences and to do so confidentially. Therefore, AWHONN supports and promotes a woman's right to evidence-based, accurate, and complete information and access to the full range of reproductive health care services. AWHONN opposes legislation and policies that limit a health care provider's ability to counsel women as to the full range of options and to provide treatment and/or referrals, if necessary.

Title VII of the Civil Rights Act of 1964 protects workers (applicants and employees) from employment discrimination based on race, color, religion, sex, national origin, or participation in certain protected activities. With respect to religious protection, Title VII applies to most U.S. employers and requires reasonable accommodation of the religious beliefs, observances, and practices of employees when requested, unless such accommodation would impose undue hardship on business operations. These protections do and should continue to apply to nurses and other health care professionals.

A nurse should retain the right to practice in his or her area of expertise following a refusal to participate in an abortion, sterilization, gender reassignment surgery, or any other procedure. This refusal should not jeopardize the nurse's employment or subject him or her to harassment. In addition, one's moral and ethical beliefs should not be used as criteria for employment, unless they preclude the nurse from fulfilling essential job functions. AWHONN asserts that these rights should be protected through written

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Family Planning Program, NAT'L FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOC. (2017) (*hereinafter* NFPRHA), https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf.

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

[3] *See* What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).

[4] *See, e.g.*, Rule *supra* note 1, at 180-185.

[5] *See* NFPRHA *supra* note 34.

[6] *See id.*

institutional policies that address reasonable accommodations for the nurse and describe the institution's required terms of notice to avoid patient abandonment.

Sincerely,

Seth A. Chase, MA
Director, Government Affairs
Association of Women's Health, Obstetric & Neonatal Nurses (AWHONN)
1800 M Street NW
Suite 740 South
Washington, DC 20036

Exhibit 33

750 W. Virginia Street
Milwaukee, WI 53204

www.AuroraHealthCare.org

March 27, 2018

Mr. Roger Severino
Director, Office for Civil Rights (OCR)
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Department of Health and Human Services, Office for Civil Rights RIN 0945-ZA03

Dear Director Severino:

On behalf of Aurora Health Care, Inc. (Aurora), we appreciate the opportunity to submit comments regarding the Department of Health and Human Services (HHS) proposed rule regarding federal conscientious and religious objection protections for health care workers.

Aurora is a not-for-profit integrated health care provider based in Milwaukee, Wisconsin, serving over 100 communities in the eastern third of the state through 15 hospitals, a physician practice comprised of 1,432 physicians, 72 pharmacies, Wisconsin's largest home health organization, and one of the state's largest intern and resident programs. As evidenced by more than 300 active clinical trials, Aurora is dedicated to delivering innovations to provide the best possible care today, and to define the best care for tomorrow.

Aurora's Provides Quality Health Care to Diverse and Unique Patient Populations in the Many Different Communities We Serve

Aurora's caregivers touch the lives of millions of diverse patients across a large geographical area, which provides us with an opportunity to improve the health outcomes of the unique patient populations we serve.

In this comment letter, Aurora is pleased to share our feedback with HHS regarding how its proposed rule would impact our integrated delivery system's ability to tackle some of the most serious health care issues facing our nation today, including combatting the alarming opioid abuse epidemic raging right here in Wisconsin, reducing chronic illnesses, eliminating health disparities and expanding access to high-quality care for vulnerable patients. Unfortunately, these complex and pervasive challenges are particularly endemic in Wisconsin, where significant patient populations live in highly urban or highly rural, low-income and underserved communities.

Therefore, any HHS proposed regulation should be assessed and evaluated by how it would impact access to care for our most vulnerable patient populations in these underserved communities.

Aurora Respects Our Health Care Professionals' Moral and Religious Beliefs

At Aurora, we respect our health care professionals' moral and religious beliefs and their conscience-based objections to certain activities. We stand by our policy to "make reasonable accommodations for requests to be excluded from activities that are in conflict with sincerely held religious, ethical or moral beliefs."

Aurora Does Not Tolerate Discrimination Towards Our Patients and Those Seeking Medical and Behavioral Health Care

At the same time, we respect our patients' rights and do not tolerate discrimination against patients. To that point, we also stand by our policy that "patients are given reasonable access to care in a safe setting without regard to race, creed, color, national origin, ancestry, religion, sex, sexual orientation, gender identity, marital status, age, disability or source of payment."

At Aurora, we seek to provide culturally competent care to every patient we serve. We are committed to fostering a culture of inclusion that embraces and nurtures our patients, colleagues, partners, physicians and communities. Patients and their caretakers come to Aurora from a wide range of backgrounds, and many of these patients have serious or multiple health challenges. Providing the right care demands sensitivity to their diverse needs. Diversity is at the very heart of Aurora's important mission of providing patient-centered care.

Aurora's Existing Policies Strike an Appropriate Balance between Caregivers and Patients

It is Aurora's position that our existing policies strike the right balance between caregiver and patient rights. Any new and additional protections for conscientious and religious objections for health care workers have the real potential of throwing off this necessary balance and negatively impacting patient access to care. Aurora's medical centers and clinics are, at times, the only connection to health care in some of Wisconsin's most rural communities. And in both rural and urban areas, we continually strive to remove barriers to health care access. The proposed rule regarding conscience objections in health care could negatively impact this critical access in an unjustified way.

Additional Federal Government Intervention is Unnecessary

It also is Aurora's position that additional protections are unnecessary because, as a health care organization, we already have a strong commitment to respecting the moral, ethical and religious beliefs of both its health care professionals and patients. This commitment is grounded in part by professional codes of ethics. The American Medical Association upholds that a physician's duties to inform[1] and refer[2] remain in situations where conscience objections

[1] "Providing information about treatment options the physician sincerely believes are morally objectionable or about how the patient might obtain objected-to treatment elsewhere is morally distant from what the physician's deeply held beliefs tell him or her is wrong. Providing information is sufficiently distant that the risk to physician integrity is outweighed by the professional obligation to inform, given the strong ethical import of informed consent. Physicians can avoid any taint of complicity by notifying prospective patients prior to initiating a patient-physician relationship about interventions or services that conscience prohibits the physician from offering." American

could worsen or limit access to treatments or health care. Aurora respects that no two patient-physician relationships are exactly alike, and that physicians must follow their individual consciences in weighing matters of professional integrity. At Aurora, clinical ethics consultation is available to health care professionals to assist in balancing these values commitments. It is our experience that a health care professional will pursue a balanced course of action that both aligns with their conscience and respects the patient's need for treatment or health care. For example, health care professionals often determine it is their responsibility to both provide information about and refer for services they personally find morally objectionable. There is not a need for the federal government to intervene with this process. Additional federal regulatory burdens could disrupt the existing patient-physician relationship which is critical to unlocking the potential of patient-driven value care.

Regulatory Relief Needed to More Effectively Address the Nation's Complex Health Challenges

Aurora appreciates HHS' current focus on eliminating and preventing additional regulatory burdens in the Medicare program and America's health care system to allow integrated networks and providers to spend more time and resources tackling the nation's most pervasive health challenges and not on paperwork. Excessive red tape not only stands as a barrier to care, but as a key driver of cost. Reducing unnecessary regulatory burdens would not only provide relief and free up limited precious resources to allocate to the most urgent and acute health needs, but would also provide an opportunity to make care more patient-centered than ever before.

Proposal Would Significantly Increase Regulatory Burdens for Delivery Systems and Providers

Unfortunately the HHS proposed rule would place significant new regulatory burdens on hospitals and their caregivers instead of reducing them. The proposed rule follows an announcement of a new Conscience and Religious Freedom Division within the HHS Office for Civil Rights (OCR) which will be tasked with enforcing these new regulations. Under the proposed rule, OCR would have new authority to initiate compliance reviews, conduct investigations, and use enforcement tools to address violations of the new rule. Under this new authority, OCR could conduct an investigation even if a formal complaint has not been filed.

In addition, the proposed rule would require recipients of federal funds to submit an assurance and certification of their compliance and to notify protected individuals and entities of their rights. Notification would require posting on Aurora's website, as well as a physical location within each of our facilities. Aurora would also need to maintain records to verify compliance with the proposed rule. The proposed rule also recommends designating an additional employee and

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Medical Association Council on Ethical and Judicial Affairs, "Physician Exercise of Conscience" (2014), page 6, https://www.ama-assn.org/sites/default/files/media-browser/public/about-ama/councils/Council%20Reports/council-on-ethics-and-judicial-affairs/i14-ceja-physician-exercise-conscience.pdf.

[2] See especially: "The greater the likelihood or severity of harm, the stronger the physician's duty to facilitate in some way the patient's access to needed care, even in the face of becoming in some measure complicit in what the physician believes is wrong," and "terminating the relationship is ethically permissible only when timeliness of care is not a factor and the physician adheres to ethical guidelines for terminating the relationship." For more, see: AMA CEJA, "Physician Exercise of Conscience," page 7.

Director Roger Severino
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resources responsible for compliance, the adoption of internal grievance procedures, and the preparation of internal compliance reports as best practices.

The need to comply with the proposed rule will unfortunately impose additional unnecessary federal regulatory burdens on providers and require resources and focus being diverted away from patient-driven and value-based care.

Addressing the Underlying Socioeconomic Contributors to Chronic Diseases

The complex but pervasive relationship between socioeconomic status and health outcomes is unfortunately highly visible throughout underserved communities across America where people living at or below the poverty line have a greater likelihood of having one or more chronic health conditions. This dynamic is playing out in Milwaukee where the city has higher than state average rates of infant mortality, obesity, sexually transmitted diseases, cancer (breast, cervical, lung, and prostate), violence, teen pregnancy, childhood lead poisoning, and mortality due to unintentional injuries. Chronic health problems - such as obesity, diabetes, heart disease and hypertension - are endemic to Milwaukee's underinsured and uninsured populations.

Any new federal regulation that would intentionally or unintentionally impede our most vulnerable patient populations from seeking and accessing care has the potential to further exacerbate both the human suffering and financial tolls being inflicted by these deadly but preventable chronic conditions.

Barriers to Accessing Behavioral Health Services

The proposed rule regarding federal conscientious and religious objections for health care workers could have significant negative unintended consequences for underserved and vulnerable patients in urgent need of critical access to behavioral and mental health care.

Wisconsin is faced with a severe shortage of behavioral health specialists right at the same time an alarming opioid overdose epidemic rages across the state. According to a recent report from the Centers for Disease Control and Prevention, Wisconsin saw the largest one-year rise across the entire nation in increased opioid overdoses, with opioid-related ED visits increasing by 109% from 2016 to 2017.

One in five Americans suffers from a diagnosable, treatable mental health condition. Minority groups — including African Americans, Hispanics, Asian Americans and Native Americans — are more likely to experience the risk factors that can cause mental health issues. Most notably, poverty contributes to the development of problems such as depression, anxiety and post-traumatic stress disorder (PTSD). They are also considerably under-represented when it comes to receiving mental health treatment.

Moreover, research suggests that lesbian, gay, bisexual, and transgender (LGBT) individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and

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human rights. Discrimination against LGBT persons has been associated with high rates of psychiatric disorders, substance abuse, and suicide.[3]

Given that mental and behavioral health resources for the general patient population are woefully inadequate in our state, we strongly urge policymakers to especially consider the potential any new regulation would have for underserved patients who are also seeking this type of care.

Conclusion

Aurora Health Care appreciates the opportunity to comment on the proposed rule regarding federal conscientious and religious objection protections for health care workers.

We strongly urge HHS to avoid implementing any policies that would result in denying care to specific groups of people.

Should you have any questions, please feel free to give me a call at (414) 299-1878 or contact Anthony Curry at (414) 299-1657.

Thank you in advance for your consideration.

Sincerely,

Cristy Garcia-Thomas
Chief Experience Officer
Aurora Health Care

[3] Office of Disease Prevention and Health Promotion. (2016). Lesbian, gay, bisexual, and transgender health. Retrieved from https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health

Exhibit 37

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 Rule, Protecting Statutory Conscience Rights in Health Care RIN 0945-ZA03

To Whom It May Concern:

I am writing on behalf of Boston Medical Center (BMC), a private, not-for-profit, 487-bed, academic medical center located in Boston, Massachusetts, in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26, 2018. BMC is the primary teaching affiliate for Boston University's School of Medicine. It is the busiest trauma and emergency services center and the largest safety net hospital in New England. BMC is dedicated to providing accessible health care to everyone. 57% of its patients are from under-served populations and 32% of patients do not speak English as a primary language. Seeing more than one million patient visits a year in over 70 medical specialties and subspecialties, BMC physicians are leaders in their fields with the most advanced medical technology at their fingertips and working alongside a highly-skilled nursing and professional staff. BMC's mission is to provide exceptional care, without exception to all patients. BMC's staff is committed to providing quality care to every patient and family member with respect, warmth and compassion.

Providing quality, consistent patient care is a priority at our hospital. Through its commitment to serve everyone, BMC offers numerous outreach programs and services. BMC offers Interpreter Services in over 250 Languages, 24 hours a day. We are proud of the diversity of our patients and employees and hold strong in our belief that many faces create our greatness. BMC has a long history of caring for lesbian, gay, bi-sexual, transgender and gender queer (gender non-conforming) (LGBTQ) patients. In 2016 BMC proudly established its Center for Transgender Medicine and Surgery (CTMS), which is the first medical center in New England to provide a comprehensive transgender health care program and is a leader nationally in the delivery of transgender medical care. BMC recognizes that the transgender patient population has been severely marginalized because of discrimination and bias, which

has resulted in significant health disparities for this group. The 2015 U.S. Transgender Survey Report, prepared by the National Center for Transgender Equality, found that one-third of the survey respondents reported having at least one negative health care related experience because of being transgender and nearly one-fourth, of the almost 28,000 respondents, did not seek health care due to a fear of mistreatment by health care providers because of being transgender. As a result of the historical harm and mistreatment faced by transgender people, many health care institutions throughout the United States are providing more targeted health care services for transgender and LGBQ patients and thereby working towards decreasing the health care disparities for LGBTQ patients that are still pervasive throughout the United States.

The Department of Health and Human Services' Proposed Rule "Protecting Statutory Conscience Rights in Health Care", as currently drafted, has the potential to significantly detract from the progress made and increase the health disparities faced by the LGBTQ patient population. First, the proposed rule, under the notion of religious protection, overreaches with an embedded catch-all provision that essentially states that no entity shall discriminate against a physician or other health care personnel for refusing to perform "**any lawful health service"** on grounds that "it is contrary to [the health care provider's] religious beliefs or moral convictions." (Proposed Rule §88.3(a)(2)(v)). **This provision is too broad.** Second, both federal and state laws already protect individual health care employees from discrimination on the basis of their religious beliefs. For example, to be in compliance with the existing federal and Massachusetts laws, BMC has a policy, as do many other hospitals, that establishes a procedure to excuse an employee from participating in a patient's care or treatment when the prescribed care or treatment conflicts with the employee's values, ethics, or religious beliefs. The existing protections are meaningful and familiar to health care providers who have navigated these personal obligations alongside their commitment to providing seamless, respectful health care to patients. There is no need to augment the existing protections. Third, HHS' proposed regulation creates a complex, burdensome notice and reporting process for organizations and hospitals that is not only unnecessary and threatens to undermine the continuity of patient care, but also results in significant additional costs at a time when we as a society are trying to bring down the cost of health care in the United States. Finally, the proposed rule does not address what should happen in emergency departments or emergent care situations in which a patient's life is in danger. There are specific requirements under the federal Emergency Medical and Labor Treatment Act (EMTALA) that prohibit hospitals with emergency departments from refusing to treat people based on their insurance status or ability to pay. EMTALA requires hospitals to provide "an appropriate medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available in emergency departments, to determine whether or not an emergency medical condition exists." (42 C.F.R. 489.24(a)(1)(i)). The proposed rule is silent on how EMTALA's requirements can be reconciled with its catch-all provision. **For these reasons and as further explained below, we urge the Department to withdraw the proposed rule.**

1. The proposed rule attempts to inappropriately broaden religious exemptions in a way that would deny patients medically necessary care and could lead to discrimination against entire patient groups.

Hospitals and health care organizations are in the business of providing health care services and information to patients and communities. The broad and undefined nature of the proposed rule gives individual providers' beliefs priority over life-saving patient care and threatens to prevent the provision of services to patients in need. The lack of definition, structure, and guidelines will leave health care providers without standards and structures to guide the provision of necessary care to the most vulnerable populations, including LGBTQ people.

The broad scope of the proposed rule's catch-all provision and the health care workers it applies to will make it possible for some providers to deny certain treatments or to decline to see certain patients. The proposed rule contemplates extending the interpretation of existing statutory exemptions, for procedures such as abortion and sterilization, far beyond the current standards. Forty-five states, including Massachusetts, have state laws that protect health care providers who object to participating in abortion procedures and several states also include protections for providers who do not want to participate in sterilization procedures.[1] Massachusetts General Law Ch. 112 §12I provides a protocol through which a health care provider shall not be discriminated against for not participating in a patient's care or treatment related to abortion and sterilization. These type of state laws and the existing federal laws (Church Amendment, Coats-Snowe Amendment and the Weldon Amendment) already provide health care provider protection. Hospital policies throughout the country should reflect compliance with their state and federal laws. For example, BMC has a policy that delineates a protocol so that an employee "shall not be required to participate in tubal ligations, vasectomies, abortions, or any other procedures that conflict with his/her ethical principles unless the patient's life is in immediate danger." The BMC policy is tailored to address specific procedures that may be contrary to a provider's religious beliefs or ethical principles, it also makes a reference to "any other procedure" that may conflict with a provider's ethical principle and outlines a specific method (in writing) by which a provider can request to be relieved from certain patient care duties, while taking patient safety into consideration. The existing protections are sound and protect the religious beliefs and moral convictions of BMC's health care providers, as well as ensure that necessary patient care is provided.

[1] "*Refusing to Provide Health Services*" Published on *Guttmacher Institute* (https://www.guttmacher.org.) March 1, 2018. See https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services

Roger Sevirino, Director of HHS' Office of Civil Rights stated in an interview that "The way these conscience claims work is that providers do not deny service to patients because of identities. What happens is providers choose not to provide or engage in certain procedures at all."[2] The problem with this approach is that the scope of what procedures are covered by the proposed rule are not clear. The proposed rule certainly emphasizes abortion, sterilization and assisted suicide, but Section 88.3 (a)(2)(v) is a catch-all provision that essentially empowers any physician or other health care personnel "to refuse to perform or assist in the performance of such service or activity on the grounds that doing so would be contrary to his or her religious beliefs or moral convictions, or because of his or her religious beliefs or moral convictions."

Under HHS' proposed rule a provider could be seen as empowered to refuse to provide **any** health care service or information for a religious or moral reason – extending beyond abortion and sterilization procedures, to other types of procedures in general and other areas of health care services, such as the provision of Pre-Exposure Prophylaxis (PrEP), infertility care, hormone therapy and other non-surgical gender transition-related services, and possibly even HIV treatment under the auspices of "any" service. The language of the proposed rule extends beyond specific procedures to health care services in general. This is problematic because, as drafted, the catch-all provision could also be viewed as protecting a health care provider who refuses to treat a transgender person for a condition that is completely unrelated to a gender transition procedure, such as providing treatment for a broken leg, cancer care, the flu or appendicitis, if the health care provider asserts that caring for a transgender person is contrary to his/her moral conviction. The language of this proposed rule potentially authorizes discrimination by health care providers towards an entire patient group regardless of the procedure, treatment or service that is needed.

2. The proposed rule conflicts with Title VII and fails to inform hospitals of the boundaries of the rule when the exemption may cause an undue hardship on the hospital.

Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e) already requires employers to reasonably accommodate the sincerely-held religious beliefs, observances, and practices of its applicants and employees, when requested, unless the accommodation would impose an undue hardship on business operations, which is defined as more than a *de minimis* cost. The proposed regulation fails to mention Title VII and the balancing of employee rights and provider hardships. BMC and other hospitals and health organizations are at a loss as to how to reconcile the proposed rule and Title VII given the dearth of litigation on the subject and the lack of explanation in the proposed rule.

[2] "*New Trump Initiatives: A win for anti-abortion activists, protections for "conscience" objections*" By Jessica Ravitz, CNN, January 19, 2018.

The Equal Employment Opportunity Commission (EEOC) addressed this problematic intersection in its public comment in response to the 2008 Federal Health Care Conscience Rule that had the substantively identical legal problem, noting that: "Introducing another standard under the Provider Conscience Regulation for some workplace discrimination and accommodation complaints would disrupt this judicially-approved balance and raise challenging questions about the proper scope of workplace accommodation for religious, moral or ethical beliefs." In this public comment the EEOC concluded that, "Title VII should continue to provide the legal standards for deciding all workplace religious accommodation complaints. HHS's mandate to protect the conscience rights of health care professionals could be met through coordination between EEOC and HHS's Office for Civil Rights, which have had a process for coordinating religious discrimination complaints under Title VII for over 25 years." On this point, Boston Medical Center agrees with the EEOC.

3. The proposed rule creates additional and unnecessary cost for hospitals.

The proposed rule requires each hospital to make routine assurances, certifications and employee and public notifications related to compliance with its requirements. The Proposed Rule's Notice Requirement, § 88.5, requires that notices concerning the Federal Health Care Conscience and Associated Anti-Discrimination Protections be placed on hospital websites, posted in prominent and conspicuous physical locations in every department where notices to the public and notices to their workforce are customarily posted. This section also makes reference to including the notification in personnel manuals, employment applications and student handbooks. The costs associated with these requirements are unnecessary because most hospitals, including BMC, already have policies and references in employee manuals that respect religious freedoms and offer relief to employees from patient care duties that conflict with an individual's religious beliefs or ethical principles.

Furthermore, according to the proposed rule's preamble (Table 4: Summary of Costs) the estimated financial burden for the proposed rule will be $312.3 million in the first year and $125.5 million, annual recurring costs, during years two to five. The total estimated burden for compliance with this proposed rule, over its first five years, is $814.3 million dollars; over three-quarters of a billion dollars. This is an exorbitant amount of money for the facilities within the health care industry to spend at a time when there are calls to action and efforts being made to bring down the cost of health care throughout the United States. The return on investment will not justify the estimated burden, especially since there are already protections in place at the federal and state level related to conscience objections to participating in procedures such as abortion, sterilization and assisted suicide.

