Exhibit 86

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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 Thus, I urge that the Rule be withdrawn.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

[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,

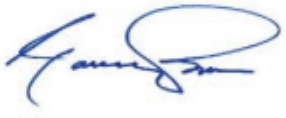

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Exhibit 87

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

March 27, 2018

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

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

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

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

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

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

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

I. Background

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

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

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

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

[2] 83 Fed. Reg. at 3881-86.

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

convictions, or because of their religious beliefs or moral convictions regarding sterilization or abortion;

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

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

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

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

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

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

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

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

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

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

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

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

[5] 42 U.S.C. § 18113(a).

[6] 83 Fed. Reg. at 3923.

(A) The Proposed Rule's Definition of "Assist in the Performance" Is Excessively Broad.

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

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

[7] 83 Fed. Reg. at 3923.

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

[9] 42 U.S.C. §§ 300a-7(b)-(d).

[10] 42 U.S.C. § 300a-7(e).

[11] 42 U.S.C. § 238n(a)(1); *see also* 42 U.S.C. § 238n.

[12] Consolidated Appropriations Act of 2017, Pub. L. 115-31, 131 Stat. 135, 562.

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

(B) The Proposed Rule's Definition of "Health Care Entity" Is Excessively Broad.

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

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

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

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

[14] 83 Fed. Reg. at 3923.

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

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

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

(C) The Proposed Rule's Definition of "Referral or Refer For" Is Excessively Broad.

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

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

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

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

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

[18] 83 Fed. Reg. at 3924.

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

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

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

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

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

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

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[19] 42 U.S.C. § 1395dd.

[20] 42 U.S.C. § 1395dd(e)(1)(A).

[21] 151 Cong. Rec. H176-77 (Jan. 25, 2005) (statement of Rep. Weldon) (emphases added).

[22] 42 U.S.C. § 18023(d).

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

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

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

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

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

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

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

[23] 42 U.S.C. § 18114.

[24] *Id.*

[25] *See infra* Section V.

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

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

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

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

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

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

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

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

[28] Table 1—Accounting Table of Benefits and Costs of All Proposed Changes, 83 Fed. Reg. at 3902.

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

[30] 42 U.S.C. § 2000e-2(a).

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

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

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

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

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[31] 29 C.F.R. § 1605.1.

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

[33] 42 U.S.C. § 18023(c)(3).

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

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

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

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

(C) The Proposed Rule Violates the Establishment Clause.

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

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

[36] 83 Fed. Reg. at 3923-24.

[37] *Id.*

[38] Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135, 521 (2017).

[39] *Estate of Thornton v. Caldor*, 472 U.S. 703, 709 (1995).

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

[41] *Id.*

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

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

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

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

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

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[42] 83 Fed. Reg. at 3918.

[43] *See supra* Section III.

[44] *E.g.*, N.Y. Pub. Health Law § 2805-b.

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

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

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

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

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

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

[49] 83 Fed. Reg. at 3913.

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

[51] *See, e.g.*, Wash. Rev. Code § 7.70.050.

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

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

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

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

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

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

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

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

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

[56] 83 Fed. Reg. at 3905, 3931.

[57] 83 Fed. Reg. at 3905.

[58] 83 Fed. Reg. at 3889.

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

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

(B) The Proposed Rule Violates the Spending Clause.

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

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

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[59] 42 U.S.C. §§ 300a-7(b)-(c)(1).

[60] 42 U.S.C. §§ 300a-7(c)(2)-(e).

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

[62] 83 Fed. Reg. at 3931.

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

[64] *Id.*

[65] 83 Fed. Reg. at 3929.

[66] 83 Fed. Reg. at 3931.

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

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

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

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

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[67] *See Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 578 (2012).

[68] *Id.* at 576.

[69] *South Dakota v. Dole*, 483 U.S. 203, 207 (1987) (internal citation omitted).

[70] *Sebelius*, 567 U.S. at 580 (internal citation and quotation marks omitted).

[71] *Dole*, 483 U.S. at 207.

[72] 83 Fed. Reg. at 3905.

[73] *Sebelius*, 567 U.S. at 581.

[74] *Id.* at 579-585.

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

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

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

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

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

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

[76] 83 Fed. Reg. at 3903.

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

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

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

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

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

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

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

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

[82] *See supra* Section II.

[83] *See supra* Section VI(A).

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

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

VIII. Conclusion

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

Respectfully submitted,

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

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Exhibit 88

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 Community Catalyst in response to the request for public comment on the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26.[1]

Community Catalyst is a national non-profit advocacy organization dedicated to quality affordable health care for all. Since 1997, Community Catalyst has been working to build the consumer and community leadership required to transform the American health system. With the belief that this transformation will happen when consumers are fully engaged and have an organized voice, Community Catalyst works in partnership with national, state and local consumer organizations, policymakers and foundations, providing leadership and support to change the health care system so it serves everyone - especially vulnerable members of society.

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

[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].

Indeed, this proposal runs in the opposite direction of everything the American health system is striving to achieve in 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. The rule improperly seeks to expand on existing religious refusal exemptions to potentially allow denial of any health care service based on a provider's personal beliefs or religious doctrine.