4. The proposed rule lacks safeguards to ensure patients would receive emergency care as required by federal law and ethical standards.

The proposed rule is dangerously silent in regards to ensuring patient wellbeing. The lack of consideration of patients' rights is evidenced by the fact that the proposed rule contains no provision to ensure that patients receive legally available, 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.

The proposed rule also fails to address potential conflicts with emergency care requirements. Under the Emergency Medical Treatment and Active Labor Act (EMTALA) (42 U.S.C. § 1395dd), a hospital receiving government funds and providing emergency services is required to provide medical screening and stabilizing treatment to a patient who has an emergency medical condition (including severe pain or labor) (42 U.S.C. § 1395dd(a) and (b)). However, the proposed regulation contains a blanket right of refusal for physicians, with no discussion of their duties under EMTALA or how conflicts should be resolved. In fact, the proposed rule's preamble specifically identifies as problematic the 2016 American Congress of Obstetricians and Gynecologists reaffirmation of its ethics opinion that providers have an obligation to provide care regardless of the provider's personal moral objections if a referral is not possible or would negatively impact the patient's health. This reaffirmation is a tenet of providing necessary care for all who are in need. The requirements of EMTALA must be reconciled with the elements of the proposed rule, since EMTALA contains significant civil penalties (up to $50,000 for each violation) to prevent hospitals and physicians from disregarding their duties in treating all patients in similar manner (42 U.S.C. § 1395dd(d)(1)).

Conclusion

BMC is committed to providing exceptional care, without exception to everyone in our community. Hospitals and health systems exist to treat patients and provide them with access to the information they need for treatment. Entities that serve patients must be committed to respecting both the values of health care workers <u>and</u> the patients and the communities they serve in a way that allows for the delivery of care. BMC respects the dignity and rights of its diverse employees and patients. Our vision is to meet the health needs of the people of Boston and beyond by providing high quality comprehensive care to all, particularly mindful of the needs of vulnerable populations. HHS's proposed rule would stymie our ability to do this. The sweeping catch-all provision and the undefined boundaries of this proposed rule will have a chilling effect on the provision of life saving and medically necessary health care, result in significant unnecessary costs and contradict existing federal and state laws. BMC strongly urges the Department to withdraw the proposed rule. Alternatively, the rule should be re-proposed and (1) narrowed in scope to, at a minimum, remove the broad and vague catch-all language found in §88.3, (2) be drafted in a way that it does not contradict or is silent towards existing federal

laws, such as Title VII and EMTALA and (3) should not include an expensive and burdensome notification and certification protocol.

If you would like additional information, please contact Melissa Shannon, Vice-President of Government Affairs at (617) 638-6732 or melissa.shannon@bmc.org or Wendoly Ortiz Langlois, Associate General Counsel at (617) 638-7901 or wendoly.langlois@bmc.org.

Sincerely,

Kate Walsh

Kate Walsh
President and Chief Executive Officer
Boston Medical Center

Exhibit 38

XAVIER BECERRA
Attorney General

State of California
DEPARTMENT OF JUSTICE

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March 27, 2018

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

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

Dear Secretary Azar:

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

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

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

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

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

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

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

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

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

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

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

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

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

b. The Proposed Rule Exceeds Congressional Authority

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

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

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

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

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

c. The Proposed Rule is Contrary to Law

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

XAVIER BECERRA
Attorney General of California

Exhibit 39

STATE OF CALIFORNIA

Dave Jones, Insurance Commissioner

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Submitted via www.regulations.gov

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 SW
Washington, DC 20201

SUBJECT: Comments on Proposed Rule RIN 0945–ZA03: "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority"

Dear Secretary Azar:

As California's Insurance Commissioner, I lead the largest consumer protection agency in the state and am responsible for regulating California's insurance market, which is the nation's largest. The California Department of Insurance implements and enforces consumer protections such as essential health benefits requirements, anti-discrimination protections, and laws pertaining to timely access to medical care.

Your proposed rule, *Protecting Statutory Conscience Rights in Health Care,* would result in delays in timely access to medical care, denials of access to medically necessary basic health care services, and would likely result in widespread discrimination in our health care system. Simply put, it undermines patient care.

Existing state and federal law provide health care provider conscience protections, but do not allow them to interfere with patient access to care or civil rights protections that prohibit discrimination. I strongly object to the proposed rule *Protecting Statutory Conscience Rights in Health Care* ("Rule"), which encourages discrimination that will harm patients and urge that it be withdrawn by your Department.

Impacts of the Proposed Rule

Under the ostensible claim of protecting religious beliefs and moral convictions, the Rule instead would give providers free rein to discriminate against people on the basis of race, sex, sexual orientation, gender, gender identity, and almost any other kind of bias. The very individuals whose rights the Office of Civil Rights ("OCR") was created to protect would now be subject to discrimination under the Rule. A provider could, ostensibly, refuse under this Rule to provide medical care to a biracial couple seeking a medically necessary health service on the grounds

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that doing so would be contrary to his or her religious beliefs or moral convictions. A medical facility, provider or insurer – by action of a scheduling assistant, intake personnel, board of directors, or medical provider – could deny treatment to a patient seeking gender reassignment surgery on the basis that he or she finds it morally objectionable. Similarly, under the proposed Rule, a woman could be denied timely access to abortion services; a provider could refuse to treat a child because her parents are lesbians and the doctor objects to their sexual orientation. In this Rule, HHS improperly pits the beliefs of providers, insurers, and other health care entities against the rights of patients.

Additionally, the Rule attacks a fundamental aspect of federalism by preventing the application of state law and consitutional protections. The U.S. Department of Health and Human Services ("HHS") cannot interfere with a state's ability to protect the civil rights of its residents. California law requires health insurance coverage for a comprehensive set of basic health care services, including reproductive health services. California's Unruh Civil Rights Act explictly prohibits discrimination:

> All persons within the jurisdiction of this state are free and equal, and no matter what their sex, race, color, religion, ancestry, national origin, disability, medical condition, genetic information, marital status, sexual orientation, citizenship, primary language, or immigration status are entitled to the full and equal accommodations, advantages, facilities, privileges, or services in all business establishments of every kind whatsoever.[1]

State law further requires that medical providers and others whose licenses are granted by the state under the provisions of the Business and Professions Code are subject to disciplinary action for refusing to provide services based on characteristics protected under the Unruh Civil Rights Act.

The right of health care providers, and entities, to hold private beliefs does not and should not trump the rights of patients to obtain the care to which they are legally entitled. Licensure as a health care provider, facility, or insurer does not provide license to discriminate. Although HHS points to some law in support of this rule, there is a substantial, contrary body of law that supports a woman's right to choose, as well as the right to not be discriminated against on the basis of a person's sex, gender, gender identity, or sexual orientation. For example, California's Supreme Court ruled that the religious freedom of a medical provider does not exempt them from complying with the anti-discrimination protections in Unruh (*North Coast Women's Medical Group, Inc. v. San Diego County Superior Court* (2008) 44 Cal.4th 1145).

[1] California Civil Code section 51, subdivision (b).

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The Rule Exceeds Legal Authority

Existing law provides sufficient protection to health care entities that refuse to participate in certain health care services, including abortion, where they find such services to be religiously or morally objectionable, as evidenced by section 88.3 of the Rule, subdivisions (a) through (d), which are largely a restatement of existing law. The Department is wrong to expand the statutory protections already provided, and has no clear authority to do so.

By providing new definitions for long-existing terms in the law, the Rule expands and distorts the meaning of these terms. The Rule attempts to redefine "assist in the performance" to include participating in "any program or activity with an articulable connection to a procedure, health services, health program, or research activity…" including, but not limited to "counseling, referral, training, and other arrangements" for the health care service. This definition is so broad as to include even the provision of basic information for a lawful or necessary health care procedure or service. As a result, a provider could refuse to tell a pregnant woman about a health care service that is vital to her health, including her future fertility.

The Rule is so broad that it makes no exception for emergency treatment, meaning that despite a woman's very life being at risk due to a miscarriage, a provider could refuse to even disclose the risk to her life on the basis of the provider's own religious beliefs or moral convictions. This is contrary to the ethical duties owed by physicians to patients, and is contrary to federal law, which allows federal funds to be used to pay for abortions in the cases where the woman's life is in danger. These duties include the doctrine of informed consent which requires a provider to inform a patient of the risks and benefits associated with a health care service or procedure, as well as available alternatives to that service or course of treatment. Informed consent is a legal obligation due from a physician to a patient; failure to receive informed consent constitutes negligence.

The Rule would expand the scope of existing federal refusal laws to almost any entity associated with health care. The Rule's broad definition of "health care entity" expands this term to include "a plan sponsor, issuer, or third-party administrator, or any other kind of health care organization, facility, or plan." Such an expansion of the law would allow an employer to deny coverage of abortion or any number of other health care services to their employees even if otherwise required by law.

The Rule also adds a definition for "referral" where one did not exist. By including public "notices" within this definition, the Rule will prevent the enforcement of California's Reproductive FACT Act, which requires facilities specializing in pregnancy-related care to disseminate notices to all clients about the availability of public programs that provide free or subsidized family planning services, including prenatal care and abortion. This Act is currently subject to ongoing court cases, including a case before the Supreme Court of the United States (*National Institute of Family and Life Advocates v. Becerra*, (9th Cir. 2016) 839 F.3d 823, *cert.*

granted (2017) 138 S.Ct. 464) in which the Court heard oral arguments on March 20th, 2018. HHS should allow the litigation process to conclude and permit the courts to decide whether state laws requiring these type of notices comply with the United States Constitution and federal law.

Similarly, this Rule would to allow a pharmacist to refuse to fill a birth control prescription or refer such a prescription to another pharmacist because they find it objectionable. HHS is attempting to circumvent settled case law, which has held that a pharmacy may not deny any lawful drug, including emergency contraceptives, to any customer for religious reasons. (*Storman's, Inc. v. Wiesman*, (9th Cir. 2015) 794 F.3d 1064, *cert. denied* (2016) 136 S.Ct. 2433). As in many other areas of the Rule, HHS has failed to narrowly tailor the Rule to apply to the specific conscience objections allowed under existing law. Failure to narrowly tailor the Rule will lead to confusion, denial of access to medically necessary care, and increase the likelihood of discrimination against patients.

Weldon Amendment Overreach

In addition to the above noted expansions, the Rule contradicts OCR's previous interpretation of the Weldon Amendment in an attempt to increase its application. As the Rule notes, in 2016 OCR issued a determination on three complaints brought against the California Department of Managed Health Care ("CDMHC") on the basis that the CDMHC required coverage of voluntary abortions as mandated by California law. In its determination in favor of CDMHC, OCR specifically noted that

> "[a] finding that CDMHC had violated the Weldon Amendment might require the government to rescind all funds appropriated under the Appropriations Act to the State of California – including funds provided to the State not only by HHS, but also by the Departments of Education and Labor…such a rescission would raise substantial questions about the constitutionality of the Weldon Amendment."

This determination was made after consultation with the U.S. Department of Justice. In making this determination, OCR pointed to the Court's reasoning in *National Federation of Independent Business v. Sebelius*, (2012) 567 U.S. 519, "that the threat to terminate significant independent grants was so coercive as to deprive States of any meaningful choice whether to accept the condition attached to receipt of federal funds."

With this proposed Rule, however, HHS now specifically intends to apply just such coercion, contrary to its prior, considered findings. HHS is reversing its position with scant legal basis for doing so. In essence, HHS seeks to confer upon health insurers a newly-created ability to make a claim of discrimination against the State of California if they refuse to cover abortions if, for example, they simply don't want to pay for this basic health care service. The Rule's frontal attack on this fundamental aspect of federalism puts the State of California in the impossible

position of either enforcing its state constitution[2] and law, with the loss of federal funding for many programs, or allowing a state-regulated health insurer to flout the state law specifically requiring coverage for all reproductive services, including abortion and sterilization. California will enforce state law. If this Rule is finalized rather than withdrawn, it will result in litigation.

The plain language of the Weldon Amendment allows providers to recuse themselves from participating in or facilitating an abortion. Similarly, existing law in California protects a health care provider who refuses to participate in training for, the arranging of, or the performance of an abortion. The proposed rule, however, goes far beyond these limited accommodations and, in conflict with the state Constitution, instead threatens already-obligated federal funding upon which vital health programs depend.

Adverse Impact on Consumers

The Rule's overlap and conflict with existing state and federal law will have a chilling effect on those seeking essential health care services. It will cause confusion for patients as they attempt to exercise their right to access the full range of medically appropriate care, as well as confusion for the very health care entities that the Rule purports to protect. This Rule is evidence of the continuing attempts by HHS to enshrine discrimination against women, LGBTQ individuals, and their families. It is so broad in scope that, under the guise of protecting the personal beliefs of corporations and other health care entities, it condones discrimination based only on a financial objection to providing services, rather than upon actual religious or moral convictions.

In November 2017, I submitted a declaration in the case of *State of California v. Wright* (subsequently renamed on appeal *State of California et al. v. Alex Azar)* regarding federal regulations that implicate both religious and moral exemptions regarding contraceptive coverage. Those rules would allow employers to exclude contraceptive coverage mandated by the Affordable Care Act from their employees' health insurance policies. A preliminary injunction was granted enjoining enforcement of the rule, which is currently under appeal. In my declaration I provided evidence that demonstrated the harm to women if the rule denying women access to contraceptives was permitted to remain in effect. Similarly, on December 15, 2017, the United States District Court for the Eastern District of Pennsylvania granted a preliminary injunction in *Commonwealth of Pennsylvania v. Trump*, a related case. At issue in this proposed Rule is the same grim burden presented by these cases: that the Rule would impose harm to women's health.

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[2] *See e.g.* Defend Reproductive Rights v. Myers, (1981) 29 Cal.3d 252 (the California Constitution, on numerous occasions, has been construed to provide greater protection than that afforded by parallel provisions of the United States Constitution. In this case the California Supreme Court held that the California state constitution requires abortion benefits to be provided under MediCal, the state Medicaid program.)

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Thanks to the Affordable Care Act, health insurance policies must cover contraceptives. Tens of millions of women across the nation benefit from the ACA provision that requires health insurance coverage of contraceptives without any co-payments or deductibles. Under this new proposed rule, women could be denied their prescribed contraception based on the moral or religious views of the pharmacy owners or employees. The Rule would permit any health care worker to interfere with a woman's constitutionally protected right to make her own reproductive health care decisions. Denying access to contraceptives and other forms of birth control (such as tubal ligation) will result in an increased number of unintended pregnancies and in abortions. Similarly, when a provider's refusal to refer a woman to a health facility where she can obtain an abortion delays the procedure, that provider is increasing health risks for that patient.

As California's Insurance Commissioner, I issued the first regulations in the nation to ensure that transgender Californians would not be discriminated against when seeking health care. We know from the 2015 U.S. National Transgender Survey that 33% of respondents who had seen a health care provider in the past year reported having at least one negative experience related to being transgender such as verbal harassment, refusal of treatment, or having to teach the health care provider about transgender people to receive appropriate care. The Rule would not only continue this significant problem, but would increase the number of patients who are refused treatment by sanctioning such actions by providers. The survey also brought to light the fact that "[i]n the past year, 23% of respondents did not see a doctor when they needed to because of fear of being mistreated as a transgender person…"[3] Again, under this Rule, that problem would only worsen.

By allowing health care providers to discriminate against LGBTQ persons through this Rule, the Administration risks exacerbating existing health disparities. The Federal Office of Disease Prevention and Health Promotion has determined that LGBT persons already face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights, stating: "Discrimination against LGBT persons has been associated with high rates of psychiatric disorders, substance abuse, and suicide."[4]

<u>The Rule Imposes a Substantial Regulatory Burden</u>

Large portions of the Rule are essentially a restatement of existing federal law (*See e.g.* §88.3(a)-(d)). As commentators raised during the rulemaking process in 2011 and HHS acknowledged, "existing law, including Title VII of the Civil Rights Act of 1964 and the federal health care provider conscience protection statutes cited in the Rule already provide protections to

[3] James, S.E., Herman, J.L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016) *The Report of the 2015 U.S. Transgender Survey*, National Center for Transgender Equality, p.10
[4] Office of Disease Prevention and Health Promotion (ODPHP), Healthy People 2020, *Lesbian, Gay, Bisexual, and Transgender Health*, retrieved from https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health

individuals and health care entities."[5] Additionally, the existing rule provides a regulatory enforcement scheme to protect and enforce the rights afforded to health care entities under these laws. The addition of an unnecessary and costly regulation is counter to the intent of Executive Order (EO) 13771. The EO promoted a policy of prudence and fiscal responsibility in the Executive Branch. This Rule satisfies neither goal. This costly Rule is unnecessary to the extent that is merely a restatement of existing law, and, because of such duplication, is likely to cause confusion.

Additionally, this Rule would unduly burden health care entities, including health insurers, states, and providers who would have to keep records to comply with a self-initiated OCR audit or rebut a complaint of discrimination; essentially, the voluminous production, retention, and production of records to prove a negative. The costs and administrative burdens associated with the assurance and certification requirements under this Rule are unnecessary given that existing law already provides sufficient protection to health care entities. Further, the compliance requirements introduce uncertainty into existing, ongoing federal grant programs, inasmuch as the requirements compel violation of state law.

In conclusion, if this rule is implemented, it would deprive women, LGBTQ individuals, their families and others of their civil rights and access to basic health care services. Patients would suffer serious and irreparable harm if this Rule was in place, with no demonstrable or justifiable benefit to providers and health care entities that are adequately protected under existing law. The proposed Rule understandably is opposed by a wide range of stakeholders. I strongly urge you to withdraw the proposed Rule.

Sincerely,

Dave Jones

DAVE JONES
Insurance Commissioner

[5] 72 Fed. Reg. at 9971

Exhibit 40

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 California LGBT Health and Human Services Network in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26. The California LGBT Health and Human Services Network is a statewide coalition of over 60 non-profit providers, community centers, and researchers working collectively to advocate for state level policies and resources that will advance LGBT health. We strive to provide coordinated leadership about lesbian, gay, bisexual, transgender, and queer (LGBTQ) health policy in a proactive, responsive manner that promotes health and wellness as part of the movement for LGBT equality.

The proposed rule goes far beyond the scope of the underlying statutes, and strays from the original purpose of the Office of Civil Rights (OCR). OCR was created to uphold the principle that all people in the United States have a right to receive health care in a nondiscriminatory manner. OCR has always been an office focused on protecting the rights of consumers and increasing access to health care. The proposed rule would stray from this core tenet of OCR, and instead restrict consumers access to nondiscriminatory health care.

The enforcement actions outlined against recipients of federal funds and subrecipients alike will have the likely impact of encouraging discrimination by health care entities. This new proposal from HHS encourages health care providers to abandon the principle of "first, do no harm" in favor of their personal beliefs. This puts transgender patients, people who need reproductive health care, and many others at risk of being denied necessary and even life-saving

care. The proposed enforcement measures are likely illegal and will result in great costs the health care industry, and to individual patients.

LGBTQ people, women, and other vulnerable groups around the country already face enormous barriers to getting the care they need.[1] In the past year, out of respondents to the 2015 U.S. Transgender Survey who saw a health care provider, one-third were denied treatment, turned away, or mistreated.[2] Accessing quality, culturally competent care and 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. By expanding the definition of a health care entity, this rule will likely make it more difficult for patients and consumers to access comprehensive and affirming sexual health care.

The proposed rule is in conflict with existing state and local nondiscrimination protections. Even in California, where we have taken proactive steps to increase accessing to affirming health care – that is available in a patient's spoken language, is developmentally appropriate, and culturally responsive – many LGBTQ people still struggle to find supportive and knowledgeable providers. And yet, this proposed rule would have us go backwards. The proposed rule tramples on California's efforts to protect patients' health and safety, including through the California Insurance Gender Nondiscrimination Act, and other rules that have made it clear that all people the right to access coverage for medically necessary care regardless of their gender identity or gender expression.[3] 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

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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), http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx; Sandy E. James et al., *The Report of the U.S. Transgender Survey* 93–126 (2016), www.ustranssurvey.org/report; 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, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

[2] James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016). The Report of the 2015 U.S. Transgender Survey. Washington, DC: National Center for Transgender Equality.

[3] *See, e.g.*, California Department of Managed Health Care, *Letter No. 12-K: Gender Nondiscrimination Requirements* (April 9, 2013), http://translaw.wpengine.com/wp-content/uploads/2013/04/DMHC-Director-Letter-re-Gender-NonDiscrimination-Requirements.pdf.

direct effects on the relationship between the Federal government and the States," and "does not implicate" federalism concerns under Executive Order 13132.

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,

Amanda Wallner

Director, California LGBT Health and Human Services Network

Exhibit 41

California Medical Association
Physicians dedicated to the health of Californians
1201 J Street, Suite 200, Sacramento, CA 95814-2906 • 916.444.5532 • Fax 916.444.5689

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 SW
Washington, DC 20201

Submitted electronically via http://www.regulations.gov

RE: Comments of the California Medical Association: Department of Health and Human Services, Office for Civil Rights RIN 0945-ZA03

Dear Secretary Azar:

On behalf of more than 43,000 physician members and medical students of the California Medical Association (CMA), we appreciate the opportunity to provide comments on the Department of Health and Human Services' (the "Department") proposed rule ("Proposed Rule") on Protecting Statutory Conscience Rights in Health Care.[1] Through a comprehensive program of legislative, legal, regulatory, economic and social advocacy, CMA promotes the science and art of medicine, the care and well-being of patients, the protection of the public health, and the betterment of the medical profession.

CMA supports the comments of the American Medical Association on the Conscience Protections Proposed Rule and offer further comments that address issues that are of particular concern to California physicians. While CMA is a strong advocate for the conscience rights of physicians, we do not believe this Proposed Rule accomplishes its purported aims. We are concerned that the implementation of this Proposed Rule may lead to discrimination that is prohibited under both federal and California law, adversely impact patient access to comprehensive care, and inappropriately insert politics into the patient-physician relationship. Moreover, current federal and California law provide extensive protections for the conscience rights of health care providers, and the supplemental administrative burdens imposed by this rule do not add any meaningful benefit.

By issuing the Proposed Rule and creating a new division within the Office of Civil Rights ("OCR") – the new "Conscience and Religious Freedom Division" – the Department would inappropriately use OCR's limited resources to encourage discrimination in health care and undermine the ability of states to enforce their own conscience and anti-discrimination

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

provisions. For these reasons, CMA urges the Department to withdraw the Proposed Rule in its entirety.