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

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

We are also concerned about potential enabling of care denials by providers based on their non-scientific personal beliefs about other types of health services. For example, certain religiously-affiliated hospitals and individual clinicians have refused to provide rape victims with emergency contraception to prevent pregnancy[5] based on the belief that it can cause an abortion, even though there is no scientific evidence that this is the case. Providers could conceivably be motivated by the proposed rule to object to administering vaccinations or refuse to prescribe or dispense Pre-exposure Profylaxis (PrEP) medication to help gay men reduce the risk of HIV transmission through unprotected sex.

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

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

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[2] *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.

[3] *See* Rule *supra* note 1, at 12.

[4] 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.

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

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

On an institutional level, the right to refuse to "assist in the performance of" a service could mean a religiously-affiliated hospital or clinic could deny care, and *then also refuse to provide a patient with a referral or transfer to a willing provider* of the needed service. Indeed, the proposed rule's definition of "referral" goes beyond any common understanding of the term, allowing refusals to provide *any information,* including location of an alternative provider, that could help people get care they need.[6]

The proposed rule thus could be read as allowing health providers to refuse to inform patients of all potential treatment options. A 2010 publication of the National Health Law Program, "Health Care Refusals: Undermining Quality of Care for Women," noted that "refusal clauses and institutional restrictions can operate to deprive patients of the complete and accurate information necessary to give informed consent."[7]

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

There have been reported instances in which pregnant women suffering medical emergencies – including premature rupture of membranes (PPROM) and ectopic pregnancies[8] -- have gone to hospital emergency departments and been denied prompt, medically-indicated care because of institutional religious restrictions.[9] This lack of protections for patients is especially problematic in regions of the country, such as rural areas, where there may be no other nearby hospital to which a patient could easily go without assistance and careful medical monitoring enroute.[10]

The proposed rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals 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

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[6] *See* Rule *supra* note 1, at 183.

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

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

[9] Stein, Rob, *Religious hospitals' restrictions sparking conflicts, scrutiny,* The Washington Post, January 3, 2011, accessed at https://www.washingtonpost.com/health-environment-science/religious-hospitals-restrictions-sparking-conflicts-scrutiny/2011/01/03/ABVVxmD_story.html?utm_term=.cc34abcbb928

[10] For example, a 2016 study found there were 46 Catholic-affiliated hospitals that were the federally-designated "sole community providers" of hospital care for their geographic regions. Women needing reproductive health services that are prohibited by Catholic health restrictions would have no other easily accessible choice of hospital care. Uttley, L., and Khaikin, C., *Growth of Catholic Hospitals and Health Systems,* MergerWatch, 2016, accessed at www.MergerWatch.org

to another facility.[11] Under EMTALA every hospital is required to comply – even those that are religiously affiliated.[12] 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 to provide care, *but would not be required to notify patients about the types of care they will not be able to receive at that hospital, pharmacy, clinic or doctor's office*.**

The rule sets forth extensive requirements for health care institutions, such as hospitals, to notify employees about their refusal rights, including how to file a discrimination complaint with OCR. The rule requires posting of such notices on the employer's website and in prescribed physical locations within the employer's building. The rule also sets forth the expectation that OCR would investigate or do compliance reviews of whether health care institutions are following the posting rule.[13]

By contrast, the rule contains no requirement that patients be notified of institutional restrictions on provision of certain types of care. Such notification is essential because research has found that patients often are unaware of service restrictions at religiously-sponsored health care institutions. [14]

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

The Proposed Rule generates chaos through its failure to account for existing laws that conflict with the refusals of care it would create. For example, the proposed rule makes no mention of Title VII,[15] the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[16] Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer.[17] For decades, Title VII has

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[11] 42 U.S.C. § 1295dd(a)-(c) (2003).

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

[13] The notice requirement is spelled out in section 88.5 of the proposed rule.

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

[15] 42 U.S.C. § 2000e-2 (1964).

[16] *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.

[17] *See id.*

established the legal framework for religious accommodations in the workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on patients, coworkers, public safety, and other legal obligations. The proposed rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both. Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.[18]

Furthermore, the language in the proposed rule would seem to put health care entities in the position of being forced to hire people who intend to refuse to perform essential elements of a position, even though Title VII would not require such an "accommodation." For example, there is no guidance about whether it is impermissible "discrimination" for a Title X-funded health center not to hire a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests because the applicant refuses to provide non-directive options counseling, even though the employer would not be required to do so under Title VII.[19] It is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

6. There is no provision protecting the rights of health care providers with religious or moral convictions to *provide* (not deny) services their patients need.

The proposed rule ignores those providers with deeply held moral convictions that motivate them to provide patients with health care, including abortion, transition-related care and end-of-life care. The rule fails to acknowledge the Church Amendment's protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce.[20]

Doctors are, in effect, forced to abandon their patients when they are prevented by health care institutions from providing a service they believe is medically-indicated. This was the case for a doctor in Sierra Vista, Arizona, who was prevented from helping end a patient's wanted, but doomed, pregnancy after she suffered premature rupture of membranes. The patient had to be sent to the nearest non-objecting hospital, which was 80 miles away, far from her family and friends. The physician described the experience as "a very gut wrenching thing to put the staff through and the patient, obviously."[21]

7. The proposed rule carries severe consequences for patients and would exacerbate existing inequities.

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

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[18] Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), *available at* https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html.
[19] *See* Rule *supra* note 1, at 180-181.
[20] *See* The Church Amendments, 42 U.S.C. § 300a-7(c) (2018).
[21] Uttley, L, et all, *Miscarriage of Medicine,* MergerWatch and the ACLU (2013), p. 16, https://www.aclu.org/report/miscarriage-medicine.