1. The Proposed Rule Expands the Scope of Existing Conscience Protections to Negatively Affect Access to Care.

CMA is concerned with the overly broad application of existing conscience protection laws and the expansion of the definitions in the Proposed Rule. The language of the Proposed Rule would allow any entity involved in a patient's care—from a hospital board of directors to the receptionist that schedules procedures to use their personal beliefs to dictate a patient's access to care. The Proposed Rule 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. For example, the definition of "assist in the performance" greatly expands the types of services that can be refused to include "any program or activity with an articulable connection to a procedure, health care service, health program, or research activity."[2] In fact, merely "making arrangements for the procedure," no matter how tangential, would be included in the reach of the Proposed Rule.[3] This means individuals not "assisting in the performance" of a procedure within the ordinary meaning of the term, such as the office scheduler, the technician charged with cleaning surgical instruments, and other medical office and hospital employees, can now assert a new right to refuse care based on their religious and moral convictions. Such an interpretation is potentially disruptive to the normal operations of a medical office or other health care facility and impede the provision of necessary care to patients.

Similarly, the Proposed Rule's definition of "referral" goes beyond any understanding of the term, allowing refusals to provide any information, "by any method, pertaining to a health care service, activity, or procedures[.]" This include information "related to availability, location, training, information resources, private or public funding or financing, or directions" that could help an individual to get the health care service they need.[4] Such an expansive definition could prevent patients from getting information about the availability of comprehensive health care options in their state. CMA believes that these overly broad definitions will result in denial of care and miscommunication to patients without meaningfully advancing physicians' rights of conscience.

Furthermore, the Proposed Rule's new and expanded definitions often exceed, or are not in accordance with, existing definitions contained within the existing laws OCR seeks to enforce. For example, "health care entity" is defined under the Coats and Weldon Amendments to include a limited and specific range of individuals and entities involved in the delivery of health care.

[2] Proposed Rule, 83 Fed. Reg. at 3923.
[3] *Id.*
[4] *Id.* at 3924.

However, 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 by including a wide range of individuals, e.g., not just health care professionals, but any personnel, and institutions, including not only health care facilities and insurance plans, but also plan sponsors and state and local governments. This impermissibly expands statutory definitions and will create confusion, impeding patients' access to needed health care services and information.

2. **CMA Opposes Discrimination in the Provision of Health Care and Supports Patient Access to Comprehensive Health Care.**

CMA is concerned that the Proposed Rule undermines anti-discrimination protections, particularly with regard to reproductive health, sexual orientation, and gender identity. Since 2012, the Office for Civil Rights has interpreted Section 1557 of the Affordable Care Act's[5] sex discrimination prohibition to extend to claims of discrimination based on gender identity or sex stereotypes and accepted such complaints for investigation. Section 1557's protections assist populations that have been most vulnerable to discrimination, including lesbian, gay, bisexual, and transgender individuals, and help provide those populations equal access to health care and health coverage. Such individuals experience discrimination in obtaining health care which lead to lack of preventative care or delayed care.[6] Section 1557 seeks to address factors that impact access to care for certain populations but does not force physicians to violate their medical judgment. Rather, covered entities, including insurers, must "apply the same neutral, nondiscriminatory criteria [used] for other conditions when the coverage determination is related to gender transition."[7]

California law explicitly prohibits discrimination based on sex, sexual orientation, or gender identity,[8] among other factors. California law provides that persons holding licenses under the provisions of the Business & Professions Code, such as physicians, are subject to disciplinary action for refusing, in whole or in part, or aiding or inciting another licensee to refuse to perform the licensed services to an "applicant" (patient) because of any characteristics under the Unruh Civil Rights Act, that is, the applicant's race, color, sex, religion, ancestry, disability, marital

[5] 45 C.F.R. §§92.2, 92.206, 92.207.
[6] LAMBDA LEGAL, WHEN HEALTH CARE ISN'T CARING: LAMBDA LEGAL'S SURVEY ON DISCRIMINATION AGAINST LGBT PEOPLE AND PEOPLE LIVING WITH HIV (2010). *Forum: How Discrimination Damages Health Care in LGBTQ Communities*, NPR (March, 21, 2018), https://www.npr.org/sections/health-shots/2018/03/21/594030154/forum-how-discrimination-damages-health-in-lgbtq-communities
[7] Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31435 (proposed May 18, 2016) (to be codified at 45 C.F.R. pt. 92).
[8] *See generally*, CAL. CIV. CODE §51 (The Unruh Civil Rights Act) ("All persons within the jurisdiction of this state are free and equal, and no matter what their sex, race, color, religion, ancestry, national origin, disability, medical condition, genetic information, marital status, sexual orientation, citizenship, primary language, or immigration status are entitled to the full and equal accommodations, advantages, facilities, privileges, or services in all business establishments of every kind whatsoever."_

status, national origin, medical condition, sexual orientation, or genetic information.[9] The California Supreme Court has held that physicians' religious freedom and free speech rights do not exempt physicians from complying with the Unruh Act's prohibition against discrimination based on a person's sexual orientation.[10]

California law also prohibits discrimination by any person under any program that receives any financial assistance from the state.[11] Additionally, the California Insurance Gender Nondiscrimination Act (IGNA) prohibits a health plan and insurer from "refusing to enter into, cancel or decline to renew or reinstate a contract because of race, color, national origin, ancestry, religion, sex, marital status, sexual orientation, or age."[12] Sex includes both gender identity and gender expression.[13] The Proposed Rule lays the groundwork to preempt California laws that have been put into place to ensure that patients in the state have access to comprehensive health care. In addition, the Proposed Rule may also conflict with policies of agencies that accredit health care institutions. For example, the Joint Commission, which accredits and certifies nearly 21,000 facilities in the U.S., has required since 2011 that the nondiscrimination policy of every accredited facility protect transgender patients.[14] The Proposed Rule would conflict with existing state laws and accreditation requirements, creating legal confusion for California physicians.

3. CMA Supports Conscience Protections that Promote the Rights of Providers without Negatively Impacting Patient Care.

CMA policy has always sought to balance the rights of patients to access needed health care with the rights of physicians to exercise their conscience. Conscientious refusals occur most commonly in the field of reproductive medicine, and in many areas of the country patients face challenges in accessing reproductive healthcare.[15] Though CMA advocates for access to abortion

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[9] CAL. BUS. & PROF. CODE §125.6
[10] *North Coast Women's Care Medical Group, Inc. v. San Diego County Superior Court* (Benitez) 189 P.3d 959 (Cal. 2008).
[11] CAL. GOV. CODE §11135.
[12] CAL. HEALTH & SAFETY CODE §1365.5; CAL. INS. CODE §10140. *See also*, Dep't. of Managed Health Care, Gender Nondiscrimination Requirements, Letter No. 12-K (April 9, 2013), *available at* http://www.dmhc.ca.gov/Portals/0/LawsAndRegulations/DirectorsLettersAndOpinions/dl12k.pdf; CAL. CODE REGS. tit 10, § 2561.2.
[13] CAL. HEALTH & SAFETY CODE §1365.59(e).
[14] Joint Commission Standards RI.01.01.01, EP29.
[15] *See, e.g.* (2017), NAT'L WOMEN'S LAW CTR., REFUSALS TO PROVIDE HEALTH CARE THREATEN THE HEALTH AND LIVES OF PATIENTS NATIONWIDE (2017), *available at* https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/08/Refusal-to-Provide-Care.pdf; CATHERINE WEISS ET AL., AM. CIVIL LIBERTIES UNION, RELIGIOUS REFUSALS AND REPRODUCTIVE RIGHTS (2002), *available at* https://www.aclu.org/report/religious-refusals-and-reproductive-rights-report; JULIA KAYE ET AL., AM. CIVIL LIBERTIES UNION HEALTH CARE DENIED (2016), *available at* https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf; KIRA SHEPHERD ET AL., PUB. RIGHTS PRIVATE CONSCIENCE PROJECT, BEARING FAITH THE LIMITS OF CATHOLIC HEALTH CARE FOR WOMEN OF COLOR, 1 (2018), *available at* https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

 HHS Conscience Rule-000151669

under accepted ethical medical standards, CMA policy provides that no physician should be required to act against their moral principles. Similarly, while CMA supports the training of all OB/GYN residents and appropriate other residents in primary care specialties in the basic skills of performing abortions, CMA also supports the concept of choice for residents in training, allowing each resident to choose whether or not to participate in elective abortions. CMA has prioritized the physician-patient relationship, and seeks to ensure that health care systems do not interfere with physician-patient communications on reproductive health care, and that access to reproductive health care services is preserved. These principles properly preserve the conscience rights of physicians and their role in providing patient care.

American Medical Association (AMA) policy also recognizes that "at times the expectation that physicians will put patients [sic] needs and preferences first may be in tension with the need to sustain moral integrity and continuity across both personal and professional life."[16] However, it recognizes that this freedom is not unlimited: "[p]hysicians are expected to provide care in emergencies, honor patients informed decisions to refuse life-sustaining treatment, and respect basic civil liberties and not discriminate against individuals in deciding whether to enter into a professional relationship with a new patient."[17] Physicians must consider the harm to patients from refusing to provide treatment and whether the patient will be able to access needed treatment from another physician. The AMA also recognizes that physicians must clearly communicate to the patient which services a physician will or will not provide before entering into a physician-patient relationship, as well as inform patients about all relevant options for treatment, even those to which the physician has conscientious objections.[18]

The Committee on Ethics of American College of Obstetricians and Gynecologists (AGOG) has adopted a number of recommendations that "maximize respect for health care professionals' conscience without compromising the health and well-being of the women they serve."[19] Similar to the AMA opinion, the ACOG opinion recommends that physicians give patients accurate and unbiased information, as well as clearly communicate any moral objections they may have. The ACOG opinion further recognizes that physicians have a duty to refer their patients to other providers for services they cannot provide due to reasons of conscience, and to provide such services in an emergency situation where a referral is impossible. ACOG concludes: "Lawmakers should advance policies that balance protection of providers' consciences with the critical goal of ensuring timely, effective, evidence-based and safe access to all women seeking

[16] American Medical Association, Policy E-1.1.7, "Physician Exercise of Conscience." *Code of Medical Ethics.* Adopted 2016.
[17] *Id.*
[18] *Id.*
[19] American College of Obstetricians and Gynecologists (ACOG*), The Limits of Conscientious Refusal in Reproductive Medicine*, ACOG Committee on Ethics Opinion Number 385, 5. Adopted November 2007. Reaffirmed 2016).

reproductive services."[20] The Proposed Rule falls short of this aim and the principles of CMA and AMA policies by expansively interpreting existing protections without properly balancing the needs of patients and physicians.

4. Current Federal and State Law Protect the Rights of Physicians and Patients

Existing federal and state laws protect the rights of physicians by allowing states to take nuanced positions on the protecting the conscience rights of health care workers, particularly with regard to abortion, sterilization, and aid-in-dying. Section 88.3 of the rule incorporates the extensive existing law protecting the conscience rights of health care providers and institutions, including, among others, the Church Amendments,[21] the Coats-Snowe Amendment[22] and the Weldon Amendment.[23] In addition, the Affordable Care Act includes health care provider conscience protections within the health insurance exchange system. The law provides that "no qualified health plan offered through an exchange may discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions."[24] Regulations implementing the Act further provide that existing laws protecting religious freedom and belief, including provider conscience laws, the Religious Freedom Restoration Act, the ACA's provisions regarding abortion services, and the ACA's preventive health services regulations, continue to apply.[25]

The Proposed Rule's provisions are not only redundant but will have a chilling effect on the enforcement of and passage of state laws that protect access to health care. The preamble of the Proposed Rule discusses at length state laws that the Department finds objectionable, including California's Department of Managed Health Care's requirement that health insurers must cover abortion services.[26] As mentioned in the Proposed Rule, California law requires most health

[20] *Id.*
[21] The Church Amendments, 42 U.S.C. § 300a-7 (2018).
[22] Public Health Service Act, 42 U.S.C. § 238n (2018).
[23] The Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009).
[24] 42 U.S.C. §18023 (2018).
[25] 45 C.F.R. §92.2(b)(2).
[26] *See* Proposed Rule, *supra* note 1, at 3888-89. The health insurers filed a complaint, and OCR found there was no violation of the Weldon Amendment. Letter from OCR Director to Complainants (June 21, 2016), *available at* http://www.adfmedia.org/files/ CDMHCInvestigationClosureLetter.pdf.

plans to cover abortion services,[27] as well as all FDA-approved methods of contraception without cost-sharing.[28]

California law already properly balances the rights of physicians and their patients. California has extensive protections for health care providers that do not want to participate in abortion for moral, ethical, or religious reasons, while protecting women who need emergency care.[29] While religiously affiliated hospitals can also exercise their rights under this provision, they must post a notice of their refusal policy so that patients are properly informed about the care they will receive.[30] California law protects the rights of physicians to "decline to comply with an individual health care instruction of health care decision for reasons of conscience"[31] Additionally, California law allows a religious employer to request an exemption from generally applicable requirements for contraceptive coverage in health plans.[32] Increasing the number of federal rules in this area is both unnecessary and will create confusion for providers and their patients.

CMA has sought to ensure that physicians' rights are protected even in an evolving health care landscape. For example, the End of Life Option Act, passed in 2015, permits individuals suffering from a terminal disease to request life-ending medication under certain circumstances.[33] This bill contains extensive provisions ensuring that health care providers with conscientious objections are not subject to any professional sanctions or legal liability for refusing to participate in actions related to the Act's activities.[34] Adding a confusing and unnecessary layer of federal regulations may prevent states from successfully passing and implementing their own conscience protections. The Proposed Rule would impede the ability of states to craft nuanced solutions, such as those found in the End of Life Option Act, that protect the rights of providers in accordance with states' own values.

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[27] See, e.g., Letter from Michelle Rouillard, Director, Dep't of Managed Health Care, to Mark Morgan, Cal. President, Anthem Blue Cross (Aug. 22, 2014), *available at* https://www.dmhc.ca.gov/portals/0/082214letters/abc082214.pdf. *See also* Cal. Dep't of Health Care Servs., Letter to all Medi-Cal Managed Care Health Plans, All Plan Letter No. 15-020: Abortion Services (Sept. 30, 2015), http://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2015/APL15- 020.pdf; Cal. Dep't of Health Care Srvs., Medi-Cal Medical Services Provider Manual Ch. Abortions at p. 1.
[28] CAL. WELF. AND INST. CODE §14132; CAL. INS. CODE §10123.196; CAL HEALTH AND SAFETY CODE § 1367.25.
[29] CAL. HEALTH & SAFETY CODE §123420.
[30] *Id.*
[31] CAL. PROBATE CODE §4734.
[32] CAL. HEALTH & SAFETY CODE §1367.25
[33] Cal. S.B. 128, Stats. 2016, ch. 1.
[34] CAL. HEALTH AND SAFETY CODE §§ 443.14-443.15.

5. CMA Opposes Unnecessary Administrative Burdens on Physicians

Finally, sections 88.4 through 88.6 of the Proposed Rule impose significant new requirements on physicians, who already face an increasing number of administrative burdens due to federal law and various existing federal program requirements. Under the Proposed Rule, physicians must submit certifications and assurance, post lengthy required notices on their website and in conspicuous physical locations, maintain detailed records, and generally ensure compliance with the new rule.[35] The Department conducts an analysis of the estimated burdens for the Proposed Rule[36] in which it looks at the implementation costs for providers. The estimate includes time for providers to familiarize themselves with the Rule and the cost to hire an attorney to review it; at least four hours of staff time to review the assurance and certification language and underlying laws; four hours of staff time to review policies and procedures and the cost of hiring an attorney to assist in the review; and the costs of printing the notice in any paper documents. These costs are burdensome enough in themselves; this analysis fails to fully consider, moreover, the significant time and resources it takes to continuously implement and enforce such a Proposed Rule, and the numerous other administrative and regulatory burdens physicians already face and the degree to which each additional burden detracts from a physician's clinical practice.[37] Excessive administrative tasks imposed on physicians divert time and focus from providing actual care to patients and improving quality, and may prevent patients from receiving timely and appropriate care. CMA opposes adding additional burdens to physicians that do nothing to improve the quality of patient care and create yet more regulatory hurdles for the practice of medicine.

As discussed above and in the Proposed Rule, federal and state laws already protect health care provider conscience rights.[38] These long-standing provisions of federal law provide sufficient protection to physicians seeking to exercise their conscience rights. Instead of guaranteeing additional protection, this Proposed Rule would negatively impact patient access to care, sanction discrimination in health care settings, and impose increased administrative burdens on physicians, including paperwork requirements and significant staff time with no demonstrable benefit to the provision of health care.

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[35] Proposed Rule, *supra* note 1, at 3928-30.
[36] *Id.* at 3912-15.
[37] *See, e.g.* Jessica Davis, *JAMA: EHRs fail to reduce administrative billing costs*, HEALTHCARE IT NEWS (Feb. 21, 2018), http://www.healthcareitnews.com/news/jama-ehrs-fail-reduce-administrative-billing-costs; Alexi A. Wright and Ingrid T. Katz, *Beyond Burnout – Redesigning Care to Restore Meaning and Sanity for Physicians*, 378 NEW ENG. J. OF MEDICINE 308 (Jan. 2018), http://www.nejm.org/doi/full/10.1056/NEJMp1716845
[38] The Church Amendments, 42 U.S.C. §§300a-7 *et seq.* (2018); Public Health Service Act, 42 U.S.C. §236(n)); and the Weldon Amendment (Consolidated Appropriations Act, 2012, Pub.L. No. 112-74, 125 Stat. 786).

Conclusion

Thank you for your consideration. If you have questions, please contact me at jrubenstein@cmanet.org or (916) 551-2554.

Sincerely,

Jessica Rubenstein
Associate Director
Center for Health Policy
California Medical Association

Exhibit 42

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March 27, 2018

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: RIN 945-ZA03
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

By Electronic Submission

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, Proposed Rule (RIN 0945-ZA03 and Docket No. HHS-OCR-2018-002

To whom it may concern:

I am writing on behalf of the California Pan-Ethnic Health Network (CPEHN) in response to the request for public comment on the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26.[1] CPEHN's mission is to improve access to health care and eliminate health disparities by advocating for public policies and sufficient resources to address the health needs of communities of color.

The proposed rule puts Californians at great risk: The rule as proposed introduces broad and poorly defined language to the existing law that already provides ample protections to health care workers that refuse to participate in a health care service to which they have a moral objection. This could result in medical care that fails to comply with established medical practice guidelines, negating long-standing principles of informed consent, undermining the ability of health facilities to provide care in an orderly and efficient manner. As written, the law could allow anyone such as providers, behavioral therapists, pharmacists, hospitals, insurers or other health care entities to be misled into believing that they may refuse on religious grounds to administer an HIV test to a gay or bisexual man or to provide mental health counseling to a transgender woman who may be at risk of self-harm. We know that this type of unjust denial of care has occurred, such as a California physician's denial of donor insemination to a lesbian couple, even though the doctor routinely provided the same service to

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

heterosexual couples. [2]

The proposed rule prioritizes the rights of health care providers over the rights of individuals: The rule puts the needs of the provider above the needs of the patient, failing even to clarify exceptions for emergency care. Under the new rule, providers would not even be required to notify the patient that they are exercising their religious or moral exemption. The language if adopted, would allow any licensed health professional to refuse treatment or referral for vulnerable clients even if it could provide the duty of care. In the event of a harmful consequence (e.g. suicide, self-injury, or harm to others) the provider could claim no responsibility by invoking their rights, thereby rendering the entire anti-discrimination clause enforceable.

Existing law already provides ample protection for health care providers who want to exercise their personal beliefs: Existing refusal of care laws (such as for abortion and sterilization services) are already being used across the country to deny patients the care they need.[3] The proposed rule attempts to expand on these laws in numerous ways that are directly contrary to the stated purpose of the existing laws including in instances where there no scientific evidence that care should be denied. For example, certain religiously-affiliated hospitals and individual clinicians have refused to provide rape victims with emergency contraception to prevent pregnancy[4] based on the belief that it can cause an abortion, even though there is no scientific evidence that this is the case.

The new rule will result in greater health disparities: 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. In California for example, Latinos and African Americans have twice the prevalence of type 2 diabetes and are twice as likely to die from the disease. These types of health disparities are often compounded for people of color who hold multiple intersectional identities (ie. women, individuals living with disabilities, LGBTQ, people living in rural communities). For example, LGBTQ and HIV-affected people of color are more likely to require medical attention as a result of hate violence when compared to other survivors. In California, African-American women are more likely to die in childbirth and less likely to access critical post-partem care. Rather than encouraging health care providers to find additional justifications for the denial of critical health care services, HHS should focus on its mission of eliminating barriers to care for those who need it the most.

The proposed rule is unwarranted and will make it impossible for OCR to do its job of ensuring patients are protected from discrimination: The proposed rule is a giant step backwards in preventing discrimination in health care settings. By issuing the proposed rule

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[2] Hardaway, Lisa, *Settlement Reached in Case of Lambda Legal Lesbian Client Denied Infertility Treatment by Christian Fundamentalist Doctors,* Lambda Legal, September 29, 2009, accessed at https://www.lambdalegal.org/news/ca_20090929_settlement-reached.

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

[4] Erdely, Sabrina, *Doctors' beliefs can hinder patient care*, SELF magazine, June 22, 2007, accessed at http://www.nbcnews.com/id/19190916/print/1/displaymode/1098/

along with the newly created “Conscience and Religious Freedom Division,” the Department seeks to use OCR’s limited resources in order to affirmatively allow institutions, insurance companies, and almost anyone involved in patient care to use their personal beliefs to deny people the care they need. As stated in the NPRM itself, between 2008 and November 2016, the Office for Civil Rights received 10 complaints alleging violations of federal religious refusal laws; OCR received an additional 34 similar complaints between November 2016 and January 2018. By comparison, during a similar time period from fall 2016 to fall 2017, OCR received more than 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.

The proposed rule tramples on states’ and local governments’ efforts to protect patients’ health and safety, including their nondiscrimination laws: The proposed rule will have a chilling effect on the enforcement and passage of state laws that protect access to health care and prevent discrimination against individuals seeking medical care. Moreover, the proposed rule invites states to further expand refusals of care by making clear that this expansive rule is a floor, and not a ceiling, for religious exemption laws.

For all these reasons, we urge the administration to put patients first, and withdraw the proposed regulations.

Sincerely,

Caroline B. Sanders, MPP
Director Policy Analysis, CPEHN

Exhibit 44

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").

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

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

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

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

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

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

LGBTQ people continue to face discrimination in many areas of their lives, including health care, on the basis of their sexual orientation and gender identity. The Department's Healthy People 2020 initiative recognizes, "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights."[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.

CALLEN-LORDE

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]

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[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.

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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.

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

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

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

The proposed rule threatens informed consent, a necessary principle of patient-centered decision-making. Informed consent relies on disclosure of medically accurate information by providers so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.[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).

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In addition, the proposed rule does not provide any protections for health care professionals who want to provide, counsel, or refer for health care services that are implicated in this rule, for example, reproductive health or gender affirming care. Due to the rule's aggressive enforcement mechanisms and its vague and confusing language, providers may fear to give care or information. The inability of providers to give comprehensive, medically accurate information and options that will help patients make the best health decisions violates medical principles such as, beneficence, no maleficence, respect for autonomy, and justice. In particular, the principle of beneficence "requires that treatment and care do more good than harm; that the benefits outweigh the risks, and that the greater good for the patient is upheld."[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).

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

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"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/.

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a. Sexually transmitted infections (STIs)

Religious refusals also impact access to sexual health care more broadly. Contraceptives and access to preventative treatment for sexually transmitted infections are a critical aspect of health care. The CDC estimates that 20 million new sexually transmitted infections occur each year. Chlamydia remains the most commonly reported infectious disease in the U.S., while HIV/AIDS remains the most life threatening. Women, especially young women, and Black women, are hit hardest by Chlamydia—with rates of Chlamydia 5.6 times higher for Black than for white Americans.[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

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[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.

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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

[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).

Exhibit 49

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 SW
Washington, DC 20201

VIA ELECTRONIC SUBMISSION

Re: Comments on Notice of Proposed Rule on Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (Docket No.: HHS–OCR–2018–0002)

We are writing to express our deep concern and full opposition to the Notice of Proposed Rulemaking ("the proposed rule" or "the NPRM") on Protecting Statutory Conscience Rights in Health Care, published by the Department of Health and Human Services ("HHS") on January 26, 2018. HHS' proposed rule clearly aims to limit access to healthcare services, including reproductive healthcare services, by grossly mischaracterizing and expanding federal healthcare refusal laws at the expense of patient care. We strongly urge HHS to withdraw this NPRM in its entirety.

Since 1992, the Center for Reproductive Rights has used the power of law to advance reproductive rights as fundamental human rights worldwide. Our litigation and advocacy over the past 26 years have expanded access to reproductive healthcare around the nation and the world. We have played a key role in securing legal victories in the United States, Latin America, Sub-Saharan Africa, Asia, and Eastern Europe on issues including access to life-saving obstetrics care, contraception, safe abortion services, and comprehensive sexuality information. We envision a world where every person participates with dignity as an equal member of society, regardless of gender; where every woman is free to decide whether or when to have children and whether or when to get married; where access to quality reproductive healthcare is guaranteed; and where every woman can make these decisions free from coercion or discrimination.

As articulated below, this NPRM should be withdrawn in its entirety because:

- It proposes expanding religious and moral refusal laws without protecting access to care, which historically has harmed women,
- LGBTQ individuals, and marginalized communities;
- It violates the Administrative Procedure Act on multiple grounds, including by severely and repeatedly exceeding the parameters and authority of the federal refusal laws it purports to enforce;
- It harmfully prioritizes healthcare provider objections over patient care; and
- It is unconstitutional.

I. **The Misapplication and Misuse of Healthcare Refusal Laws Harms Women and Marginalized Individuals and Violates International Human Rights Law.**

A. **Where religious and moral refusal laws are implemented without protecting access to healthcare, including reproductive healthcare, women are harmed.**

The proposed rule attempts to expand religious and moral refusal laws at the expense of ensuring access to care. In general, religious and moral refusal laws allow an individual to opt out of providing a specific healthcare service on religious or moral grounds. Because religious and moral refusals to healthcare inherently create an impediment to the provision of healthcare, refusals must be balanced with the patient's right to receive a healthcare service or benefit, and should be implemented in a way that ensures the patient's right to care is protected.[1] This principle is protected and advanced by numerous laws, including the Emergency Medical Treatment and Labor Act (EMTALA), international human rights standards,[2] and professional standards set by various medical associations, such as the American College of Obstetricians and Gynecologists and the American Medical Association.[3]

When implemented without balancing, religious and moral refusal laws can be and have been exploited to limit access or deny care, particularly in the field of reproductive healthcare. Refused services include access to safe pregnancy termination, miscarriage management, and contraception, which are all necessary to ensure women's health and wellbeing.

Where healthcare entities prioritize refusals without also ensuring access to care, they risk the health and safety of patients. For example, researchers have documented numerous instances in which the Ethical and Religious Directives ("the Directives") at Catholic hospitals have led hospital administrators to prohibit doctors from treating patients. Rape survivors have been denied access to and information about emergency contraception at hospitals that prioritize religious concerns over patient wellbeing. Likewise, pharmacists with religious objections have denied women emergency contraception,[4] making it impossible for some women to obtain emergency contraception in time to prevent pregnancy.[5]

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[1] The Supreme Court has held in the past that religious exemptions must be balanced against the impact on women's healthcare. In Zubik v. Burwell, the Court ordered the parties to resolve their cases in a way that ensured there would be *no* impact on women's access to seamless contraceptive coverage. Zubik v. Burwell, 136 S. Ct. 1557, 1560 (2016). Similarly, Burwell v. Hobby Lobby rejected the notion that for-profit corporations' religious beliefs must be accommodated regardless of the impact—specifically noting that the new accommodation would have an impact on women that "would be precisely zero." Burwell v. Hobby Lobby, 134 S. Ct. 2751 (2014).

[2] Brief for foreign and international law experts, Lawrence O. Gostin, et al. as Amici Curiae supporting respondents, Zubik v. Burwell, 136 S. Ct. 1557 (2016) (Nos. 14-1418, 14-1453, 14-1505, 15-35, 15-105, 15-119, and 15-191), http://www.scotusblog.com/wp-content/uploads/2016/02/02.17.16_amicus_brief_in_support_of_respondents-_crr.pdf.

[3] The American College of Obstetricians and Gynecologists and the American Medical Association both recognize a duty to refer in order to safeguard patients' rights and access to certain reproductive healthcare. *See, e.g.,* American College of Obstetricians and Gynecologists Committee on Ethics, *Committee Opinion No. 385: The limits of conscientious refusal in reproductive medicine*, 2007, https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Ethics/The-Limits-of-Conscientious-Refusal-in-Reproductive-Medicine ("Physicians and other health care providers have the duty to refer patients in a timely manner to other providers if they do not feel that they can in conscience provide the standard reproductive services that patients request."); American Medical Association, *AMA Code of Medical Ethics Opinion 1.1.7: Physician Exercise of Conscience*, https://www.ama-assn.org/delivering-care/physician-exercise-conscience ("In general, physicians should refer a patient to another physician or institution to provide treatment the physician declines to offer.").

[4] Pharmacists in at least twenty-four states have refused to sell birth control or emergency contraception to women. *See* Gretchen Borchelt, *Pharmacists Can't Be Allowed to Deny Women Emergency Contraception*, U.S. NEWS & WORLD REPORT, Oct. 15, 2012, http://www.usnews.com/opinion/articles/2012/10/15/pharmacists-cant-be-allowed-to-deny-women-emergency-contraception.

[5] *See* Catholics for Choice (formerly Catholics for a Free Choice), *Second Chance Denied: Emergency Contraception in Catholic Hospital Emergency Rooms* (Jan. 2002), http://www.catholicsforchoice.org/wp-content/uploads/2013/12/2002secondchancedenied.pdf.

Similarly, a study of care for ectopic pregnancies concluded that some Catholic hospitals, based on the Directives, were "precluding physicians from providing women with ectopic pregnancies with information about and access to a full range of treatment options [. . .] resulting in practices that delay care and may expose women to unnecessary risks."[6] And in one case of miscarriage mismanagement, a woman named Tamesha Means was sent home twice by a Catholic hospital, even though her water had broken after only 18 weeks of pregnancy and she was in excruciating pain.[7] The hospital justified its denial of care based on a Directive prohibiting pre-viability pregnancy termination. Even when Tamesha returned for the third time, now presenting with an infection, the hospital denied her care until she began to deliver, when the hospital finally tended to her miscarriage.[8]

Mis-implementation of refusal laws may also result in severe sanctions for those who prioritize patient care over religious concerns. In a widely-reported case, a Catholic hospital provided an abortion to a woman whose risk of mortality was "close to 100 percent" if she continued the pregnancy.[9] The hospital administrator, Sister Margaret McBride, was promptly excommunicated,[10] and the diocese stripped the hospital of its Catholic affiliation.[11] The U.S. Conference of Catholic Bishops supported the sanctions and issued a memo confirming that the Directive in question does not permit the direct termination of a pregnancy—even to save a woman's life.[12]

The prioritization and exploitation of refusals over patient care, even in emergency situations, has already resulted in harm to women who are deprived of healthcare, especially reproductive healthcare. The NPRM dangerously continues in this vein by failing to address the impacts on patient care, and may exacerbate the types of harm described above. The NPRM should therefore be withdrawn in its entirety.

B. Religious and moral refusal laws disproportionately affect marginalized individuals, including economically disadvantaged women, rural women, and LGBTQ individuals.

By significantly expanding the reach of federal refusal laws without guaranteeing access to care, the proposed rule threatens harm to all patients, but may particularly increase the risk of

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[6] A.M. Foster et al., *Do Religious Restrictions Influence Ectopic Pregnancy Management? A National Qualitative Study (Abstract)*, 21 WOMEN'S HEALTH ISSUES (Mar.-Apr. 2011), http://www.ncbi.nlm.nih.gov/pubmed/21353977.
[7] ACLU, *Tamesha Means v. United States Conference of Catholic Bishops*, updated June 30, 2015, https://www.aclu.org/cases/tamesha-means-v-united-states-conference-catholic-bishops?redirect=reproductive-freedom-womens-rights/tamesha-means-v-united-states-conference-catholic-bishops.
[8] In another example, a patient who was 19 weeks pregnant presented with a miscarriage. Instead of providing a uterine evacuation, the Catholic hospital transferred her to a tertiary medical center and refused to provide medical care even when she became septic with a 106-degree fever—all because a fetal heartbeat could still be discerned. *See* Lori R. Freedman et al., *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, 98 AM. J. PUB. HEALTH 1774 (2008), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.
[9] Barbara Bradley Hagerty, *Nun Excommunicated for Allowing Abortion*, NPR, May 19, 2010, http://www.npr.org/templates/story/story.php?storyId=126985072.
[10] Id. Ms. McBride has since regained good standing with the Catholic Church. *McBride un-excommunicated*, AMERICA MAGAZINE, Dec. 14, 2011.
[11] Dan Harris, *Bishop Strips Hospital of Catholic Status After Abortion,* ABC NEWS, Dec. 22, 2010, http://abcnews.go.com/Health/abortion-debate-hospital-stripped-catholic-status/story?id=12455295.
[12] U.S. Conference of Catholic Bishops, *The Distinction between Direct Abortion and Legitimate Medical Procedures* (June 23, 2010), http://www.usccb.org/about/doctrine/publications/upload/direct-abortion-statement2010-06-23.pdf.

exploitation and abuse of refusals at the expense of marginalized individuals. While an objecting provider presents an obstacle to any patient, it may impose a particularly challenging burden on marginalized individuals. Economically disadvantaged women, rural women, and LGBTQ individuals already face barriers to care, including limited financial means, language and cultural differences, medical providers' unconscious biases, historic discrimination, and geography.[13] And now a healthcare provider's religiously motivated refusal to provide care may force a patient to choose between foregoing care or taking on the burden of locating and traveling to a non-refusing provider.

An individual who needs to plan a new visit to a non-objecting provider will often need a flexible work schedule and faces added transportation and child care costs. This creates an additional hardship, especially for economically disadvantaged women.[14] In rural areas, the closest non-objecting provider may be located far away. For example, after being denied emergency contraception by her local pharmacist, a woman in Ohio was forced to drive 45 miles to another pharmacy in order to obtain it.[15] Many women in similar situations do not have the means to make these additional trips.[16] The impact of refusals therefore falls heavily on rural women, who are four times more likely to reside in medically underserved areas.[17] Reproductive health services are especially difficult for them to access, since obstetrics/gynecologic services and other medical specialties are even less common in rural settings.[18] The inappropriate expansion of refusals under the NPRM will undoubtedly exacerbate this harm.

LGBTQ individuals also face particularly acute barriers to receiving the healthcare they need, which are compounded by religious and moral refusal laws. Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a doctor or other healthcare provider had refused to see them because of their actual or perceived sexual orientation in the year before the survey.[19] 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 healthcare they need at another hospital if they were turned away.[20] 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.[21] When they are able to access care, many individuals report "that health care professionals have used harsh language towards them, refused to touch them or used excessive precaution, or blamed the individuals for their health

[13] American College of Obstetricians and Gynecologists, *Committee Opinion No. 516: Health Care Systems for Underserved Women* (Jan. 2012), http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-Systems-for-Underserved-Women.
[14] *See, e.g.*, Kaiser Family Foundation, *Women and Health Care: A National Profile* 24 (July 2005), *available at* https://kaiserfamilyfoundation.files.wordpress.com/2013/01/women-and-health-care-a-national-profile-key-findings-from-the-kaiser-women-s-health-survey.pdf.
[15] Gretchen Borchelt, *Pharmacists Can't Be Allowed to Deny Women Emergency Contraception*, U.S. NEWS & WORLD REPORT, Oct. 15, 2012, http://www.usnews.com/opinion/articles/2012/10/15/pharmacists-cant-be-allowed-to-deny-women-emergency-contraception.
[16] Id.
[17] *See* National Women's Law Center, *Fact Sheet: If You Care about Religious Freedom You Should Care about Reproductive Justice!* (2014), https://nwlc.org/resources/if-you-care-about-religious-freedom-you-should-care-about-reproductive-justice/, (citing U.S. Department of Health & Human Services, *Facts about . . . Rural Physicians*, http://www.shepscenter.unc.edu/rural/pubs/finding_brief/phy.html).
[18] Id.
[19] *See* Jaime M. Grant et al., *Injustice at Every Turn: a Report of the National Transgender Discrimination Survey*, NATIONAL GAY AND LESBIAN TASK FORCE & NATIONAL CTR. FOR TRANSGENDER EQUALITY (2011), http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf.
[20] 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-accessing-health-care.
[21] Id.

status."[22] Nearly one-quarter of transgender individuals report delaying or avoiding medical care when sick or injured, at least partially due to medical providers' discrimination and disrespect.[23]

The proposed expansion of federal refusal laws' reach will fall hardest on these populations, which already face hurdles in accessing care. As a result, the proposed rule may result in even more marginalized individuals being harmed as a result of not being able to obtain needed healthcare. Therefore, the NPRM should be withdrawn in its entirety.

C. The NPRM's proposed interpretation of religious and moral refusal laws violates international human rights laws and standards.

International human rights law requires that conscientious objections are permitted only to the extent that they do not infringe on others' access to healthcare. This requires the government to ensure that healthcare personnel's refusals to provide reproductive healthcare, including abortion care, on grounds of conscience do not jeopardize women's access to reproductive healthcare. Indeed, international human rights bodies have consistently noted the need for governments to strike a balance between protecting the right to demonstrate one's freedom of conscience and the right of women to obtain safe and legal reproductive health services. By expanding religious and moral refusals while completely failing to address how patient care will still be protected, the proposed rule violates international law.

While international human rights standards recognize the right of medical personnel to conscientiously object to the provision of sexual and reproductive health services, the exercise of this right cannot constitute a barrier to the effective enjoyment of sexual and reproductive rights. United Nations (UN) human rights treaty monitoring bodies have explicitly specified that, at a minimum, regulatory frameworks must ensure an obligation on healthcare providers to refer women to alternative health providers in a timely manner,[24] must not allow institutional refusals of care,[25] and must guarantee that an adequate number of healthcare providers willing and able to provide abortion services are available at all times in health facilities and within reasonable

[22] National Women's Law Center, *Fact Sheet: Health Care Refusals Harm Patients: The Threat to LGBT People and Individuals Living with HIV/AIDS,* May 2014, http://www.nwlc.org/sites/default/files/pdfs/lgbt_refusals_factsheet_05-09-14.pdf (citing 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/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf).

[23] National Center for Transgender Equality, *The Report of the 2015 U.S. Transgender Survey: Executive Summary* 3 (2016), https://transequality.org/sites/default/files/docs/usts/USTS-Executive-Summary-Dec17.pdf; National Women's Law Center, *Fact Sheet: Health Care Refusals Harm Patients: The Threat to LGBT People and Individuals Living with HIV/AIDS,* May 2014, http://www.nwlc.org/sites/default/files/pdfs/lgbt_refusals_factsheet_05-09-14.pdf (citing Jaime M. Grant, et. al., *Injustice at Every Turn: A Report of the National Transgender Discrimination Survey*, NATIONAL GAY AND LESBIAN TASK FORCE & NATIONAL CTR. FOR TRANSGENDER EQUALITY (2011), http://www.thetaskforce.org/downloads/reports/reports/ntds_full.pdf (internal quotations omitted)).

[24] *See, e.g.*, Report of the Committee on the Elimination of Discrimination Against Women, General Recommendation No. 24, 20th-21st Sess., Jan. 19-Feb. 5, June 7-25, 1999, ch. I, ¶ 11, U.N. Doc. A/54/38/Rev.1, GAOR, 44th Sess., Supp. No. 38 (1999) [hereinafter CEDAW, General Recommendation No. 24]; Committee on Economic, Social, and Cultural Rights, General Comment No. 22 (2016) on the Right to Sexual and Reproductive Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights), ¶¶ 14, 43, U.N. Doc. E/C.12/GC/22 (May 2, 2016) [hereinafter CESCR, General Comment No. 22]; Committee on the Elimination of Discrimination Against Women, Concluding Observations on the Combined Fourth and Fifth Periodic Reports of Croatia, ¶ 31, U.N. Doc. CEDAW/C/HRV/CO/4-5 (July 28, 2015); Committee on the Elimination of Discrimination Against Women, Concluding Observations on the Combined Seventh and Eighth Periodic Reports of Hungary, 54th Sess., Feb. 11-Mar. 1, 2013, ¶¶ 30-31, U.N. Doc. CEDAW/C/HUN/CO/7-8 (Mar. 1, 2013); Committee on Economic Social, and Cultural Rights, Consideration of Reports Submitted by States Parties under Articles 16 and 17 of the Covenant (Poland), 43d Sess., Nov. 2-20, 2009, ¶ 28, U.N. Doc. E/C.12/POL/CO/5 (Dec. 2, 2009). *See also* Committee on the Elimination of Discrimination Against Women, Concluding Observations on the Seventh Periodic Report of Italy, ¶¶ 41-42, U.N. Doc. CEDAW/C/ITA/CO/7 (July 24, 2017).

[25] *See* Committee on the Rights of the Child, Concluding Observations on the Combined Third to Fifth Periodic Reports of Slovakia, ¶ 41(f), U.N. Doc. CRC/C/SVK/CO/3-5 (July 20, 2016).

geographical reach.[26] In addition, any regulations must ensure that allowing conscientious objections does not inhibit the performance of services in urgent or emergency situations.[27]

For example the UN Human Rights Committee, which is charged with interpreting and monitoring countries' implementation of the International Covenant on Civil and Political Rights ("ICCPR"), has affirmed that governments must ensure that medical professionals' refusals to provide abortion care on grounds of conscience do not impede women's access to legal abortion services.[28] The United States has ratified the ICCPR, meaning that the United States is obligated to comply with and implement the provisions of the treaty subject to any reservations. The UN Human Rights Committee and the UN Committee on Economic, Social and Cultural Rights ("CESCR Committee") have found that states must introduce regulations and implement appropriate referral mechanisms in cases of provider conscientious objection.[29] The Committee on the Elimination of All Forms of Discrimination Against Women[30] has echoed the need for adequate referral mechanisms and has noted that "[i]t is discriminatory for a state party to refuse to provide legally for the performance of certain reproductive health services for women."[31] Similar findings have also been reached by other UN human rights experts.[32] Likewise, the European Court of Human Rights has found that states are obligated to organize health services in such a way as to ensure that conscience-based refusals do not prevent women from obtaining reproductive health services, including abortion services, to which they are legally entitled.[33]

UN human rights experts have noted the United States' particular obligations in this regard. While conducting a fact-finding visit to the country in 2015, the UN Working Group on Discrimination Against Women examined U.S. federal and state policies and found that they do not adequately protect women's access to reproductive health services. The Working Group's report on the visit provided recommendations for improving efforts to eliminate discrimination and reiterated that:

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[26] Committee on Economic, Social, and Cultural Rights, General Comment No. 22 (2016) on the Right to Sexual and Reproductive Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights), ¶¶ 14, 43, U.N. Doc. E/C.12/GC/22 (May 2, 2016).
[27] Id., at ¶ 43.
[28] Human Rights Committee, Consideration of Reports Submitted by States Parties under Article 40 of the Covenant (Poland), 100th Sess., Oct. 11-29, 2010, ¶ 12, U.N. Doc. CCPR/C/POL/CO/6, (Nov. 15, 2010); Human Rights Committee, Concluding Observations on the Seventh Periodic Report of Poland, ¶¶ 23-24, U.N. Doc. CCPR/C/POL/CO/7 (Nov. 23, 2016).
[29] *See* Human Rights Committee, Concluding Observations on the Sixth Periodic Report of Italy, ¶¶ 16-17, U.N. Doc. CCPR/C/ITA/CO/6 (May 1, 2017); Human Rights Committee, Concluding Observations on the Seventh Periodic Report of Colombia, ¶¶ 20-21, U.N. Doc. CCPR/C/COL/CO/7 (Nov. 17, 2016); Committee on Economic, Social and Cultural Rights, Concluding Observations on the Sixth Periodic Report of Poland, ¶¶ 46-47, U.N. Doc. E/C.12/POL/CO/6 (Oct. 26, 2016). *See also* Human Rights Committee, Concluding Observations on the Seventh Periodic Report of Poland, ¶¶ 23-24, U.N. Doc. CCPR/C/POL/CO/7 (Nov. 23, 2016).
[30] Although the United States has not yet ratified the Convention on the Elimination of All Forms of Discrimination Against Women or the International Covenant on Economic, Social, and Cultural Rights, as a signatory, it nevertheless has international obligations with respect to each. Michael H. Posner, Assistant Sec'y of State, Bureau of Democracy, Human Rights, and Labor, *Address to the American Society of International Law: The Four Freedoms Turn 70* (Mar. 24, 2011) (transcript available at https://2009-2017.state.gov/j/drl/rls/rm/2011/159195.htm) ("While the United States is not a party to the [ICESCR], as a signatory, we are committed to not defeating the object and purpose of the treaty."). Specifically, a country that has signed a treaty has an obligation "to refrain from acts which would defeat the object and purpose of a treaty" until it expresses its intention not to become a party. Vienna Convention on the Law of Treaties art. 18, Jan. 27, 1980, 1155 U.N.T.S. 331. While the United States is not a party to the Vienna Convention, it recognizes that many of the Convention's provisions have become customary international law and has signaled its intention to abide by the principles contained in treaties it has signed. *See Vienna Convention on the Law of Treaties*, U.S. DEP'T OF STATE, http://www.state.gov/s/l/treaty/faqs/70139.htm.
[31] Report of the Committee on the Elimination of Discrimination Against Women, General Recommendation No. 24, 20th-21st Sess., Jan. 19-Feb. 5, June 7-25, 1999, ch. I, ¶ 11, U.N. Doc. A/54/38/Rev.1, GAOR, 44th Sess., Supp. No. 38 (1999).
[32] *See* Interim Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, ¶¶ 24, 65(m), U.N. Doc. A/66/254 (Aug. 3, 2011).
[33] *See* R.R. v. Poland, No. 27617/04 Eur. Ct. H.R (2011); P. and S. v. Poland, No. 57375/0 Eur. Ct. H.R. (2012).