Across the country, refusals of care based on personal beliefs have been invoked in countless ways to deny patients the care they need.[22] One woman experiencing pregnancy complications rushed to the only hospital in her community, a religiously affiliated facility, where she was denied the miscarriage management she needed because the hospital objected to this care.[23] Another woman experiencing pregnancy loss was denied care for 10 days at a religiously affiliated hospital outside Chicago, Illinois.[24] In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy.[25] A patient in Arkansas endured a number of dangerous pregnancy complications and could not risk becoming pregnant again. She requested a sterilization procedure at the time of her Cesarean delivery, but her Catholic hospital provider refused to give her the procedure.[26] Another woman was sent home by a religiously affiliated hospital with two Tylenol after her water broke at 18 weeks of pregnancy. Although she returned to the hospital twice in the following days, the hospital did not give her full information about her condition and treatment options.[27]

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

Refusals of care based on personal beliefs already make it difficult for many individuals to obtain health care and have real consequences for those denied the care they need because of a clinician's or hospital's religious beliefs. When women and families are uninsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services or travel to another location, refusals bar access to necessary care.[28] This is especially true for immigrant patients who often lack access to transportation and may have to travel great distances to get the care they need.[29] In rural areas there may be no other sources of health and life preserving medical care.[30] When these individuals encounter refusals of care, they may have nowhere else to go.

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[22] *See, e.g.*, *supra* note 2.

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

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

[25] *See* Kira Shepherd, et al., *supra* note 23, at 29..

[26] *See The Patient Should Come First: Refusals to Provide Reproductive Health Care*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/05/Refusals-FS.pdf; Sandhya Somashekhar, *A Pregnant Woman Wanted her Tubes Tied. Her Catholic Hospital Said No.*, WASH. POST (Sept. 13, 2015), https://www.washingtonpost.com/national/a-pregnant-woman-wanted-her-tubes-tied-her-catholic-hospital-said-no/2015/09/13/bd2038ca-57ef-11e5-8bb1-b488d231bba2_story.html?utm_term=.8c022b364b75.

[27] *See* Kira Shepherd, et al., *supra* note 23, at 27.

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

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

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

This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals. For example, new research shows that In 19 states, women of color are more likely than white women to give birth in Catholic hospitals.[31] Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provide guidance on a wide range of hospital matters, including reproductive health care, and can keep providers from offering the standard of care.[32] Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals, and as a result, women were delayed care or transferred to other facilities at great risk to their health.[33] The reach of this type of religious refusal of care is growing with the proliferation of both the types of entities using religious beliefs to discriminate and the number of religiously affiliated entities that provide health care and related services.[34]

We concur with the comments submitted by the National Health Law Program (NHeLP) that the regulations fail to consider the impact of refusals on persons suffering from substance use disorders. Rather than promoting the evidence-based standard of care, the rule could allow practitioners to refuse to provide, or even recommend, Medication Assisted Treatment (MAT) and other evidence-based interventions due simply to a personal objection.

Stigma associated with drug use stands in the way of saving lives.[35] America's prevailing cultural consciousness -- after decades of treating the disease of addiction as largely a criminal justice and not the public health issue it is -- 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 harm and do not increase drug use.[36] One commissioner even quoted the Bible as he voted to shut it down. Use of MAT to reverse overdose has been decried as "enabling these people" to go on to overdose again.[37]

In this frame of mind, only total abstinence is seen as successful treatment for substance use disorders, usually as a result of a 12-step or faith-based program, even though evidence for 12-step

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[31] *See* Kira Shepherd, et al., *supra* note 23, at 12.
[32] *See id.* at 10-13.
[33] Lori R. Freedman, *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.
[34] *See, e.g.*, *Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care*, AM. CIVIL LIBERTIES UNION & MERGER WATCH (2013), https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf.
[35] 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.*, https://www.vox.com/science-and-health/2017/7/20/15937896/medication-assisted-treatment-methadone-buprenorphine-naltrexone.
[36] 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.
[37] 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.

programs is weak. 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."[38]

People with substance use disorders already suffer due to stigma and have a difficult time finding appropriate care. This rule, which allows misinformation and personal feelings to get in the way of science and lifesaving treatment, would not help achieve the goals of the administration; it could instead trigger countless numbers of deaths.

By expanding refusals of care, the proposed rule will exacerbate the barriers to health care services patients need. It is evident that the harm caused by this proposed rule will fall hardest on those most in need of care. The Department should remember, under Executive Order 13563, an agency may only propose regulations where it has made a reasoned determination that the benefits justify the costs and where the regulations are tailored "to impose the least burden on society."[39] The proposed rule plainly fails on both counts. Although the proposed rule attempts to quantify the costs of compliance, it completely fails to address the costs and burdens to patients who may be denied care and who then may incur and experience even greater social and medical costs.[40] Moreover, the Establishment Clause of the First Amendment requires the government to adequately account for just these sorts of consequences when considering whether to grant religious exemptions and, in fact, bars granting an exemption when it would detrimentally affect any third party.[41] Because the proposed rule would cause substantial harm, including to patients, it would violate the Establishment Clause.[42]

8. The Department is abdicating its responsibility to patients

The proposed rule exceeds OCR's authority by abandoning OCR's mission to address health disparities and discrimination that harms patients.[43] Instead, the proposed rule appropriates language from civil

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[38] 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

[39] *Improving Regulation and Regulatory Review*, Executive Order 13563 (Jan. 18, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review.

[40] *See* Rule *supra* note 1, at 94-177.

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

[42] Respecting religious exercise may not "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling." *See Burwell v. Hobby Lobby*, 134 S. Ct. at 2787. When considering whether the birth control coverage requirement was the least restrictive means in Hobby Lobby, the Court considered that the accommodation offered by the government ensured that affected employees "have precisely the same access to all FDA-approved contraceptives as employees of companies whose owners have no religious objections to providing coverage." *See id.* at 2759. In other words, the effect of the accommodation on women would be "precisely zero." *Id.* at 2760.

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

rights statutes and regulations that were intended to improve access to health care and applies that language to situations for which it was not intended. By taking the language of civil rights laws and regulations out of context, the proposed rule creates a regulatory scheme that is not only nonsensical but is affirmatively harmful. For example, the notice and certification of compliance and assurance requirements simply do not make sense when applied to the laws the proposed rule seeks to enforce.[44]

The Department, including OCR, has an important role to play in ensuring equal opportunity to access health care and ending discriminatory practices that contribute to poor health outcomes and health disparities.[45] If finalized, however, the proposed rule will represent a radical departure from the Department's mission to combat discrimination, protect patient access to care, and eliminate health disparities. Through robust enforcement of civil rights laws, OCR has worked to reduce discrimination in health care by ending overtly discriminatory practices such as race segregation in health care facilities, segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.[46]

Nevertheless, there is still work to be done, and the proposed rule seeks to divert limited resources away from ending discrimination. De facto segregation, for example, continues to contribute to poorer health outcomes for Black people. According to one study, over half of the racial disparity in survival for heart attack patients can be attributed to the lower performance of hospitals that serve predominantly people of color.[47] Black women are three to four times more likely than white women to die during or after childbirth.[48] According to a recent report, doctors often fail to inform Black women of the full range of reproductive health options regarding labor or delivery, possibly due to stereotypes about Black women's sexuality and reproduction.[49] Young Black women said they felt they were shamed by

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programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").

[44] *See* Rule *supra* note 1, at 203-214.

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

[46] *See, e.g., Serving People with Disabilities in the Most Integrated Setting: Community Living and Olmstead*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/community-living-and-olmstead/index.html; *Protecting the Civil Rights and Health Information Privacy Rights of People Living with HIV/AIDS*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/hiv/index.html; *National Origin Discrimination*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/index.html; *Health Disparities*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/health-disparities/index.html.

[47] *See* Skinner et al., *Mortality after Acute Myocardial Infarction in Hospitals that Disproportionately Treat African-Americans*, NAT'L INSTIT. OF HEALTH 1 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1626584/pdf/nihms13060.pdf.

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

[49] CTR. FOR REPROD. RIGHTS, NAT'L LATINA INST. FOR REPROD. HEALTH & SISTERSONG WOMEN OF COLOR REPROD. JUSTICE COLLECTIVE, *Reproductive Injustice: Racial and Gender Discrimination in U.S. Health Care* 20-22 (2014), *available at*

providers when seeking sexual health information and contraceptive care, due to their age and in some instances, sexual orientation.[50]

Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.[51] Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a health care provider had refused to see them because of their actual or perceived sexual orientation or gender identity in the year before the survey.[52]

As NHelP's comments note, many people with disabilities receive home and community-based services (HCBS), including residential and day services, from religiously-affiliated providers. Historically, people with disabilities who rely on these services have sometimes faced discrimination, exclusion and a loss of autonomy due to provider objections. Group homes have, for example, refused to allow residents with intellectual disabilities who were married to live together in the group home.[53] Individuals with HIV – a recognized disability under the Americans with Disabilities Act (ADA) – have repeatedly encountered providers who deny services, necessary medications and other treatments citing religious and moral objections. One man with HIV was refused care by six nursing homes before his family was finally forced to relocate him to a nursing home 80 miles away.[54] Given these and other experiences, the extremely broad proposed language at 45 C.F.R. § 88.3(a)(2)(vi) that would allow any individual or entity with an "articulable connection" to a service, referral, or counseling described in the relevant statutory language to deny assistance due to a moral or religious objection is extremely alarming and could seriously compromise the health, autonomy and well-being of people with disabilities.

OCR must work to address these disparities, yet the proposed rule seeks to prioritize the expansion of existing religious refusal laws beyond their statutory requirements and create new religious exemptions where none had previously existed rather than using already limited resources to protect patient access to health care. The proposed rule will harm patient care and is antithetical to OCR's mission—to eliminate discriminatory practices that contribute to persistent health inequality.[55]

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https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/CERD_Shadow_US_6.30.14_Web.pdf [hereinafter *Reproductive Injustice*]; IN OUR OWN VOICE: NAT'L BLACK WOMEN'S REPROD. JUSTICE AGENDA, *The State of Black Women & Reproductive Justice* 32-33 (2017), *available at* http://blackrj.org/wp-content/uploads/2017/06/FINAL-InOurVoices_Report_final.pdf.

[50] *Reproductive Injustice*, *supra* note 10, at 16-17.

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

[52] *See* Jaime M. Grant et al., *Injustice at Every Turn: a Report of the National Transgender Discrimination Survey*, NAT'L GAY AND LESBIAN TASK FORCE & NAT'L CTR. FOR TRANSGENDER EQUALITY, http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf.