> [l]aws on religious or conscience based refusals to provide reproductive health care in the United States should be reconciled with international human rights standards. Refusal to provide sexual and reproductive health services on the grounds of religious freedom should not be permitted where such refusal would effectively deny women immediate access to the highest attainable standard of reproductive health care and affect the implementation of rights to which they are entitled under both international human rights standards and domestic law.[34]

The NPRM moves in the opposite direction of the recommendations, and instead prioritizes religious and moral refusals at the cost of patients' well-being by allowing a healthcare entity's moral or religious beliefs to supersede a patient's access to healthcare. Furthermore, the proposed rule appears to allow healthcare entities to refuse to provide information about available healthcare options, without disclosing the fact that they are choosing to withhold some information to patients, thus lacking safeguards to ensure continuity of quality patient care when a provider objects on religious or moral grounds.

In addition to attempting to allow providers to refuse to provide care or information without any consideration of patient needs, the NPRM, as further explained below, expands the scope of who can lodge a complaint alleging a violation of religious and moral beliefs to the HHS Office for Civil Rights ("OCR"), what practices or policies they can complain about, and the consequences of such complaints against providers and healthcare institutions. This dangerous expansion will create a chilling effect on providers of certain types of healthcare, leading to further reductions in healthcare access. The NPRM should therefore be withdrawn in its entirety.

II. The Proposed Rule Violates the Administrative Procedure Act

The proposed rule violates the Administrative Procedure Act ("APA") on multiple grounds. Not only does the NPRM suffer from several procedural defects, HHS fails to justify the proposed rule based on underlying facts and data, and it fails to engage in an appropriate cost-benefit analysis. Moreover, the proposed rule is arbitrary and capricious, an abuse of discretion, and not in accordance with law, because it mischaracterizes and inappropriately expands the scope of underlying federal refusal laws. For all of these reasons, HHS must withdraw the proposed rule in its entirety.

A. The proposed rule exhibits procedural flaws under the APA and the Paperwork Reduction Act (PRA).

Under the APA, "agency action, findings, and conclusions found to be . . . without observance of procedure required by law" shall be "held unlawful and set aside."[35] The NPRM suffers from multiple procedural defects. First, HHS failed to include any mention of an intent to regulate on this issue within the Unified Regulatory Agenda, as required by Executive Order 12866.[36]

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[34] Human Rights Council, 33d Sess., Report of the Working Group on the Issue of Discrimination Against Women in Law and in Practice on Its Mission to the United States of America, ¶¶ 71, 95(i), U.N. Doc. A/HRC/32/44/Add.2 (Aug. 4, 2016).
[35] 5 U.S.C.§ 706(2)(D).
[36] Exec. Order No. 12866, 58 F.R. 51735 at Sec. 4(b)-(c) (Oct. 4, 1993).

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Through this omission, HHS failed to put impacted entities, including other federal agencies, on notice of possible rulemaking in this area.

Second, prior to publication in the Federal Register, rules 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…and do not conflict with the policies or actions of another agency."[37] 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 issued in the Federal Register.[38] Standard review time for OIRA is upward of 45 days (and often closer to 90 days).[39] One week was plainly insufficient time for OIRA to review the proposed rule and provide "meaningful guidance and oversight."

In particular, 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. This is evidenced by the NPRM lacking key review and analysis on how the notice and compliance requirements interact with existing law such as EMTALA (discussed in more detail in Section IV. B. of this comment) or Title VII of the Civil Rights Act of 1964, which prohibits employment discrimination based on race, color, religion, sex and national origin. In promulgating a regulation that is inconsistent with federal statutes and regulations, HHS engaged in arbitrary and capricious rulemaking, and their conduct was further compounded by a complete failure by OIRA to engage in appropriate review.

Finally, the proposed rule would also impose burdens that are inconsistent with the Paperwork Reduction Act ("PRA"). The PRA was in part established to minimize the federal paperwork burden for individuals, small businesses, and state, local, and tribunal governments; minimize the cost of collecting and disseminating information; and maximize the usefulness of the information collected by the federal government.[40] For paperwork that is required by any new regulations, agencies must minimize the burden on the public to the extent "practicable"[41] and must obtain OMB approval before requesting or collecting most types of information from the public. This NPRM requires recipients and sub-recipients to post a new notice, as well as requiring certain assurances and certifications from recipients. The costs associated with the paperwork burden created by the proposed rule could be substantial, and the practical utility of the information that HHS seeks may be negligible to the proper performance of the functions of HHS, but it is not clear that OMB has even analyzed the impacts of the NPRM under the PRA.[42]

B. This proposed rule violates the APA because it is not justified by underlying facts and data, and it fails to engage in an appropriate cost-benefit analysis.

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[37] Id. at Sec. 6(b).
[38] OIRA Conclusion of EO 12866 Regulatory Review, *Ensuring Compliance with Certain Statutory Provisions in Health Care; Delegations of Authority*. HHS/OCR. RIN: 0945-ZA03. Received date: 01/12/18. Concluded date: 01/19/18. https://www.reginfo.gov/public/do/eoDetails?rrid=127838.
[39] Exec. Order No. 12866, 58 FR 51735 at Sec. 6(b) (Oct. 4, 1993).
[40] 44 U.S.C. § 3501.
[41] 44 U.S.C. § 3507 (a)(1).
[42] The NPRM currently lacks a PRA control number, which would notify the public that OMB has approved the rule's information collection requirements under the Paperwork Reduction Act of 1995.

Under the APA, "agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" shall be set aside.[43] 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."[44] The proposed rule is arbitrary and capricious because HHS failed to consider relevant data and articulate a satisfactory basis for the promulgation of this NPRM. As stated in the proposed regulation itself, HHS OCR only received ten complaints based on religious and moral refusal laws from 2008 to 2016, and only 34 complaints from November 2016 to early January 2018. These numbers pale in comparison to the total number of complaints OCR receives annually alleging civil rights violations and Health Insurance Portability and Accountability Act ("HIPAA") violations. For example, from Oct 1, 2016 through Sept. 30, 2017, OCR received approximately 30,166 complaints.[45] If 34 of them were complaints alleging a violation of religious or moral exemption laws, that constitutes less than one percent of the total volume. These data do not justify or support the NPRM, nor the related addition of a new office dedicated exclusively to these types of complaints.

Further, as the proposed rule details, under the existing regulatory scheme, HHS already investigates complaints, and has found violations and negotiated resolutions. The evidence of past enforcement where complaints were filed and violations found confirms there is no lack of enforcement here that would warrant rulemaking. In addition, HHS' existing grant-making documents already "make clear that recipients are required to comply with the federal health care provider conscience protection laws."[46] The proposed rule is therefore arbitrary and capricious because it is not justified by relevant data or facts.

Additionally, this NPRM is arbitrary and capricious because it fails to adequately assess the costs imposed by this proposed rule by underestimating certain quantifiable costs and completely ignoring the significant additional costs that would result from delayed or denied care. Executive Order 13563 requires that each agency make a "reasoned determination that its benefits justify its costs."[47] It also states that "each agency is directed to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible."[48] But this NPRM makes no attempt to conduct a reasoned cost-benefit analysis. For example, the cost-benefit analysis provides no quantifiable benefit for the rule's very purpose—expanding religious and moral refusal rights—as HHS could not find any quantifiable data to support the purported benefit of such an expansion.

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[43] 5 U.S.C.A. § 706(2)(A).
[44] 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)). Typically, a court will find an agency action to be arbitrary and capricious if the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (internal citations omitted); Envtl. Def. Fund, Inc. v. Costle, 657 F.2d 275, 283 (D.C. Cir. 1981) ("While we are admonished from rubber stamping agency decisions as correct, our task is complete when we find that the agency has engaged in reasoned decisionmaking within the scope of its Congressional mandate.") (internal citations and quotations omitted).
[45] U.S. Department of Health and Human Services FY19 Budget in Brief 124, https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf.
[46] Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 76 Fed. Reg. 9968, 9972 (2011).
[47] Exec. Order No. 13563, 76 FR 3821 at Sec. 1(b) (Jan. 18, 2011).
[48] Id. at Sec. 1(c).

More importantly, the cost-benefit analysis omits entirely any mention of the significant costs the rule would impose on women and other patients who are denied access to care, despite well-documented research that shows the significant healthcare costs women experience when they face healthcare denials, discussed in more detail in Section IV. D. of this comment.[49] Service denials result in delays for patients, who must then spend additional time and resources searching for a willing provider. Delays also have the effect of increasing the cost of an abortion.[50] Moreover, delays raise the cost of each step of obtaining an abortion—not just the cost of the procedure, but also incidental costs such as being required to travel farther to obtain an abortion, thereby incurring additional travel and related expenses, such as lost wages and childcare.[51] As a result, healthcare denials that result in a delay in care can significantly drive up the cost of care for a woman seeking an abortion.

Healthcare refusals without adequate safeguards may also have negative consequences on the long-term socioeconomic status of women. A recent study in the American Journal of Public Health found that women who were denied a wanted abortion had higher odds of poverty six months after denial than did women who received abortions, and that women denied abortions were also more likely to be in poverty for four years following denial of abortion.[52] The agency does not even attempt to quantify these broader medical, social, and economic costs that result from service refusals, and entirely fails to take these costs into account in justifying this NPRM. Thus, this NPRM should be withdrawn for failing to consider, and put the public on notice of, all relevant costs.

C. The NPRM is arbitrary and capricious, an abuse of discretion, and not in accordance with law, because it mischaracterizes and inappropriately expands the scope of underlying federal refusal laws.

Although agencies have broad authority to engage in rulemaking, that authority is not without limits. Under the Administrative Procedure Act, "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. In proposing an expanded enforcement scheme for the Church amendments (42 U.S.C. § 300a-7), the Coats-Snowe amendment (42 U.S.C. § 238n.) and the Weldon amendment (Consolidated Appropriations Act, 2017, Public Law 115-31, Div. H, sec. 507(d)(1), 131 Stat. 135.), the NPRM inappropriately exceeds the parameters of the plain text of these statutes, as well as their legislative intent, in a manner that violates the APA. As a result, the proposed rule should be withdrawn in its entirety.

i. The NPRM misinterprets, and exceeds the parameters and intent of, the Church amendments.

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[49] National Women's Law Center, *When health care providers refuse: The impact on patients of providers' religious and moral objections to give medical care, information or referrals*, Apr. 2009, https://www.nwlc.org/wp-content/uploads/2015/08/April2009RefusalFactsheet.pdf.
[50] Rachel K. Jones et al., *Differences in Abortion Service Delivery in Hostile, Middle-Ground and Supportive States in 2014*, WOMEN'S HEALTH ISSUES (2018), http://www.whijournal.com/article/S1049-3867(17)30536-4/abstract.
[51] Rachel K. Jones & Jenna Jerman, *How Far Did US Women Travel for Abortion Services in 2008*, 22 J. WOMEN'S HEALTH 706 (2013).
[52] Diana Greene Foster et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 108 AM. J. PUB. H. 407 (2018), http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2017.304247.

Consisting of four substantive provisions codified at 42 U.S.C. § 300a-7, the Church amendments prohibit recipients of federal funding from discriminating against entities and individuals who refuse to perform, or "assist in the performance" of, sterilizations or abortions on the basis of religious or moral objections. The Church amendments also prohibit discrimination against those who do choose to provide abortion or sterilization. Although the operative text of the proposed rule prohibits, as the Church amendment requires, discrimination on the basis of past performance of abortion or sterilization in addition to refusals to perform these services, the silence on this topic in the proposed rule's preamble speaks volumes. The preamble entirely neglects to mention the Church amendment's protection of individuals and entities that choose to provide abortion and sterilization services, indicating clearly that HHS intends to prioritize enforcement with respect to complaints related to religious and moral refusals over discrimination against providers who choose to give care.[53]

In the NPRM, HHS proposes to define certain terms that appear in the Church amendments in a manner that greatly expands the universe of individuals covered by the statute and controverts the actual text of the statute and the intent of Congress. Therefore, the NPRM is arbitrary and capricious, an abuse of discretion, and is not in accordance with law.

As a threshold matter, the Church amendments are, as discussed further below, specifically and deliberately tailored. Nothing in the statutory text or legislative history supports the broadening of scope attempted by the NPRM. Even what is arguably the most expansive provision, 42 U.S.C. § 300a-7(d), was meant to apply only to biomedical and behavioral research contexts, as it was enacted under the National Research Service Award Act of 1974, under Title II of the Act which was specifically titled "Protection of Human Subjects of Biomedical and Behavioral Research."[54] Legislative debates at the time of passage confirm this limitation. Then-Senator Biden, stating his support for an exemptions amendment to the Biomedical Research Act—which eventually became codified as 42 U.S.C. § 300a-7(c)(2) through 42 U.S.C. § 300a-7(d)—stated the goal of the amendment was to ensure that "no individual or entities shall be required to participate in biomedical research or experimentation if such activities are contrary to the intended participants' religious beliefs or moral convictions."[55] Thus, it is arbitrary and capricious, and not in accordance with law for HHS to conclude that any part of the Church amendments authorize the agency's overbroad interpretations as follows:

"Individual" and "Workforce." Neither "individual" nor "workforce" is defined by the Church amendments. The proposed rule defines "individual" as "member of the workforce of an entity

[53] The substantive provisions of the Church amendments, which begin at 42 U.S.C. § 300a-7(b), are as follows: § 300a-7(b) states that those receiving federal funds cannot require an individual to "perform or assist in the performance of any sterilization procedure or abortion" if it would be against the individual's religious or moral beliefs, and entities similarly cannot be forced to make their facilities available or provide any personnel for the performance or assistance in the performance of sterilization or abortion. § 300a-7(c) prohibits discrimination in the "employment, promotion, or termination of employment," of physicians or other "health care personnel," and discrimination "in the extension of staff or other privileges," on the basis of one's past performance or past refusal to perform a sterilization or abortion. § 300a-7(c) further specifies that any entity receiving a grant or contract for biomedical or behavioral research is prohibited from discriminating in the same context (employment, staff privileges, etc.) because of a physician or healthcare personnel's past performance or past refusal to perform a sterilization or abortion. § 300a-7(d) states that no individual shall be required to perform or assist in the performance of "any part of a [federally funded] health service program or research activity" if it would be contrary to the individual's religious or moral beliefs. Finally, § 300a-7(e) specifies that no entity that receives certain federal funds may deny admission or otherwise discriminate against any applicant for training or study because of the applicant's unwillingness to participate in the performance of abortions or sterilizations contrary to the applicant's religious or moral beliefs.
[54] National Research Service Award Act of 1974, Pub. L. No. 93-348, 353-54 (1974).
[55] 120 Cong. Rec. 16, 21540 (June 27, 1974) (Statement of Sen. Biden).

or health care entity;" "workforce" is defined as "employees, volunteers, trainees, contractors, and other persons whose conduct, in the performance of work for an entity or health care entity, is under the direct control of such entity or health care entity, whether or not they are paid by the entity or health care entity, as well as health care providers holding privileges with the entity or health care entity." By including volunteers, contractors, and other non-employees within these definitions, the proposed rule attempts to significantly and inappropriately broaden the universe of people who could now claim to be assisting in a procedure under the Church amendments.

The Church amendments' legislative history demonstrates that only hospitals themselves and individual physicians and nurses were intended to be protected by the original statute, now consisting of 42 U.S.C. § 300a-7(b) through 42 U.S.C. § 300a-7(c)(1). On the Senate floor, the amendment sponsors focused on whether federal funding could be used to force religiously affiliated hospitals or individual medical personnel to provide abortions or sterilizations against their beliefs.[56] In clarifying to whom the Church amendments would apply, Senator Frank Church specified that the amendments were "meant to give protection to the physicians, to the nurses, to the hospitals themselves, if they are religious affiliated institutions."[57]

The articulation of "physicians, . . . nurses, . . . hospitals" stands in clear contrast with the NPRM's proposed class of individuals within the workforce. The NPRM's definitions open the door for religious and moral refusals from precisely the type of individuals that the amendments' sponsor sought to exclude. This arbitrary and capricious broadening of the amendments' scope goes far beyond what was envisioned when the Church amendments were enacted.

"Assist in the performance." This term is undefined in the text of the Church amendments. Words that are not terms of art and that are not statutorily defined are customarily given their ordinary meaning.[58] The proposed rule provides a definition of "assist in the performance" that goes far beyond the common understanding of the term. By defining the term as meaning "to participate in any activity with an articulable connection to a procedure, health service, health program, or research activity," the NPRM proposes an unreasonably broad and vague standard that could allow virtually any member of the healthcare workforce to argue that they are assisting in the performance of a procedure, from the nurse who sanitizes instruments to a receptionist scheduling appointments or to a contractor who disposes of a hospital's waste. The phrase "articulable connection to a procedure" also disregards the meaning of the word "performance," attempting to cast a wider net to those not directly responsible for performing the health care service.

Legislative history demonstrates that the NPRM's definition is contrary to the intended scope of "assisting in the performance." On the floor of the Senate, Senator Long asked Senator Church, "[T]his would not, in effect, say that one who sought such an operation would be denied it because someone working in the hospital objected who had no responsibility, directly or indirectly, with regard to the performance of that procedure." Senator Church replied, "The

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[56] 119 Cong. Rec. 8, 9595-9596 (1973).
[57] 119 Cong. Rec. 8, 9597 (1973); *see also* statement from Sen. Buckley, 119 Cong. Rec. 8, 9601 ("In this amendment, we seek to protect the right not only of institutions, but of individual doctors and individual nurses.").
[58] In the absence of a statutory definition, "we construe a statutory term in accordance with its ordinary or natural meaning." FDIC v. Meyer, 510 U.S. 471, 476 (1994).

Senator is correct."[59] Senator Church went on to assert: "There is no intention here to permit a frivolous objection from someone unconnected with the procedure to be the basis for a refusal to perform what would otherwise be a legal operation."[60] The NPRM proposes to broaden the amendments' scope by permitting anyone with a mere "articulable connection" to a procedure to file a complaint. But a connection that is no more than "articulable" is exactly the kind of frivolous objection that the amendment's sponsor sought to avoid. From its inception, the Church amendments have demanded a clear and direct connection to the performance of the procedure—and the NPRM's proposed definition is plainly not in accordance with that statutory intent.

ii. The NPRM misinterprets, conflicts with, and exceeds the parameters of the Coats-Snowe amendment.

The Coats-Snowe amendment (42 U.S.C. § 238n) prohibits governments from discriminating against any "health care entity" that refuses to train for abortion care, or that attends a medical training program that does not provide abortion training or "refer for" training or abortion care. It also prevents a government from denying accreditation of a physician training program based on its refusal to provide abortion training. It is intentionally tailored solely to the context of medical training. As demonstrated below, the proposed rule's definitions of "health care entity" and "referral or refer for" go far beyond the plain language of the Coats-Snowe amendment and the intent of Congress in passing it, and as such the NPRM is not in accordance with law.

"Health care entity." The proposed rule's definition of "health care entity" conflicts with and far exceeds the statutory bounds set by Congress. 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."[61] The proposed rule's definition of the same term expands, without justification or rationale, to add healthcare personnel, laboratories, plan sponsors and third-party administrators, as well as components of state and local governments. This definition could allow virtually any staff member of a healthcare facility to refuse to provide or participate in training for abortion care or abortion-related referrals, or to provide such care.

"Referral or *refer for."* This term is undefined in the Coats-Snowe amendment. The proposed rule's definition seeks not only to allow providers to opt out of referring patients to a non-objecting physician, but also to allow providers to withhold any medical information that could lead a patient to choose a healthcare service, activity, or procedure to which the treating physician objects. As explained below, this definition is arbitrary and capricious, and not in accordance with law.