[53] See *Forziano v. Independent Grp. Home Living Prog.*, No. 13-cv-00370 (E.D.N.Y. Mar. 26, 2014) (dismissing lawsuit against group homes, including a religiously affiliated group home, that refused to allow married couple with intellectual disabilities live together). Recent regulations have reinforced protections to ensure available choice of roommates and guests. 42 C.F.R. §§ 441.301(c)(4)(vi)(B) & (D).

[54] NAT'L WOMEN'S LAW CTR., *Fact Sheet: Health Care Refusals Harm Patients: The Threat to LGBT People and Individuals Living with HIV/AIDS,* (May 2014), *available at* https://nwlc.org/wp-content/uploads/2015/08/lgbt_refusals_factsheet_05-09-14.pdf.

[55] *See supra* note 42.

9. The proposed rule will make it harder for states to protect their residents

The proposed rule will have a chilling effect on the enforcement of and passage of state laws that protect access to health care and prevent discrimination against individuals seeking medical care. The preamble of the proposed rule discusses at length state laws that the Department finds objectionable, such as state laws that require anti-abortion counseling centers to provide information about where reproductive health care services can be obtained or whether facilities have licensed medical staff, as well as state laws that require health insurance plans to cover abortion.[56] 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.[57]

10. The proposed rule will undermine critical federal health programs, including Title X

The proposed rule would seemingly allow health care entities to receive grants and contracts under HHS-funded programs or other federal health programs, such as Title X, the only domestic family planning program, while refusing to provide key services required by those programs.[58] For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling[59] and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.[60] 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.[61] 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.[62] 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.[63]

Conclusion

The proposed rule will allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care. The proposed rule is discriminatory, violates multiple federal statutes, ignores

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[56] *See, e.g.*, Rule, *Supra* note 1, at 3888-89.
[57] *See id.*
[58] *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 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.
[59] *See, e.g.*, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).
[60] *See* What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).
[61] *See, e.g.*, Rule *supra* note 1, at 180-185.
[62] *See* NFPRHA *supra* note 34.
[63] *See id.*

congressional intent, fosters confusion and harms patients, all of which are contrary to the Department's stated mission. For all of these reasons, Community Catalyst calls on the Department to withdraw the proposed rule in its entirety.

Respectfully submitted,

Robert Restuccia
Executive Director
Community Catalyst

Exhibit 89

National
Family Planning
& Reproductive Health Association

March 27, 2018

US 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

Attn: Protecting Statutory Conscience Rights in Health Care NPRM, RIN 0945-ZA03

The National Family Planning & Reproductive Health Association (NFPRHA) is pleased to provide comments on the US Department of Health and Human Services' (HHS) notice of proposed rulemaking (NPRM), "Protecting Statutory Conscience Rights in Health Care," RIN 0945-ZA03.

NFPRHA is a national membership organization representing the nation's publicly funded family planning providers, including nurse practitioners, nurses, administrators, and other key health care professionals. NFPRHA's members operate or fund a network of more than 3,500 health centers and service sites that provide high-quality family planning and other preventive health services to millions of low-income, uninsured, or underinsured individuals in 50 states and the District of Columbia. Services are provided through state, county, and local health departments as well as hospitals, family planning councils, Planned Parenthoods, federally qualified health centers and other private nonprofit organizations.

NFPRHA is deeply concerned that this NPRM 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. Because they receive Title X, Medicaid, and other HHS funds, NFPRHA members would have no choice but to comply with this rule: failure to do so could lead to termination of current or pending HHS funds, as well as return of money previously paid to NFPRHA members for services they have provided. This means hundreds of millions of dollars in federal funding are at stake for NFPRHA members if they run afoul of the rule. Without federal support, many of our members would be forced to drastically scale back the services they provide to their patients or to close completely. Because NFPRHA members represent the vast majority of Title X clinical locations that serve people who cannot afford to pay for health care on their own, this would leave many low-income and uninsured or under-insured patients without access to family planning and other critical health care services.

Although this NPRM claims the authority to interpret numerous statutes of concern and interest, NFPRHA will limit its comments primarily to the unjustified and unauthorized expansion of the Church amendments (42 USC 300a-7), Coats-Snowe amendment (42 USC 238n), and Weldon amendment (e.g. Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, Tit. V, sec. 507(d)) (together, "Federal health care refusal statutes"). Because this NPRM encourages unprecedented discrimination against patients and opens the door to undermining the intent and integrity of key HHS programs, including the Title X family planning program, it should be withdrawn.

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Background on the 2008 Health Care Refusal Regulations

In the decades-long history of the federal health care refusal statutes, none of which delegate rulemaking authority to HHS, regulations purporting to clarify and interpret these laws have been promulgated only once, in late 2008.

In 2008, HHS promulgated an NPRM purporting to interpret and enforce the federal health care refusal statutes claiming "concern…that there is a lack of knowledge on the part of States, local governments, and the health care industry" of the refusal rights contained within these statutes. (73 Fed. Reg. at 50, 278). Despite allowing only a 30-day comment period, HHS received more than 200,000 comments in response to the proposed rule—the vast majority of which opposed the rule as unnecessary, unauthorized, and overbroad.[1] Notably, HHS conceded, it received "no Comments indicating that there were any [federal] funding recipients not currently compliant with [the underlying statutes]" (73 Fed. Reg. at 78,095). HHS published a final rule on December 19, 2008, which did not materially differ from the NPRM and was immediately subject to legal challenge by multiple parties, including NFPRHA and seven state attorneys general.[2]

In 2011, HHS rescinded those aspects of the 2008 rule that were "unclear and potentially overbroad in scope," but maintained those parts of the rule establishing an enforcement process for the Federal health care refusal statutes and began an "initiative designed to increase the awareness of health care providers about the protections provided by the health care provider conscience statutes, and the resources available to providers who believe their rights have been violated." (76 Fed. Reg. at 9969). This rule remains in effect.