The legislative history of the Coats-Snowe amendment demonstrates an intent to protect, not undermine, access to care. Debates on the Senate floor demonstrate that the amendment was a compromise provision intended to protect women's health while maintaining the status quo for,

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[59] 119 Cong. Rec. 8, 9597 (1973).
[60] Id. Sen. Church went on to reiterate that "[t]his amendment makes it clear that Congress does not intend to compel the courts to construe the law as coercing *religious affiliated hospitals, doctors, or nurses* to perform surgical procedures against which they may have religious or moral objection," 9601 (emphasis added); *see also* statement from Sen. Buckley, 119 Cong. Rec. 8, 9601 ("In this amendment, we seek to protect the right not only of institutions, but of individual doctors and individual nurses.").
[61] 42 USC § 238n(c)(2).

not expanding, providers' refusal rights. The amendment was a direct response to a provision passed by the House of Representatives that threatened women's access to care.[62] Senator Olympia Snowe, lead sponsor of the Coats-Snowe amendment, described the amendment's purpose as ensuring access to healthcare services even where a provider opted out:

> "[. . . T]his amendment would not only make sure that women have access to quality health care with the strictest of standards when it comes to quality and safety but it also will ensure that they have access to physicians who specialize in women's health care."[63]

Senator Snowe's remarks demonstrate an intent to protect and prioritize women's access to care, particularly in the context of refusals. In the NPRM, HHS completely fails to address how it will ensure this access to care. Moreover, HHS lacks the authority to interpret the terms "health care entities" or "referral or refer for" so broadly, because the legislative intent of these amendments was to create a targeted, narrow carve out that will still protect women's health. The NPRM's interpretation of the Coats-Snowe amendment is therefore arbitrary and capricious, and not in accordance with law, and the NPRM should therefore be withdrawn in its entirety.

iii. The NPRM misinterprets and exceeds the parameters of the Weldon amendment.

The Weldon amendment prohibits federal funds appropriated annually as part of the HHS Appropriations Act from being made available to any federal agency or program, or state or local government that discriminates against any "institutional or individual healthcare entity" on the basis that the entity does not "provide, pay for, provide coverage of, or refer for abortions."[64] As set forth below, the proposed rule's definitions of "health care entity" and "refer for" arbitrarily and inappropriately exceed both the statutory text and Congressional intent of this amendment.

"Health care entity." The Weldon amendment defines "health care entity" as 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."[65] As noted above, the proposed rule goes far beyond this definition, adding healthcare personnel, laboratories, plan sponsors, and third-party administrators, as well as components of state and local governments, to the list of protected parties. This goes directly against Congressional intent. Plan sponsors and third-party

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[62] Sen. Snowe: "[I]n the House of Representatives they have already passed legislation that would allow Federal funds to go to an unaccredited institution. [. . .] So the choice was not to address the reality of what is taking place in the House or making sure, more importantly, that the Senate was on record in opposition to that kind of language and developing a compromise with the Senator from Indiana to ensure that we maintained the accreditation standards for all medical institutions to advance the quality health care for women and at the same time to allow training for abortion for those who want to participate in that training or for the institutions who want to provide it. Because that is the way it is done now. That is the status quo, and that is not changing. [. . .] This is a compromise to preserve those standards. This is a compromise to ensure that it does not jeopardize the 273 ob-gyn programs that otherwise would have been affected if this compromise was not before us. That is the risk, and that is why I worked with the Senator from Indiana to ensure that would not happen." 142 Cong. Rec. 38, 2269 (Mar. 19, 1996).
[63] 142 Cong. Rec. 38, 2268 (Mar. 19, 1996).
[64] Consolidated Appropriations Act of 2017, Pub. L. 115-31, Div. H, sec. 507(d)(1), 131 Stat. 135 (2017).
[65] Id.

administrators are not themselves health insurers, health plans, or even health organizations and therefore cannot and should not naturally be considered healthcare entities. By expressly defining the term "health care entity," Congress implicitly rejected the inclusion of the other terms and meanings HHS now attempts to insert. Further, at the time the amendment was adopted, Rep. Weldon himself repeatedly enumerated the entities he intended to protect, and listed only entities that are themselves providers of healthcare, but never the recipients of insurance benefits or purchasers of insurance.[66]

Moreover, the proposed definition contradicts OCR's prior conclusion that the Weldon amendment's protection of health insurance plans "included issuers of . . . plans but not institutions or individuals who purchase or are insured by those plans."[67] Without justification or basis, the NPRM now proposes to newly protect even plan sponsors—e.g., employers or universities—and third-party administrators in this category.[68] An agency can only change an existing policy if it provides a "reasoned explanation" for disregarding or overriding the basis for the prior policy—but HHS never offers this reasoned explanation in the NPRM.[69] Instead, the proposed rule seeks to allow individuals as far removed as lab workers and ambulance drivers to refuse to perform their essential job duties because, for example, the results of analyzing an amniocentesis could lead to a woman choosing an abortion, or transporting a pregnant, miscarrying woman to a hospital could allow the woman's treatment to include a pregnancy termination. The NPRM's proposed definition plainly exceeds the definition that Congress intended and the Department's own prior policy without justification or basis, in a manner that is arbitrary and capricious, and not in accordance with law.

"Referral or *refer for."* This term is undefined in the Weldon amendment. As mentioned previously, terms that are not statutorily defined are customarily assigned their ordinary meanings.[70] Extraordinary interpretations are generally not in accordance with law. The term "referral" in the medical context is understood to mean "A written order from [a] primary care doctor for [the patient] to see a specialist or get certain medical services."[71] When a "deeply held, well-considered personal belief leads a physician to also decline to refer," medical ethics require providers to "offer impartial guidance to patients about how to inform themselves regarding access to desired services."[72] But the proposed rule's definition stretches the plain meaning beyond recognition and in violation of medical practice and principles of medical ethics. HHS proposes that a definition of "referral" would include "the provision of any information…by any method…pertaining to a service, activity, or procedure" when the referring entity "understands that particular health care service, activity, or procedure to be a purpose or possible outcome of the referral."[73]

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[66] 150 Cong. Rec. 135, 10090 (Nov. 20, 2004) (Statement of Rep. Weldon).
[67] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3890 (Jan. 26, 2018).
[68] "Because the Weldon Amendment protects not only the health insurance issuer, but also the health plan itself, it can also be raised, at minimum, by the plan sponsor on behalf of the plan." Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3890 (Jan. 26, 2018).
[69] Encino Motorcars, 136 S. Ct. at 2125-2126.
[70] In the absence of a statutory definition, "we construe a statutory term in accordance with its ordinary or natural meaning." FDIC v. Meyer, 510 U.S. 471, 476 (1994).
[71] Healthcare.Gov, *Glossary: Referral.*, last visited March 22, 2018, https://www.healthcare.gov/glossary/referral/.
[72] American Medical Association, *Code of Medical Ethics Opinion 1.1.7,* AMA CODE OF MEDICAL ETHICS, last visited March 22, 2018 at https://www.ama-assn.org/delivering-care/physician-exercise-conscience.
[73] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3894-95 (Jan. 26, 2018).

With this definition of referral, HHS seeks to allow providers not only to opt out of referring patients to a non-objecting physician, but also to allow healthcare personnel to withhold any medical information that could create even a possibility that the patient would choose a healthcare service, activity, or procedure to which that individual or entity objects. The average reasonable person would not assume that a medical referral includes just about anything that might eventually, down the line, allow the patient to obtain the services they need, nor that a provider could single-handedly decide that a patient may not access the care they need. This definition goes far beyond the common understanding of the term and violates medical ethics in a manner that will cause significant harm to patients. Here and throughout, the NPRM's construction of the Weldon amendment is arbitrary and capricious, and not in accordance with law.

iv. HHS's definition of "discrimination" is arbitrary, capricious, an abuse of discretion, and not in accordance with law.

"Discrimination." In the NPRM, "discrimination" is defined as "to withhold, reduce, exclude, terminate, restrict, or otherwise make unavailable or deny any grant, contract, subcontract, cooperative agreement, loan, license, certification accreditation, employment, title, or other similar instrument, position or status;" withholding . . . "any benefit or privilege . . . utilize any criterion, method of administration, or site selection, including the enactment, application, or enforcement of laws, regulations, policies, . . ., that *tends to* subject individuals or entities to any adverse effect . . . or to *have the effect of* defeating or substantially impairing accomplishment of a health program or activity with respect to individuals, entities, or conduct protected . . . or *otherwise engage in any activity* reasonably regarded as discrimination" (emphasis added).[74]

HHS adopts a definition unsupported by any federal refusal statute. The word "discrimination" is not defined in any of the Church, Coats-Snowe, or Weldon amendments or any of the other underlying statutes the rules purport to enforce. When combined with the definitions of other terms in the NPRM, including "assist in the performance," "referral," and "workforce," this extremely broad definition of discrimination takes on a whole new and unprecedented force, giving HHS authority to take action against recipients whenever virtually any employee who can claim an "articulable connection" to a procedure makes an objection. The proposed rule appears to give these religious and moral refusals precedence over all other interests, taking no account of the negative impact on patients, other employees, or the burdens on health care providers. This is a significant expansion beyond the scope of the underlying statutes that will impact all healthcare providers who receive federal funding through HHS, including, for example, both public and private hospitals, Medicaid/Medicare recipients, and Title X recipients.

As noted above, the authors of federal refusal laws such as Church, Coats-Snowe, or Weldon amendments envisioned granting certain healthcare entities and individuals the option to opt out of providing abortion or sterilization care or coverage, not to control the conduct of others.[75] This proposed definition of discrimination, in contrast, would expand religious and moral refusal

[74] Id. at 3892.
[75] *See, e.g.*, 119 Cong. Rec. 8, 9603 (1973). (Sen. Javits: "I wish to make it clear that that particular amendment [on discrimination] simply will protect anybody who works for that hospital against being fired or losing his hospital privileges if he does not agree with the policy of the hospital and goes elsewhere and does what he wishes to do" Sen. Church: "I am in full accord with that.").

rights at the expense of a protected liberty interest—access to healthcare—with devastating consequences for women and members of the LGBTQ community who may be denied access to necessary and even emergency healthcare, as described in greater detail throughout these comments. Under this definition, important practices and policies that ensure access to healthcare—such as a basic hospital policy requiring that employees must provide care to anyone who walks through the door—could be deemed discriminatory. Further, such a vague and inappropriate definition provides no functional guidance to entities on how to comply with the applicable requirements, thereby fostering confusion. Further, compliance with the NPRM, based on what the rules appear to require, is in conflict with other federal antidiscrimination laws, as discussed in greater detail below. It will not be feasible for recipients to comply with the NPRM and, for example, EMTALA, Title VI, Title VII, and a host of other requirements that entities face when seeking accreditation.

To conclude, many of the definitions in the NPRM, but particularly the definitions of "health care entity," "assist in the performance," "individual," "workforce," "referral or refer for," and "discrimination," expand the federal healthcare refusal laws beyond their stated and intended parameters. Together, these definitions significantly and inappropriately broaden the scope and application of the underlying statutes, attempting to extend religious and moral refusal protections to individuals and entities that were plainly not contemplated. These definitions are arbitrary and capricious, and not in accordance with law, and because they inform the entire enforcement scheme proposed by the NPRM, the proposed rule must be withdrawn in its entirety.

III. The NPRM Proposes a Set of Compliance and Enforcement Mechanisms that Are Arbitrary, Capricious, an Abuse of Discretion, and Not in Accordance with Law

A. The NPRM proposes an enforcement scheme that lacks due process and is therefore unconstitutional.

In the proposed rule, HHS states that as a remedial measure for a violation, HHS will consider using all "legal options, up to and including termination of funding and return of funds," which could include "the temporary withholding of cash payments in whole or part, pending correction of the deficiency, the denial of funds and any applicable matching credit in whole or in part, the suspension or termination of the Federal award in whole or in part, the withholding of new Federal financial assistance or other Federal funds from HHS," and other remedies.[76] The NPRM does not include any notice, hearing or appeal procedures to govern such termination or withholding of funds.

The lack of notice, hearing, and appeal procedures violates the due process clause enshrined in the 5th and 14th amendments to the U.S. Constitution.[77] Recipient and sub-recipients of HHS' federal financial assistance have a protected property interest in federal financial assistance,

[76] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3898 (Jan. 26, 2018).
[77] U.S. CONST. amend. V, XIV.

which triggers certain procedural due process requirements.[78] These procedural due process requirements commonly consist of timely and adequate notice, the right to counsel, opportunity to address the fact-finder, an explanation of the decision, and chance for appeal.[79] The fact that HHS is requesting specific comment on whether the proposed rule should establish notice, hearing, and appeal procedures similar to those established in other HHS-administered programs indicates that the agency already is aware of procedural due process requirements, yet has explicitly chosen to exclude due process from its proposed rule. Failure to include mechanisms to ensure due process renders the NPRM unconstitutional. Therefore, the NPRM should be withdrawn in its entirety.

B. Many of the NPRM's proposed enforcement and compliance procedures are coercive, exceed enforcement norms, and create a chilling effect that would harm patients.

The NPRM contains certain proposed enforcement and compliance requirements that are arbitrary and capricious, an abuse of discretion, and not in accordance with law because they are coercive, exceed other enforcement norms, and create a chilling effect.

Restricting a broader range of funds and/or a broader category of entities
In its proposed rule, HHS asserts that, in order to enforce federal healthcare refusal laws, OCR may restrict "a broader range of funds or broader categories of covered entities" for "noncompliant entities."[80] HHS does not clarify what the "broader range of funds" or the "broader categories of covered entities" would encompass. Rather, the deliberate vagueness of the phrase suggests that HHS is attempting to grant itself the power to withhold not only the type of funding used in violation of program terms, but also withhold any other federal funding, even if unrelated to the offense. It also indicates that HHS would like to be free to withhold or terminate funding not only to those entities found to have committed a violation, but also those entities who may somehow be tangentially related to an entity that has been found to have committed a violation.

This proposed text has no basis in the underlying statutes the NPRM seeks to enforce, and in fact OCR has previously found this type of broad withholding of federal funding to raise "substantial questions about constitutionality" under the Spending Clause.[81] In addition, this proposed enforcement mechanism is wholly inconsistent with, and far exceeds, the regulations that govern implementation and enforcement of civil rights laws, *see e.g.* 45 C.F.R. 80. In civil rights enforcement, suspension or termination of federal funding assistance is limited to the particular grantee and the particular program or part thereof in which noncompliance was found.[82] By

[78] *See* Perry v. Sindermann, 408 U.S. 593 (1972); *see also* Citizens Health Corp. v. Sebelius, 725 F.3d 687 (7th Cir. 2013) (holding that a legitimate claim of entitlement "may arise from a contract, a statute, or a regulation, provided the source of the claim is specific enough to require the provision of the benefit on a nondiscretionary basis.").
[79] Goldberg v. Kelly, 397 U.S. 254 (1970).
[80] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3898 (January 26, 2018).
[81] Letter from OCR Director to Complainants (June 21, 2016) available at http://www.adfmedia.org/files/CDMHCInvestigationClosureLetter.pdf. ("A finding that CDMHC has violated the Weldon Amendment might require the government to rescind all funds appropriated under the Appropriations Act to the State of California – including funds provided to the State not only by HHS but also by the Departments of Education and Labor, as well as other agencies. HHS' Office of General Counsel, after consulting with the Department of Justice, has advised that such a rescission would raise substantial questions about the constitutionality of the Weldon Amendment.").
[82] 45 C.F.R. § 80.8.

potentially putting all HHS funding streams at jeopardy if a single refusal violation is found, and by putting similar entities who themselves have not committed a violation at jeopardy, the proposed rule attempts to create a blunt tool with the apparent intention of intimidating federal funding recipients and sub-recipients. Such unusually harsh and coercive compliance mechanisms render this proposed rule arbitrary and capricious, an abuse of discretion, and not in accordance with law.

Proactive reporting requirements
Under the NPRM, if a recipient or sub-recipient is subject to an OCR compliance review, investigation, or complaint filed with OCR based on religious and moral refusal laws, the recipient or sub-recipient must inform any Departmental funding component of such review, investigation, or complaint and must in any new or renewed application disclose and report on the existence of such reviews or complaints for *five years* from such complaints' filing.[83] This applies even when a violation is not found; anyone subject to a Department-initiated compliance review, investigation, or even subject to a complaint would have to undergo this process.

This compliance requirement is dangerous and likely to create a chilling effect, given that the definitions described above broadly expand the universe of those who might file complaints, and given further that anyone can file a complaint on behalf of another covered individual or entity. The proposed rule does not narrow the reporting requirement to credible instances in which the agency concluded that there was a violation; even the most frivolous complaint would have to be disclosed and reported on every funding application for five years. This is again an inappropriate compliance measure that seeks not only to intimidate recipients and sub-recipients, but also encourage outsiders to make complaints in bad faith against healthcare entities in order to mount more regulatory hurdles for such entities. It also raises concerns over whether frivolous complaints could influence a grant recipient's eligibility for future grants. These types of extreme compliance measures have no basis in the underlying statutes, exceed other enforcement norms, and are wholly inappropriate for HHS, whose mission is to ensure that Americans can get the healthcare they need. Therefore, the NPRM should be withdrawn.

IV. The Proposed Rule Should be Withdrawn Because It Harmfully Prioritizes Healthcare Provider Objections Above the Needs of Patients

A. The proposed rule is designed to have a chilling effect on the provision of abortion care.

The proposed rule seeks to intimidate abortion providers by significantly and inappropriately broadening the pool of individuals who may avail themselves of the complaint process. As articulated above, from the overly broad definitions to the excessively punitive enforcement measures, the proposed rule seeks to ensure that virtually anyone in the workforce of a healthcare entity that provides abortions—and even workers outside of an entity's core workforce, such as contractors—would be permitted to file a complaint. The proposed rule seems designed to make providers hesitant to perform abortion care for fear that their funding may be jeopardized by a

[83] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3930 (Jan. 26, 2018).

tenuously connected employee who may not even be involved in the performance of abortion care.

The chilling effect is strengthened by the enhanced compliance requirements the rule proposes. Because many clinics depend heavily on federal financial funds to serve low-income populations in their family planning programs, they may be reluctant to continue offering or referring for abortion services for fear of entrapment by anti-abortion extremists.

The types and varieties of institutions and care potentially affected by this NPRM are numerous. Below are lists of just some of the entities and care that may be affected.

Types and variety of institutions where access to care may be impacted:

- Hospitals
- Nursing facilities
- Family planning centers
- Freestanding ambulatory surgical and emergency centers
- Pharmacies
- HMO medical centers
- Medical laboratories
- Diagnostic imaging and screening centers
- Ambulance services
- Outpatient care centers
- Continuing care retirement communities and hospices
- Colleges, universities, and professional schools
- Individual physicians, nurses, and health practitioners

Types and variety of care potentially affected, including counseling for such care:

- Abortion and post-abortion care
- Miscarriage management and ectopic pregnancy care
- Sterilization care, such as tubal ligation
- Gender confirmation surgery
- Hormone therapy
- Contraceptive care
- Assisted reproductive technologies, such as in-vitro fertilization
- Hysterectomy and other reproductive care
- Amniocentesis and other prenatal diagnostic care
- Advanced directives and end-of-life care
- HIV prophylaxis, including pre-exposure and post-exposure prophylaxis
- Sexually transmitted infections screening and care
- Mental health services

The far reach of this NPRM means anyone receiving federal funding—from hospitals to independent providers—is likely to be impacted. If finalized as written, the rule could ultimately result in barriers to care for women and other individuals at multiple access points in the

healthcare system, compounding limitations to care and making it difficult for some individuals to access care at all.

B. The proposed rule fails to safeguard access to care, including information about available or optimal care and access to emergency treatment.

The proposed rule entirely fails to evaluate or consider the potential impact on access to healthcare. The foreseeable and anticipated result of the proposed rule's attempted vast expansion of religious and moral healthcare refusal rights will likely be that a larger number of individuals will use refusal laws as a basis to deny care—in addition to the number of entities that the rule seeks to intimidate into not providing certain healthcare services at all. In promulgating this rule, HHS is prioritizing the religious and moral beliefs of healthcare providers over the needs of patients in violation of its own mission statement—to "enhance and protect the health and well-being of all Americans."[84]

The proposed rule also fails to ensure the treatment of patients facing emergency health situations, including emergencies requiring miscarriage management or abortion. EMTALA 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.[85] Every hospital that has a Medicare provider agreement and an emergency room—even those that are religiously-affiliated—is required to comply with EMTALA. Because the proposed rule does not mention EMTALA or safeguard emergency care in any way, it creates confusion that may lead some institutions to mistakenly believe they are not required to comply with EMTALA. As articulated earlier in this comment, failure to comply with EMTALA has resulted in harm to women. Moreover, because religious institutions have violated EMTALA in the past,[86] the NPRM's failure to address a healthcare entity's legal obligation to follow EMTALA's directives is a critical omission.

In adopting the religious and moral refusal laws that the NPRM now misappropriates, Congress explicitly considered and sought to protect against the types of harm that can result from service refusals, particularly in an emergency situation. As previously discussed, congressional records on the Church amendment indicate that some Senators, even back in 1973, anticipated and sought to curb the negative health impacts that the proposed amendment could have in rural and underserved areas, and the problems with informed consent that could arise.[87] Between the limitation on access to care that this NPRM will likely create and the complete failure to address emergency situations, the proposed rule is plainly not in accordance with underlying statutes it seeks to enforce.

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[84] U.S. Department of Health and Human Services, *About HHS*, visited Mar. 26, 2018, https://www.hhs.gov/about/index.html.
[85] *See* 42 U.S.C. § 1395dd(a)-(c).
[86] *See, e.g.* Julia Kaye et al., *Health Care Denied: Patients and physicians speak out about Catholic hospitals and the threat to women's health and lives*, May 2016, https://www.aclu.org/report/report-health-care-denied?redirect=report/health-care-denied.
[87] Senator Church based his amendment, and reassured other Senators, on the assumption that "no area of [my home state] would be without a hospital within a reasonable commuting distance which would perform abortion or sterilization procedures. Moreover, in an emergency situation—life or death type—no hospital, religious or not, would deny such services. There is no problem here."