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[1] Comments to Provider Conscience Regulations, 73 Fed. Reg. 50274 (August 26, 2008) (to be codified at 45 CFR 88).

[2] *National Family Planning and Reproductive Health Association et al v. Leavitt*, No. 09-cv-00055 (Dist. Conn. Jan. 15, 2009) *State of Conn. et al. v. United States of America*, No. 09-cv-00054 (Dist. Conn. Jan. 15, 2009); *Planned Parenthood Federation of America v. Leavitt*, No. 09-cv-00057 (Dist. Conn. Jan. 15, 2009); *State of Conn. et al. v. United States of America*, No. 09-cv-00054 (Dist. Conn. Jan. 15, 2009).

According to the current NPRM, since 2008, "OCR [Office for Civil Rights] has received a total of forty-four complaints [related to Federal health care refusal laws], the large majority of which (thirty-four) were filed since the November 2016 election." (83 Fed. Reg. at 3886). To place that figure into context, OCR in total received approximately 30,166 complaints in fiscal year (FY) 2017.

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The NPRM overstates statutory authority and seeks to dramatically expand the reach of the underlying statutes.

For decades, federal health care refusal statutes have given specified individuals and institutions certain rights to refuse to perform, assist in the performance, and/or refer for abortion and/or sterilization services. Despite the lack of a congressional mandate to do so, the NPRM seeks to dramatically expand the scope and reach of these laws, as well as grant overall responsibility for ensuring and enforcing compliance with those statutes to OCR, using identical language to many aspects of the now-rescinded 2008 regulation that faced widespread opposition at that time.[3]

The Church amendments were enacted by Congress in the 1970s in response to debates about whether the receipt of federal funds required recipients to provide abortion or sterilization services. These provisions make clear, among other things, that:

- The receipt of federal funding under the Public Health Service Act (PHSA) (42 U.S.C. § 201 et seq.) does not itself obligate any individual to perform or assist in the performance of sterilization or abortion procedures if those procedures are contrary to the individual's religious or moral beliefs (Church (b)(1)); and,
- Health care personnel employed by certain federally funded programs and facilities cannot be discriminated against in terms of employment, promotion, or the extension of staff or other privileges for performing or assisting in the performance of sterilization or abortion services, or refusing to perform or assist in the performance of such services based on their religious or moral beliefs (Church (c)(1)).

In 1996, Congress adopted the Coats amendment in response to a decision by the accrediting body for graduate medical education to require OB/GYN residency programs to provide or permit abortion training. The Coats amendment prohibits federal, state, and local governments from discriminating against health care entities, such as "individual physicians, postgraduate physician training programs, or . . . participant[s] in a program of training in the health profession," that refuse to provide or require training in abortions or individuals who refuse to be trained to provide abortions.

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[3] Comment of the National Family Planning & Reproductive Health Association to Provider Conscience Regulations, Tracking Number 8072403d to 73 Fed. Reg. 50274 (proposed August 26, 2008) (comment dated September 25, 2008) (to be codified at 45 CFR 88).

Since 2004, Congress has attached the Weldon amendment to the annual appropriations measure that funds the Departments of Labor, Health and Human Services, and Education (Labor-HHS). That amendment prohibits federal agencies and programs and state and local governments that receive money under the Labor-HHS Appropriations Act from discriminating against individuals, health care facilities, insurance plans, and other entities because they refuse to provide, pay for, provide coverage of, or refer for abortion.

The Church, Coats-Snowe, and Weldon amendments were never intended to provide individual health care providers and/or entities with the myriad and expansive rights of refusal this NPRM seeks to achieve. Without statutory authorization, the NPRM expands the reach of the Church, Coats-Snowe, and Weldon Amendment beyond what was contemplated by Congress and is permitted by existing federal law, by expanding the categories of individuals and entities whose refusals to provide information and services are protected; expanding the types of services that individuals and entities are allowed to refuse to provide; and expanding the types of entities that are required to accept such refusals. For example:

- Despite the plain language of the Weldon amendment, the NPRM attempts to extend it to apply to funding beyond that appropriated by Labor-HHS appropriations and to non-governmental entities, as well. The statute of the Weldon amendment states:

  > "(1) 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.

  Yet § 88.3(c) of the NPRM adds new language that applies the Weldon amendment's prohibitions not only to federal agencies and programs and state and local governments that receive Labor-HHS funds, but also to "***[a]ny entity that receives funds through a program administered by the Secretary or under an appropriations act for the Department that contains the Weldon amendment***" [emphasis added].

  This language broadens Weldon's reach in two impermissible ways: 1) it extends the restrictions to entities that do not even receive funding via Labor-HHS appropriations, to apply to funding through any program administered by HHS; and, 2) it applies the restrictions of the Weldon amendment beyond the statutory reach of federal agencies or programs, or state or local governments, to any entity receiving certain federal funds. These extensions of Weldon's reach are clearly contrary to both the plain language of the Weldon amendment and to congressional intent.