Even for non-emergency care, the Supreme Court has held that religious objections must be balanced against their impact on women's healthcare. In *Zubik v. Burwell*,[88] the Court reviewed alternative approaches to respecting religious objections while ensuring women maintain seamless contraceptive coverage, and ordered the parties to resolve those cases in a way that ensured there would be no impact on women's access to health care.[89] The Court in *Zubik* required that an accommodation of religious exercise must still ensure that women "receive full and equal health coverage, including contraceptive coverage.'"[90] Similarly, *Burwell v. Hobby Lobby*[91] rejected the notion that for-profit corporations' religious beliefs must be accommodated regardless of the impact—specifically noting that a new accommodation at issue in the case would have an impact on women that "would be precisely zero."[92]

Undeniably, the impact on women's health under this rule would be greater than zero. While abortion is an extremely safe procedure throughout pregnancy,[93] abortion in the earliest stages of pregnancy is safest: major complications in first-trimester abortions occur at a rate of less than 0.5 percent.[94] In fact, a comprehensive report on the safety and quality of abortion care in the United States released by the National Academies of Sciences, Engineering and Medicine this month found that "safety and quality are enhanced when the abortion is performed as early in pregnancy as possible."[95] Denying a woman an abortion—and thus forcing her to carry the pregnancy to term—increases the risk of injury and death. Approximately 28.6 percent of hospital deliveries involve at least one obstetric complication, compared to the one percent to four percent for first-trimester abortion.[96] A woman is 14 times more likely to die from giving birth than as a result of an abortion.[97] Yet the proposed rule is likely to lead to increased delays and denials of abortion care, resulting in increased harm to women.

C. The proposed rule undercuts fundamental principles of patient care.

The proposed rule's new and expanded definitions interact to encourage entities and individuals who seek to refuse care on religious grounds, and intimidate providers who want to provide care.

In addition, the proposed definition of "referral or refer for" puts informed consent at risk. Informed consent is a necessary principle of patient-centered decision-making intended to help balance the power dynamics between health providers and patients and ensure patients have full autonomy over what is to happen to their bodies. Informed consent requires providers to disclose relevant and medically accurate information about treatment choices and alternatives so that

[88] Zubik v. Burwell, 136 S. Ct. 1557 (2016).
[89] Id. at 1560; Catholic Health Care Sys. v. Burwell, 195 L. Ed. 2d 260 (2016).
[90] *Zubik*, 136 S. Ct. at 1559.
[91] Burwell v. Hobby Lobby, 134 S.Ct. 2751 (2014).
[92] Id.
[93] *See, e.g.*, Advancing New Standards In Reproductive Health (ANSIRH), *Safety of abortion in the United States* (Dec. 2014), https://www.ansirh.org/sites/default/files/publications/files/safetybrief12-14.pdf.
[94] Guttmacher Institute, *Fact sheet: Induced Abortion in the United States* (Jan. 2018), https://www.guttmacher.org/fact-sheet/induced-abortion-united-states.
[95] National Academies of Sciences, Engineering and Medicine, *Press Release: The Quality of Abortion Care Depends on Where a Woman Lives, Says One of Most Comprehensive Reviews of Research on Safety and Quality of Abortion Care in the U.S.* (Mar. 16, 2018), http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=24950.
[96] Cynthia J. Berg et al., *Overview of Maternal Morbidity During Hospitalization for Labor and Delivery in the United States,* 113 OBSTETRICS & GYNECOLOGY 1075, 1077 (2009).
[97] Raymond & Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 OBSTETRICS & GYNECOLOGY 215, 216-217 & tbl. 1 (2012) (analyzing data from 1998 to 2005).

patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.

The proposed rule puts this important principle at risk by allowing health care entities to opt out of providing any information when the entity understands that an objected-to healthcare service, activity, or procedure is even a "possible outcome of the referral."[98] For example, the proposed rule could allow entities to refuse to provide information about any other entity that might refer for an abortion, or to withhold pertinent medical information about a woman's pregnancy if the provider fears that the woman may choose to seek out an abortion or sterilization provider. It could also allow providers to not inform patients that they are withholding medical information.

Further, the proposed definition could negatively impact states' efforts to increase transparency and informed consent in pregnancy counseling. The proposed rule specifically singles out California's FACT Act, which requires all centers that provide pregnancy counseling to post information about the availability of free or low-cost family planning and abortion services under California's public programs, but targets all states' efforts to regulate fake women's health centers. These fake clinics mislead and misinform women in an attempt to prevent them from accessing abortion care. It is well-documented that many of these so-called "crisis pregnancy centers" operate under false pretenses, luring pregnant women onto their premises with the promise of free medical care and then regaling them with misinformation about abortion care and their pregnancy status.[99] Nonetheless, the rule seeks to allow such fake medical clinics to opt out of providing critical information to patients and continue their practice of deceit.

By allowing providers, including hospital and healthcare institutions, to refuse to provide patients with information, the proposed rule seeks to deprive patients of full information regarding their treatment options. While HHS claims the rule will improve communication between patients and providers, in truth it will deter open, honest conversations that are vital to ensuring that a patient can control their medical circumstances.

The proposed rule also contravenes key and well-established principles of quality care: that care must be timely, in the best interest of the patient, and according to medical need.[100] With regards to abortion specifically, the World Health Organization has stated that:

> "Information, counselling and abortion procedures should be provided as promptly as possible without undue delay . . . The woman should be given as much time as she needs to make her decision, even if it means returning to the clinic later. However, the advantage of abortion at earlier gestational ages in terms of their greater safety over abortion at later ages should be explained. Once the decision is made by the woman, abortion should be provided as soon as is possible to do so."[101]

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[98] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3924 (Jan. 26, 2018).

[99] *See, e.g.* Brief For Planned Parenthood Federation of America and Physicians for Reproductive Health As Amici Curiae Supporting Respondents, No. 16-1140, NIFLA v. Becerra, No. 16-1140 (U.S. 2018).

[100] Institute of Medicine (now the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine). *Crossing the Quality Chasm: A New Health System for the 21st Century* (Mar. 2001) http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf.

[101] World Health Organization, *Safe Abortion: Technical and Policy Guidance for Health Systems* (2nd ed.) 36 (2012), http://apps.who.int/iris/bitstream/10665/70914/1/9789241548434_eng.pdf.

Moreover, the current proliferation of mergers between Catholic and secular hospitals is resulting in a dangerous spread of healthcare refusals, as the subsidiary secular hospitals agree to operate under the Directives. The number of Catholic owned or affiliated hospitals increased by 22 percent between 2001 and 2016—while the overall number of acute care hospitals decreased by six percent.[102] In 46 geographic regions, hospitals operating under the Directives are now the sole community healthcare providers of short-term acute hospital care; [103] nationwide, one in six acute care hospital beds is in a Catholic owned or affiliated hospital.[104] Under the proposed rule, some patients seeking life-saving treatment may be left with no place to turn for emergency care.

By permitting providers to refuse to provide or refer for care, and utterly failing to build any safeguards for patients seeking care, the proposed rule arbitrarily and capriciously undermines the best interests of the patient.

D. The proposed rule's potential increase in healthcare refusals would increase healthcare costs.

Healthcare refusals can result in significant costs for patients. When a patient is turned away at the doctor's office or a hospital without a referral, they must find a willing provider to access the healthcare they need. This means potentially significant time researching other available providers, and taking additional time off from work for a new appointment. In areas with a limited number of healthcare providers, a patient may need to drive long distances in order to access care, requiring additional expenses for overnight stays and childcare. The additional time and expense falls most heavily on low income individuals and those without the job flexibility to take paid sick time.

There may also be a significant increase in the healthcare costs themselves. For example, a woman who has a cesarean section and wishes to have a post-partum tubal ligation immediately following delivery cannot do so at a Catholic hospital, even though having the procedure at that time is medically recommended, presents fewer risks to the patient, and is more cost-effective than delaying the procedure to a later time. If the patient cannot have the procedure immediately following delivery, she must first recover from the cesarean surgery and then schedule the tubal ligation at least six weeks later when she is busy caring for her newborn. She will be required to go to another hospital and possibly a different doctor, and will have to transfer her medical records.[105]

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[102] Lois Uttley & Christine Khaikin, *Growth Of Catholic Hospitals And Health Systems: 2016 Update Of The Miscarriage Of Medicine Report*, MergerWatch (2016), http://static1.1.sqspcdn.com/static/f/816571/27061007/1465224862580/MW_Update-2016-MiscarrOfMedicine-report.pdf?token=sNLtMbWH41ZXGppQwJUb6n2ztV8%3D.

[103] Id.

[104] Id.

[105] National Women's Law Center, *When health care providers refuse: The impact on patients of providers' religious and moral objections to give medical care, information or referrals* (Apr. 2009), https://www.nwlc.org/wp-content/uploads/2015/08/April2009RefusalFactsheet.pdf. *See also*, Debra B. Stulberg et al., *Tubal Ligation in Catholic Hospitals: A Qualitative Study of Ob-Gyns' Experiences*, 90 CONTRACEPTION 422 (2014) ("Cesarean delivery in Catholic hospitals raised frustration for obstetrician-gynecologists when the hospital prohibited a simultaneous tubal ligation and, thus, sent the patient for an unnecessary subsequent surgery. [. . .] Some obstetrician-gynecologists reported that Catholic policy posed greater barriers for low-income patients and those with insurance restrictions.").

Because of the national shortage of abortion providers in the United States, a woman who is denied abortion care may also find it difficult to find an available provider in a reasonable timeframe. Eighty-nine percent of counties in the United States do not have a single abortion clinic, and some counties that have a clinic may only provide abortion services on certain days.[106] Several states have only one clinic that provides abortion care.[107] Because of the provider shortage, many women must travel long distances to access care.[108] In addition, in some areas, the shortage results in significantly increased wait times[109] and, in some cases, patients may be turned away altogether.[110]

When women face delays in obtaining an abortion, the logistical and financial burdens they face multiply. On average, a woman must wait at least a week between when she attempts to make an appointment and when she receives an abortion.[111] Delays also have the effect of increasing the cost of an abortion. Abortion in the first trimester is substantially less expensive than in the second trimester: the median price of a surgical abortion at ten weeks is $508, while the cost rises to $1,195 at week 20.[112] The rising cost of abortion as gestational age increases poses a profound challenge to the affordability of the procedure for lower-income women. As one Utah woman explained: "I knew the longer it took, the more money it would cost . . . We are living paycheck to paycheck as it is, and if I [had] gone one week sooner, it would have been $100 less."[113] Moreover, delays raise the cost of each step of obtaining an abortion—not just the cost of the procedure. For example, one recent study found that Utah's mandatory waiting period caused 47 percent of women having an abortion to miss an extra day of work.[114] More than 60 percent were negatively affected in other ways, including increased transportation costs, lost wages by a family member or friend, or being required to disclose the abortion to someone whom they otherwise would not have told.[115] And because many clinics do not offer second-trimester abortions, a woman who has been delayed into the second trimester will typically be required to travel farther to obtain an abortion, thereby incurring additional travel and related costs, such as lost wages.[116] As a result, healthcare denials that result in a delay in care can significantly drive up the cost of care for a woman seeking abortion care.

In addition, healthcare refusals without adequate safeguards may also have negative consequences on the long-term socioeconomic status of women. A recent study in the American

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[106] National Partnership for Women & Families, *Bad Medicine: How a Political Agenda is Undermining Abortion Care and Access* 13 (Mar. 2018), http://www.nationalpartnership.org/research-library/repro/bad-medicine-third-edition.pdf.
[107] Id.
[108] Id.
[109] *See generally, e.g.*, Texas Policy Evaluation Project, *Research Brief: Abortion Wait Times in Texas: The Shrinking Capacity of Facilities and the Potential Impact of Closing Non-ASC Clinics* (Oct. 2015), http://sites.utexas.edu/txpep/files/2016/01/Abortion_Wait_Time_Brief.pdf.
[110] *See, e.g.*, Brief for National Abortion Federation and Abortion Providers as Amici Curiae in Support of Petitioners at 20, Whole Woman's Health v. Cole, 136 S. Ct. 499 (2015) (No. 15-274), *sub nom.* Whole Woman's Health v. Hellerstedt, 136 S. Ct. 2292 (2016).
[111] The median is seven days, while the average is 10 days. Moreover, poorer women wait two to three days longer than the typical woman. See Lawrence B. Finer et al., *Timing of Steps and Reasons for Delays in Obtaining Abortions in the United States*, 74 CONTRACEPTION 334, 338-43 (2006).
[112] Rachel K. Jones et al., *Differences in Abortion Service Delivery in Hostile, Middle-Ground and Supportive States in 2014,* WOMEN'S HEALTH ISSUES (2018), http://www.whijournal.com/article/S1049-3867(17)30536-4/abstract.
[113] Sarah C.M. Roberts et al., *Utah's 72-Hour Waiting Period for Abortion: Experiences Among a Clinic-Based Sample of Women*, 48 PERSPECTIVES ON SEXUAL & REPRODUCTIVE HEALTH 179, 184 (2016).
[114] Jessica N. Sanders et al., *The Longest Wait: Examining the Impact of Utah's 72-Hour Waiting Period for Abortion*, 26 WOMEN'S HEALTH ISSUES 483, 485 (2016).
[115] Id.; *Accord* Deborah Karasek et al., *Abortion Patients' Experience and Perceptions of Waiting Periods: Survey Evidence Before Arizona's Two-Visit 24-hour Mandatory Waiting Period Law*, 26 WOMEN'S HEALTH ISSUES 60 (2016).
[116] Rachel K. Jones & Jenna Jerman, *How Far Did US Women Travel for Abortion Services in 2008*?,22 J. WOMEN'S HEALTH 706 (2013).

Journal of Public Health found that six months after denial of abortion, women were less likely to be employed full time and were more likely to receive public assistance than were women who obtained abortions, differences that remained significant for 4 years.[117] The study also found that women who were denied a wanted abortion were almost four times more likely to be below the federal poverty level compared to those who received an abortion.[118] Women who were denied a wanted abortion were also less likely to achieve aspirational plans for the coming year,[119] and more likely to remain in relationships with partners who subject them to physical violence.[120] Healthcare refusals that lead to delays or effective denials of care, particularly reproductive health care, therefore not only affect women's immediate health costs but also have fundamental negative economic and social consequences over many years—factors that HHS completely fails to acknowledge or take into account in this proposed rule.

The proposed rule's potential impact on women's healthcare, related healthcare costs, and economic security is substantial. Nonetheless, the NPRM entirely disregards these costs, particularly in the cost-benefit analysis portion of the rule. HHS's priorities are clear: to expand the healthcare refusals, no matter the consequence. The NPRM's failure to properly consider the very real and severe costs to women that could result from this regulatory proposal constitutes arbitrary and capricious rulemaking, and therefore the proposed rule should be withdrawn in its entirety.

E. The proposed rule would have negative health impacts on vulnerable populations worldwide.

The proposed rule seeks to expand the definition of healthcare entities in a way that potentially covers global health providers, encouraging individuals working under global health programs funded by HHS to refuse critical care in international settings. By including organizations that receive foreign aid funds through global health programs, the proposed rule extends the harm of refusals to vulnerable populations abroad. For example, in many of the countries where HHS implements global AIDS relief programs ("PEPFAR"), the populations served already face numerous barriers to care, including the broad and harmful refusal provision contained within the statute governing PEPFAR.[121]

The proposed rule opens up an additional front for discrimination against these populations by encouraging individual healthcare providers to deny the information and services they need. Such action undermines the purpose of global health programs and the rights of those they intend to serve. This is particularly harmful in developing countries where many health systems are weak, there are shortages of healthcare providers and supplies, and individuals often travel long

[117] Diana Greene Foster et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 108 AM. J. PUB. H. 407 (2018), http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2017.304247.
[118] Id.
[119] Ushma D. Upadhyay et al., *The Effect of Abortion on Having and Achieving Aspirational One-Year Plans*, 15 BMC WOMEN'S HEALTH, no.102, 1 (2015).
[120] Sarah C.M. Roberts et al., *Risk of Violence from the Man Involved in the Pregnancy after Receiving or Being Denied an Abortion*, 12 BMC MEDICINE no. 144, 1 (2014).
[121] 22 U.S.C. 7631(d) ("(d) Eligibility for assistance: An organization, including a faith-based organization, that is otherwise eligible to receive assistance . . . (1) shall not be required, as a condition of receiving such assistance—(A) to endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or (B) to endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection").

distances to obtain the services they need. Many of the individuals that encounter refusals will have nowhere else to go.

F. Provisions in the proposed rule go against HHS' own mission statement/purpose.

By its own statement, HHS' mission is to "enhance and protect the health and well-being of all Americans [. . .] providing for effective health and human services."[122] But the proposed rule does not make even a feeble attempt at addressing how the rule would preserve, much less enhance, the health of patients who are treated by providers who avail themselves of federal refusal laws.

It is well-documented that discrimination already limits access to services for more vulnerable populations, and some religious entities have demonstrated a willingness to flout laws that seek to protect access to care. In the past, HHS' OCR has investigated numerous complaints from transgender patients about being denied certain health services, ranging from routine to life-saving care, due to the patient's gender identity.[123] In one such case, a transgender patient was denied a genetic screening for breast cancer because the insurer said the test was only for women, even though the screening was recommended by a doctor.[124] Similarly, as articulated earlier in this comment, many women seeking emergency care for their pregnancies have had their care severely delayed, or outright denied, at Catholic hospitals.[125] HHS should focus on enforcing EMTALA and other healthcare laws that make sure that patients get the care they need, not encourage entities to refuse to provide care. HHS's failure to ensure that above all, patients receive the care they require indicates that the proposed rule is driven by ideology, instead of HHS' mission to enhance the health of all Americans.

Finally, the proposed rule's preamble fails to clarify protections for individuals and entities whose religious and moral values compel them to provide care—even though the Church amendment's statutory text explicitly protects providers and entities that choose to provide abortion and sterilization services. The imbalance exposes the administration's clear bias against abortion providers and foreshadows an OCR that will enforce federal refusal of care laws with an entirely one-sided focus that seeks to undermine access to care.

V. The Proposed Rule Is Unconstitutional

In additional to the constitutional issues previously raised in this comment, including the proposed rule's violation of due process rights and the substantial questions about constitutionality under the Spending Clause, the proposed rule is likely impermissible because it creates exemptions that run afoul of the Establishment Clause.

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[122] U.S. Department of Health and Human Services, *About HHS*, last visited Mar. 26, 2018, https://www.hhs.gov/about/index.html.
[123] Dan Diamond, *Transgender patients' complaints to HHS show evidence of routine discrimination*, POLITICO, Mar. 7, 2018, https://www.politicopro.com/health-care/article/2018/03/transgender-patients-complaints-to-hhs-show-evidence-of-routine-discrimination-390755.
[124] Id.
[125] *See, e.g.*, Julia Kaye et al., *Health Care Denied: Patients and physicians speak out about Catholic hospitals and the threat to women's health and lives*, May 2016, https://www.aclu.org/report/report-health-care-denied?redirect=report/health-care-denied.

Federal law, and all regulations promulgated under federal law, must comply with the Constitution, including the Establishment Clause, which prohibits the government from creating religious exemptions to neutral, generally applicable rules in a manner that imposes burdens on third parties. [126] Yet that is precisely what the NPRM proposes: HHS seeks to allow providers not only to opt out of providing care, but also to refuse to refer patients to a non-objecting physician and to even withhold information that could lead a patient to choose healthcare to which the provider objects. As a result, this rule would effectively constitute imposing a provider's religious belief on a patient in a manner that burdens the patient, acting as a veto on the patient's access to the care they request and need.

As discussed previously, denials and delays in healthcare, especially reproductive care, result in serious medical and even socioeconomic costs—burdens on third parties that this proposed rule completely fails to mitigate or even account for. But in this case, HHS has chosen to unconstitutionally prioritize certain religious ideologies that would impose harms on women over the government's interest in eliminating discrimination, advancing women's equality, and promoting access to healthcare. By granting a greater universe of objecting institutions and individuals the power to deny healthcare without ensuring that the patients will receive care, and thereby imposing harms on these third parties, the proposed rule violates the Establishment Clause of the U.S. Constitution and therefore should be withdrawn.

VI. Conclusion

In conclusion, we strongly oppose this proposed rule. For all the reasons stated above, we urge HHS to withdraw this regulation in its entirety. Thank you for the opportunity to comment.
Sincerely,

The Center for Reproductive Rights

[126] U.S. CONST. amend. I.

Exhibit 53

RESOLUTION 2018-30233

A RESOLUTION OF THE MAYOR AND CITY COMMISSION OF THE CITY OF MIAMI BEACH FLORIDA, OPPOSING A RULE PROPOSED BY THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ENTITLED "PROTECTING STATUTORY CONSCIENCE RIGHTS IN HEALTH CARE; DELEGATIONS OF AUTHORITY" WHICH, AMONG OTHER THINGS, WOULD BROADLY EXPAND OPPORTUNITIES FOR HEALTH CARE WORKERS TO REFUSE TO PARTICIPATE IN CERTAIN MEDICAL PROCEDURES ON THE BASIS OF A MORAL OR RELIGIOUS OBJECTION; AND DIRECTING THE CITY ATTORNEY TO TRANSMIT THIS RESOLUTION AND THE COMMENTS SET FORTH HEREIN TO THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES.

WHEREAS, the City of Miami Beach ("City") Human Rights Ordinance, codified in Chapter 62 of the City Code, declares that "there is no greater danger to the health, morals safety and welfare of the city and its inhabitants than the existence of prejudice against one another and antagonistic to each other because of actual or perceived differences of race, color, national origin, religion, sex, intersexuality, gender identity, sexual orientation, marital and familial status, age, disability, ancestry, height, weight, domestic partner status, labor organization membership, familial situation, or political affiliation"; and

WHEREAS, the Human Rights Ordinance also declares that "prejudice, intolerance, bigotry and discrimination and disorder occasioned thereby threaten the rights and proper privileges of its inhabitants and menace the very institutions, foundations and bedrock of a free, democratic society"; and

WHEREAS, in view of this policy, the City's Human Rights Ordinance prohibits discrimination in employment, public accommodations, housing, and public services, on the basis of the classification categories identified above; and

WHEREAS, the City is a longstanding municipal leader in ensuring the civil rights of its diverse and cosmopolitan population; and

WHEREAS, on January 28, 2018, the Office of Civil Rights ("OCR"), Office of Secretary of Health and Human Services ("HHS") published a notice of proposed rule, entitled "Protecting Statutory Conscience Rights in Health Care; Delegation of Authority" ("Proposed Rule"); and

WHEREAS, the Proposed Rule creates a new "Conscience and Religious Freedom Division" in the HHS OCR; and

WHEREAS, the stated purpose of the Proposed Rule is to "protect the rights of persons, entities, and health care entities to refuse to perform . . . health care services or research activities to which they may object for religious, moral, ethical, or other reasons"; and

WHEREAS, the Proposed Rule authorizes HHS and, specifically, the OCR to protect workers and penalize organizations that do not allow workers to express their religious and moral objections; and

WHEREAS, the Proposed Rule will also allow providers and facilities to opt out of providing counselling services, referring services in Medicaid and Medicare Advantage programs, advance directives, Global Health Programs, and compulsory health programs, such as immunization, hearing screening, occupational illness testing, and mental illness testing; and

WHEREAS, the Proposed Rule is estimated to impact somewhere between 364,640 to 571,412 entities, including public and private hospitals, specialty hospitals (substance abuse, maternity, cancer), youth services, shelters, nursing and hospice facilities, offices of mental health practitioners, and family planning centers; and

WHEREAS, the Proposed Rule may have far-reaching consequences and be used to justify discrimination against the City's constituents, including women, members of the LGBTQ+ community, and persons living with HIV; as well as individuals seeking birth control prescriptions, emergency contraception, lifesaving abortion, in-vitro fertilization (including for unmarried patients, same-sex couples, and interracial couples), hormone therapy for transgender or intersex patients, gender confirmation surgery, human papillomavirus ("HPV") vaccines, counseling, mental health care or a reference for mental health services; and

WHEREAS, the City Commission of the City of Miami Beach respects the right of individuals to freely practice their religion but opposes any measure that permits the use of religion to perpetuate prejudice and authorize discrimination against others.