- While the Church amendment prevents PHSA funds from being used to require individuals and institutions to, among other things, "assist in the performance" of abortions and sterilizations, and prevents employment discrimination against those who refuse to do so, § 88.3 of the NPRM

transforms this statutory shield into a sword, creating out of whole cloth a categorical right of refusal for any recipient of PHSA funds. Moreover, § 88.2 of the NPRM provides an unprecedentedly and unjustifiably broad definition of the term "assist in the performance" that runs counter to congressional intent and common sense. The NPRM would define "assist in the performance" as participating "in ***any activity*** with an ***articulable connection*** to a procedure, health service or health service program, or research activity" [emphasis added]. In other words, HHS proposes to create refusal rights for anyone who can ***simply express a connection*** between something they do not want to do and an abortion or sterilization procedure (e.g., scheduling appointments, processing payments, or treating complications). Even the sole instance of previous rulemaking under the Church amendments in 2008, which was rescinded before it ever took effect, was not so broad.

- Likewise, the NPRM's definition of referral/refer seeks to dramatically expand the scope and reach of the Coats-Snowe and Weldon amendments and runs counter to congressional intent and common sense. Section 88.2 of the NPRM defines "referral/refer for" abortion to include:

  > "the provision of any information (including but not limited to name, address, phone number, email, website, instructions, or description) by any method (including but not limited to notices, books, disclaimers, or pamphlets, online or in print), pertaining to a health care service, activity, or procedure, including related to availability, location, training, information resources, private or public funding or financing, or directions that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity, or procedure, where 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."

  This definition would impair the ability of health care professionals to fulfill their legal and ethical duties of providing complete, accurate, and unbiased information to their patients. For example, as discussed further below, the NPRM could be read to permit employees of Title X-funded health centers and other federally funded entities to refuse to provide information and referrals to patients, without ever addressing patient needs and in clear violation of the fundamental tenets of informed consent.

As interpreted by the NPRM, the Church, Coats-Snowe, and Weldon amendments would be radically expanded to create far-reaching protections for individuals and entities that would refuse to provide patients not only with health care services, but also the most basic information about their medical options and that seek to obstruct the ability of certain patients to access any care at all. This is impermissible and, as discussed below, would cause unprecedented harm to patients and undermine the integrity of key HHS programs.

This NPRM goes beyond HHS' statutory authority and should be withdrawn. If HHS promulgates a final rule, however, it must identify the source of its legal authority, if any at all, to promulgate these regulations and to alter and expand the meaning of the statutory language.

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The NPRM attempts to grant OCR oversight authority and enforcement discretion that is overly broad and vague; unduly punitive; and ripe for abuse.

While some of the investigative authority and enforcement powers of the current NPRM appear to comport with similar provisions in other areas subject to OCR oversight and enforcement authority, the NPRM 1) includes new, troubling provisions that are vague, overly broad, and overly punitive; and 2) as a whole, appear to impart in OCR authority and enforcement discretion that is ripe for abuse.

Indeed, while the NPRM claims to "borrow...from enforcement mechanisms already available to OCR to enforce similar civil rights laws," the NPRM contains troubling differences. For example, the NPRM states that investigations may be based on anything from 3rd party-complaints to news reports, and yet at the same time appears to give OCR the authority to withhold federal financial assistance and suspend award activities, based on "threatened violations" alone, without first allowing for the completion of an informal resolution process. (See 83 Fed. Reg. at 3891, 3930-31). By contrast, the Department of Justice (DOJ) regulations implementing Title VI of the Civil Rights Act of 1964 (prohibiting discrimination on the basis of race in federally funded programs) state that DOJ will not take such drastic steps to respond to actual or threatened violations unless noncompliance cannot first be corrected by informal means. (See 28 C.F.R. § 42.108(a)). When combined with other aspects of the NPRM, concern over the breadth and potential harm of such provisions is obvious and legitimate. For instance:

- Under § 88.6, the NPRM includes a 5-year reporting requirement that requires any recipient or sub-recipient subject to an OCR compliance review, investigation, or complaint related to the health care refusal rules to inform any current HHS "funding component" of the review/investigation/complaint, as well as to disclose that information in any application for new or renewed "Federal financial assistance or Departmental funding." Once again, this is distinct from the DOJ regulations enforcing Title VI, which only require disclosure of compliance reviews (not every investigation or complaint, regardless of whether it is unfounded) over the past two years. (28 C.F.R. § 42.406(3)). Yet the NPRM fails to explain the purpose of the vastly expanded reporting requirement and period. In light of the broad investigative authority and harsh penalties described above, this leaves affected entities with significant concern about how such information is intended to be used and whether it will unfairly prejudice consideration of applicants for federal funds or penalize currently funded entities in ways that could be extremely harmful.

The NPRM also includes very troubling language that appears to be little more than a pretext for defunding entire classes of providers, which it cannot do. The preamble text accompanying § 88.7

states, "The Director may, in coordination with a relevant Department component, restrict funds for noncompliant entities in whole or in part, including by ***limiting funds to certain programs and particular covered entities, or by restricting a broader range of funds or broader categories of covered entities***" [emphasis added]. This delegation of authority is not only far beyond the scope of the underlying laws but seems designed to grant arbitrary authority that is ripe for abuse, with no mechanism of due process or oversight to prevent entire categories of providers or programs from being penalized without cause. To the extent § 88.7 seeks to create a back door to excluding certain family planning providers from the Title X and Medicaid programs—efforts that have been repeatedly rejected by the courts—it, again, exceeds the scope of the agency's authority and will do nothing more than harm the health and well-being of patients.