NOW, THEREFORE, BE IT DULY RESOLVED BY THE MAYOR AND CITY COMMISSION OF THE CITY OF MIAMI BEACH, FLORIDA, that the Mayor and the City Commission hereby oppose the rule proposed by the U.S. Department of Health and Human Services, entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" which, among other things, would broadly expand opportunities for health care workers to refuse to participate in certain medical procedures on the basis of a moral or religious objection; and direct the City Attorney to transmit this Resolution and the comments set forth herein to the U.S. Department of Health and Human Services.

PASSED and **ADOPTED** this 7 day of March, 2018.

ATTEST:

3/16/18

Rafael Granado
City Clerk

Dan Gelber
Mayor

(Sponsored by Commissioner Michael Gongora)

MIAMI BEACH INCORPORATED MARCH 26TH 1915

APPROVED AS TO
FORM & LANGUAGE
& FOR EXECUTION

City Attorney 3-5-18 Date

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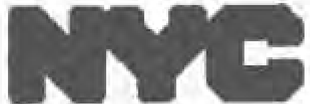
Exhibit 54



March 27, 2018

Via electronic submission

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (Docket No.: HHS-OCR-2018-0002)

To Whom It May Concern:

The New York City Commission on Human Rights, the New York City Department of Health and Mental Hygiene, the New York City Department of Social Services, and NYC Health + Hospitals write to express our opposition to the United States Department of Health and Human Services' (HHS) proposed regulations entitled, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority.

HHS' proposed rule will cause serious harm to the health and well-being of New Yorkers. It will erect barriers to the delivery and receipt of timely, high quality health care. It will foster a new standard of selective and discriminatory treatment for many of our most vulnerable populations. It will also multiply the administrative burdens that health care organizations shoulder to address time-sensitive health conditions. Finally, it will infringe on the ability of state and local governments to enforce their laws and policies. In the face of these significant harms, we urge HHS to rescind this rule.

The Proposed Rule Will Harm Patients

The proposed rule elevates healthcare providers' personal beliefs over patient health. It gives providers wide latitude in opting out of treating patients. Undoubtedly, providers will deny care to patients who need it. At a minimum, a denial will mean that patients who are turned away will experience delays and increased expenses in receiving care. But in many cases, delay will effectively mean denial, particularly where time is of the essence or locating a suitable alternate provider is not feasible. The denial of care will be the end of the road in many patients' search for treatment.

Indeed, finding an alternate provider is no simple task. Health plans have limited provider networks, caps on the number of specialty visits, and steep cost-sharing obligations. Workers have limited or no sick leave, and forcing them to visit a second provider to accommodate the first provider's beliefs means that many patients will have to decide between taking care of their health and making a living. That is no choice at all, and many patients will forego care that they otherwise would have received.

Similarly, many people live in areas with a limited number of primary care doctors, specialists, and specialty care facilities. They may be forced to travel great distances to find a provider willing to treat them. Patients who are elderly, patients with disabilities, and patients under the age of majority may be completely unable to access an alternate healthcare provider if refused

care. During an emergency such as a national disaster, there may be only one accessible provider.

The denials of care that will result if the proposed rule is adopted will have severe and often irreversible consequences: unintended pregnancies, disease transmission, medical complications and anguish in the last days of life, and death. For example:

- Post-exposure prophylaxis for HIV should be initiated within 36 hours, but not beyond 72 hours after potential exposure.
- Emergency contraception is most effective at preventing pregnancy if taken as soon as possible after sexual intercourse.
- Contraceptives and pre-exposure prophylaxis for HIV are effective only if accessed prior to a sexual encounter.
- There is a window for a safe, legal abortion, and a narrower window for medication abortion. In the case of ectopic pregnancy or other life-threatening complication, an abortion may need to be performed immediately.
- Opiate users denied methadone or buprenorphine remain at increased risk of overdose, and naloxone must be administered quickly to reverse drug overdose.
- Persons with suicidal ideation need immediate care to prevent self-harm.
- Refusing to honor a person's end-of-life wishes prolongs suffering.

In short, the proposed rule will cause long-lasting and irreparable harm to patients.

The breadth of the proposed rule is extraordinary, all but guaranteeing that patients will be denied essential health care. Extending protections to health plans, plan sponsors, and third-party administrators that receive federal funds may prompt health plans to cease coverage for abortion, contraceptives, health care related to gender transition, and other services. Allowing anyone "with an articulable connection to a procedure, health service, health program or research activity" to raise an alleged conscience objection, means that the myriad of participants in a healthcare encounter—from intake and billing staff to pharmacists, translators, radiology technicians, and phlebotomists—can refuse to participate in service delivery. This will cause untold disruptions and delays for patients. And the expansive definitions of "assist in the performance" and "referral" mean that healthcare providers – after refusing to care for a patient – will not even need to provide a referral or other necessary information for a patient to seek care elsewhere.

The negative health impact of denied care is profound. In the case of infectious disease, there is societal impact: delays in diagnosis, prophylaxis and treatment increase the likelihood of individual disease progression and transmission to others. The consequences of untreated substance use disorders are likewise far-reaching. Compounding matters, the harmful effects of the proposed rules will be felt most acutely by individuals and communities that already face great challenges accessing the care that they need: people of color, low-income persons, women, children, people with substance use disorders, and lesbian, gay, bisexual, transgender, queer, intersex and gender nonconforming ("LGBTQI") persons.

The Proposed Rule Will Lead to Discrimination Against Already Vulnerable Populations

The rule gives healthcare providers a free pass to discriminate based on a patient's identity and against any patient whose actions or decisions conflict with the provider's alleged conscience objection.

Discrimination by health care providers marginalizes and stigmatizes patients, driving them away from care systems. It has long-term destructive consequences for the health and well-being of patients and communities that already bear the brunt of discrimination. Women and LGBTQI people will find themselves denied care at alarming rates. Providers may refuse to prescribe contraceptives to women who are not married, fertility treatment to same-sex couples, pre-exposure prophylaxis to gay men, or counseling to LGBTQI survivors of hate or intimate partner violence. Transgender patients are likely to be refused medically necessary care like hormone therapy, and substance users may be denied medications to treat addiction or reverse drug overdose.

The impact of such discrimination extends far beyond the individual patient encounter. For example, LGBTQI youth that are denied services and psychosocial support show a lasting distrust of systems of care.[i] Concerns regarding stigma may also make patients reluctant to reach out to loved ones for support, as has been shown with women who have had abortions.[ii]

This never-before-seen license to pick and choose the type of patient and nature of care that a clinician or organization will provide runs counter to principles of comprehensiveness and inclusion that have long guided the federal government's oversight of key health care programs and the operation of the country's health care delivery system.

The Proposed Rule Creates New Administrative Burdens for a Strained Health Care System

The extraordinary breadth of the proposed rule will result in significant and costly administrative burdens on an already-strained healthcare system. The proposed rule places healthcare entities in the precarious position of having to accommodate various ethical beliefs held by thousands of staff, regardless of how tenuous those staffs' connection to the clinical encounter. Also, by prohibiting employers from withholding or restricting any title, position or status from staff that refuse to participate in care, healthcare entities are limited in being able to move staff into positions where they will not disrupt care and harm patients. Thus, doctors in private practice will be prohibited from firing any staff who refuses to assist, and thereby stigmatizes and harms, LGBTQI patients. Emergency departments, ambulance corps, mental health hotlines, and other urgent care settings may need to increase the number of shift staff to ensure sufficient coverage in case of a refusal to work with a patient. This will have a very real financial impact on healthcare facilities, including government-run and subsidized clinics and hospital systems. This is a costly proposition that flies in the face of the federal government's stated goal of reducing administrative burdens within the health care system.

The Proposed Rule Infringes on State and Local Governments' Ability to Enforce Their Laws and Policies and Conflicts with Patient Protections

The proposed rule may impact the ability of State and local governments to enforce the full scope of their health- and insurance-related laws and policies by conditioning the receipt of federal funding on compliance with the rule. Similarly, it may leave providers caught between conflicting mandates. The New York City Human Rights Law ("City Human Rights Law"), for example, like many state and local nondiscrimination laws, protects patients from discrimination based on sexual orientation, gender (including gender identity), marital status, and disability.

Protecting vulnerable populations from discrimination and misinformation is of paramount importance to New York City. The City Human Rights Law is one of the most comprehensive civil rights laws in the nation, prohibiting discrimination in health care settings based on, among other things, a patient's race, age, citizenship status, and religion. A provider's refusal to serve a patient pursuant to the proposed rule may be a violation of state and local laws, some of which are enforced through the imposition of injunctive relief and substantial financial penalties. Violations of the City Human Rights Law, for example, can lead to the imposition of penalties of up to $250,000 per violation.

We oppose regulations that allow personal beliefs to trump science at the expense of vulnerable populations' access to health care. We oppose systems that compromise our duty to protect and improve the health of City residents. We oppose actions that sanction discrimination against patients based on who they are or what health conditions they have.

We urge HHS to rescind the proposed rule.

Sincerely,

Steven Banks
Commissioner
New York City Department of
Social Services

Mary T. Bassett, MD, MPH
Commissioner
New York City Department of
Health and Mental Hygiene

Mitchell Katz, MD
President and Chief Executive Officer
New York City Health and Hospitals

Carmelyn P. Malalis
Chair and Commissioner
New York City Commission on
Human Rights

[1] Substance Abuse and Mental Health Services Administration. Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth. HHS Publication No. (SMA) 15-4928. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015.

Exhibit 56

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:

The Colorado Consumer Health Initiative (CCHI) is writing in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26, 2018. CCHI is a state-based nonprofit, nonpartisan membership organization dedicated to ensuring access to quality, affordable, and equitable health care for all Coloradans. Through our forty-five member organizations, CCHI represents about 500,000 Coloradans.

This proposed regulation would exacerbate the challenges that many patients—especially women, LGBTQ people, people of color, immigrants and low-income people—already face in getting the timely and affordable health care they need. This rule would expose vulnerable patients to increased discrimination and denials of medically-indicated care by broadening religious health care provider exemptions. Moreover, while protecting health providers who deny care, the rule would provide *no protections for patients who are being denied care—even in emergencies.* As drafted, the rule would not even require that patients be informed of all their potential treatment options and referred to alternative providers of needed care.

This proposal is in direct opposition of the pursuit of "patient-centered care." We urge the administration to put patients first, and withdraw the proposed regulation because of the serious problems enumerated below.

1. **Expanding religious refusals can exacerbate the barriers to care that LGBTQ Coloradans already face and potentially allow denial of any health care service based on a provider's personal beliefs or religious doctrines.**

LGBTQ people, along with other vulnerable groups around the country, already face enormous barriers to getting the care they need.[1] Accessing quality, culturally competent care, and overcoming outright discrimination is an even greater challenge for those living in areas with already limited access to health providers. The proposed regulation threatens to make access to care even harder, and for some people nearly impossible.

For example, a nationwide 2015 survey of nearly 28,000 transgender adults found that respondents needed to travel much further to seek care for gender dysphoria, than for other services.[2] 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.[3] 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.

Existing refusal of care laws (such as for abortion and sterilization services) are already being used across the country to deny patients the care they need[4]. The

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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), http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx; Sandy E. James et al., The Report of the U.S. Transgender Survey 93–126 (2016), www.ustranssurvey.org/report; 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, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

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

[3] 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-accessing-health-care.

[4] *See, e.g., Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/;

proposed rule attempts to expand on these laws. Specifically, the Department and its Office for Civil Rights (OCR) are attempting to require a broad swath of entities to allow individuals to refuse "any lawful health service or activity based on religious beliefs or moral convictions."[5]

This expansive interpretation could lead to provider denials based on personal beliefs that are biased and discriminatory, such as objections to providing care to people who are transgender or in same-sex relationships. In Colorado, 21% of surveyed LGBT Coloradans reported health care workers refused services, and 28% reported their sexual orientation prevented them from receiving needed care. [6]

We are concerned about further enabling care denials by providers based on their non-scientific personal beliefs about other types of health services.

2. **The proposed rule conflicts state and local government efforts to protect patients' health and safety, including their nondiscrimination laws.**

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, including Colorado's own anti-discrimination laws[7]. Moreover, the proposed rule invites states to further expand refusals of care by making clear that this expansive rule is a floor, and not a ceiling, for religious exemption laws.[8]

3. **The regulation lacks safeguards to protect patients from harmful refusals of care, especially in emergency situations.**

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

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Uttley, L., et al, *Miscarriage of Medicine*, MergerWatch and the ACLU (2013), https://www.aclu.org/report/miscarriage-medicine.

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

[6] http://www.one-colorado.org/wp-content/uploads/2012/01/OneColorado_HealthSurveyResults.pdf

[7] http://www.ncsl.org/research/civil-and-criminal-justice/state-public-accommodation-laws.aspx

[8] *See, e.g.*, Rule, *Supra* note 1, at 3888-89.

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.

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. Because the proposed rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

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

The rule sets forth extensive requirements for health care institutions, such as hospitals, to notify employees about their refusal rights, including how to file a discrimination complaint with OCR. The rule requires posting of such notices on the employer's website and in prescribed physical locations within the employer's building. The rule also sets forth the expectation that OCR would investigate or do compliance reviews of whether health care institutions are following the posting rule.[9]

By contrast, the rule contains no requirement that patients be notified of institutional restrictions on provision of certain types of care. Such notification is essential because research has found that patients are often unaware of service restrictions at religiously-sponsored health care institutions. [10]

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[9] The notice requirement is spelled out in section 88.5 of the proposed rule.
[10] *See*, for example, Freedman, Lori R., Luciana E. Hebert, Molly F. Battistelli, and Debra B. Stulberg, *Religious hospital policies on reproductive care: what do patients want to know?* American Journal of Obstetrics & Gynecology 218, no. 2 (2018): 251-e1, accessed here: http://www.ajog.org/article/S0002-9378(17)32444-4/fulltext; also Guiahi, Maryam, Jeanelle Sheeder, and Stephanie Teal, *Are women aware of religious restrictions on reproductive health at Catholic hospitals? A survey of women's expectations and preferences for family planning care*, Contraception and Stulberg, D., et all, accessed here: http://www.contraceptionjournal.org/article/S0010-7824(14)00358-8/fulltext; *Do women know when their hospital is Catholic and how this affects their care? Restrictions in Catholic Hospitals (PARRCH) national*

Conclusion

The proposed rule goes far beyond established law and most importantly will put the health and potentially even the lives of patients at risk. We urge you to withdraw the proposed rule. The proposed rule will allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care. The proposed rule is discriminatory, violates multiple federal statutes and the Constitution, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons the Colorado Consumer Health Initiative calls on the Department to withdraw the proposed rule in its entirety.

Sincerely,

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survey, Contraception, Volume 96, Issue 4, 268-269,accessed here: http://www.contraceptionjournal.org/article/S0010-7824(17)30235-4/fulltext; a

Exhibit 57

March 27, 2018

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience PROPOSED RULE, 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

The Commonwealth of Pennsylvania Departments of Aging, Health, Human Services, Drug and Alcohol Programs, and Insurance have prepared the following in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26, 2018. These agencies have deep concerns that this proposed rule ignores the needs of the patients and individuals served by HHS' programs and creates confusion about the rights and responsibilities of health care providers and entities. Additionally, there is uneasiness in that this proposed rule overstates statutory authority and seeks to dramatically expand the reach of the underlying statutes with potentially disastrous consequences. Not only does this proposed rule put at risk positive health care outcomes and access to health care for tens of thousands of people, it treads on states' efforts to protect patients and constituents and puts millions of federal funds in jeopardy. Thus, the agencies stated above urge the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) to withdraw the proposed rule.

Exacerbating Barriers to Quality Health Care for Vulnerable

Dr. Rachel Levine, Secretary for the Pennsylvania Department of Health, met with Roger Severino, the Director for the HHS Office of Civil Rights, on November 14, 2017 to particularly discuss LGBTQ health issues. Despite this, the proposed rule does not consider the health issues raised during that meeting. Pennsylvania agencies are concerned that this rule will hinder their efforts to address negative and disparate patient health care outcomes and access to health care especially for LGBTQ people, women, and other vulnerable groups that already face enormous barriers to getting competent and affirming care.

For those living in areas with already limited access to health providers, finding quality, culturally competent care is already a challenge. If then they are turned away or refused treatment, it will be harder if not impossible for them to find a viable alternative. For example, in a recent study published by the Center for American Progress, 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 from settings where they currently receive care. 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. 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.

These populations already experience significant discrimination from health care providers, and in many cases these vulnerable populations have little recourse or resources to seek justice. However, through the Conscience and Religious Freedom Division, health care providers would be able deny patients care and remain protected under the guise of religious liberty according to HHS.

The following are examples of scenarios that have and will occur:

- Doctors refusing to see transgender patients, even for general medical concerns
- Health professionals refusing care to someone living with HIV/AIDS, or refusing prescriptions for pre-exposure prophylaxis
- Pediatricians refusing to treat the children of same-gender couples
- Emergency Department/Emergency Medical Services workers refusing to transport or provide emergency care to minority patients
- Medical professionals refusing to acknowledge homophobic rape (i.e., rape perpetrated due to perceived sexual or gender identity)
- Medical professionals denying care to individuals who have had abortions at any point for any reason, or denying pre- or post- care for terminated pregnancies
- Behavioral health professionals refusing to provide information or counseling

This proposed rule attempts to expand religious exemptions while ignoring the prevalence of discrimination and damage it causes especially in vulnerable communities. If finalized, the rule would significantly expand the ability of heath care providers to withhold treatment or services based on religious or moral ground. And, thus will put thousands of people at risk of facing negative health consequences simply from the increased barriers or steps to acquiring care.

Broad Expansion That Lacks Safeguards

Though religious exemptions can have value, OCR fails to balance the need for exemptions with limitations or safeguards relating to the needs of patients and their own rights. Thus, the rule conflicts with the Establishment Clause of the First Amendment which 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. Furthermore, the proposed rule is in conflict with many existing patient protections in federal laws like the Affordable Care Act, Emergency Medical Treatment and Active Labor Act, and it conflicts with established standards such as Title VII.

These inconsistencies create confusion and will allow for unprecedented discrimination and refusal of services, which undermines the intent and integrity of health and human services programs, and even runs contrary to HHS' own mission. HHS' belief that it is appropriate to apply the general principles of nondiscrimination on the basis of religious belief or moral conviction is nonsensical. It is unclear how doctors and nurses can adhere to their professional standards and ethics codes while also claiming religious belief or moral conviction as a basis to not provide health care services. A shift in this direction by HHS will increase religious-based mistreatment. It will invite health and human services professionals to ignore existing law and medical standards, and it will go against person-centered approaches and

evidence-based practices that have been at the core of social service and public health delivery for decades.

Ignores States' Efforts to Protect Patients

Pennsylvania agencies are concerned that this proposed rule is an attempt to supersede laws and policies passed by state and local governments to ensure patients' access to health care and human services. Pennsylvania Governor Tom Wolf and his administration are committed to doing right by all Pennsylvanians and providing people the protections and respect they deserve. Since Pennsylvania is one of the states that lacks a comprehensive and consistent framework of legal protections in areas like non-discrimination, the commonwealth is particularly susceptible to shifts of this kind at the federal level. This is why the Governor and his administration have been champions for equal protections. Such efforts include expanding prohibitions in non-discrimination language in employment and contracting, promoting access to affirming and affordable health care through, for example, Medicaid expansion, and calling on the General Assembly to pass comprehensive non-discrimination laws and resource reproductive health programs.

This proposed rule grants OCR broad investigative authority and the ability to expand reporting requirements and allows for harsh penalties. For these reasons, Pennsylvania Health and Human Services Departments have significant concerns with how OCR will use such powers and information gathered by the office. There are concerns that this could lead to prejudice in consideration of future applications for federal funds or penalize a currently funded entity in ways that would be extremely harmful or costly. Additionally, the oversight provisions are vague, which undermines the federal government's own ability to properly enforce its own laws and regulations.

In summary, the Pennsylvania Departments of Aging, Health, Human Services, Drug and Alcohol Programs, and Insurance vehemently oppose the proposed rule entitled "Protecting Statutory Conscience Rights in Health Care" published January 26, 2018 and strongly urge HHS to withdraw the rule. The proposed rule will increase barriers for tens of thousands of people seeking health care of all types and lead to a multitude of adverse health outcomes. The proposed rule is vague and in conflict with numerous federal laws and statutes, which will lead to great confusion among health and human services practitioners and difficulty in enforcing regulations for OCR. Lastly, the proposed rule greatly impedes states' efforts and responsibility to protect their constituents and threatens the distribution and receipt of millions of dollars in federal funds.

Sources:

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

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

Sandy E. James et al., The Report of the U.S. Transgender Survey 93–126 (2016), www.ustranssurvey.org/report;

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, Discrimination Prevents LGBTQ People from Accessing Health Care (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care

Exhibit 63

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March 22, 2018

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.

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

To: The Honorable Alex Azar, Secretary of Health and Human Services
Re: Comment on Docket HHS-OCR-2018-0002 (RIN 0945-ZA03)
March 22, 2018
Page 2 of 8

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).