Given the lack of evidence that the system currently in place cannot adequately handle complaints, as well as any sufficient justification for departing from the processes used to ensure compliance with other federal statutes, HHS must, at a minimum, adequately explain the reason for these changes, what safeguards exist to prevent abuse, and demonstrate that this language is not simply a pretext for unlawfully excluding certain categories of providers from participating in federally funded programs.

***

The NPRM opens the door to undermining the intent and integrity of key HHS programs, including the Title X family planning program.

The NPRM ignores the reality that some individuals and entities are opposed to the essential health services that are the foundation of longstanding, critical HHS programs like Title X. In the arena of health care, and particularly family planning and sexual health, HHS-funded programs cannot achieve their fundamental, statutory objectives if grantees, providers, and contractors have a categorical right to refuse to provide essential services, such as non-directive pregnancy options counseling.

The Title X family planning program was created by Congress in 1970 "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services" (42 USC 300). Title X projects are designed to "consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children" (42 CFR 59).

In 2014, more than 20.2 million women in the United States were in need of publicly funded contraceptive services. Women in need of publicly funded family planning services is defined as follows: "1) they were sexually active (estimated as those who have ever had voluntary vaginal intercourse, 2) they were able to conceive (neither they nor their partner had been contraceptively sterilized, and they did not believe they were infecund for any other reason); 3) they were neither intentionally pregnant nor trying to become pregnant; and, 4) they have a family income below 250% of the federal poverty level. In addition, all women younger than 20 who need contraceptive services, regardless of their family income are assumed to need publicly funded care because of their heightened need—for reasons of

confidentiality—to obtain care without depending on their family's resources or private insurance."[4] In the face of this widespread need, publicly funded family planning and sexual health care provides a crucial safety net for women and families. The impact of these services cannot be underestimated. Without publicly funded family planning services, there would be 67% more unintended pregnancies (1.9 million more) annually than currently occur.[5]

Congress has specifically required that "all pregnancy counseling shall be non-directive" (Public Law 110-161, p. 327), and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination (42 CFR 59.5(a)(5)). Despite the incredible success of the Title X program and the critical services it provides, Title X has been chronically underfunded, with no new service dollars allocated in nearly a decade. It is a testament to the dedication of the existing Title X network to meeting the goals of the program that, despite limited resources, these providers still serve more than four million patients per year.[6]

However, in addition to the overly broad definitions of "referral" and "assist in the performance" discussed above, by proposing a definition of "discrimination" that appears to jettison the longstanding framework that balances individual conscience rights with the ability of health care entities to continue to provide essential services to their patients, the NPRM seems designed to allow entities that refuse to provide women with the basic information, options counseling, and referrals required by law to compete on the same footing for federal money with family planning providers who adhere to the law and provide full and accurate information and services to patients. The NPRM thus threatens to divert scarce family planning resources away from entities that provide comprehensive family planning services to organizations that refuse to provide basic family planning and sexual health care services. Diverting funds away from providers offering the full range of family planning and sexual health services would not only seriously undermine public health, especially for the low-income, uninsured, and under-insured, but would also be contrary to congressional intent and explicit statutory requirements of the Title X family planning program.

The NPRM likewise creates confusion about whether Title X grantees may ensure that the subrecipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. To the extent that the rule seeks to immunize subrecipients who refuse to provide essential services and complete information about all of a woman's pregnancy options, it undermines the very foundation of the Title X program and the health of the patients who rely on it.

In addition to potential issues with the selection of grantees and subrecipients, the proposed definition of "discrimination" also poses significant employment issues for all Title X-funded health centers. As

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[4] Jennifer Frost et al, *Contraceptive Needs and Services, 2014 Update* (New York: Guttmacher Institute, 2016).
[5] Jennifer Frost et al, *Publicly Funded Contraceptive Services at U.S. Clinics, 2015* (New York: Guttmacher Institute, April 2017).
[6] Christina Fowler, *Family Planning Annual Report: 2016 national summary* (Research Triangle Park, NC: RTI International, 2017).

discussed further below, the language in the NPRM could put Title X-funded health centers in the position of being forced to hire people who intend to refuse to perform essential elements of a position. For example, the rule provides no guidance about whether it is impermissible "discrimination" for a Title X-funded health center not to hire a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests because the individual refuses to provide non-directive options counseling. Furthermore, the NPRM does not provide guidance on whether it is impermissible "discrimination" for a Title X-funded state or local health department to transfer such a counselor or clinician out of the health department's family planning project to a unit where pregnancy counseling is not done.

Because the NPRM threatens to undermine the integrity of key HHS programs, including the Title X family planning program, HHS must, at a minimum, clarify that any final rule does not conflict with preexisting legal requirements for and obligations of participants in the Title X program, or of employers, as set forth under Title VII of the Civil Rights Act of 1964, discussed below.

***

The NPRM fails to sufficiently address patient needs or achieve the careful balance struck by existing civil rights laws and encourages unprecedented discrimination against patients that will likely impede their access to care and harm their health.

The stated mission of HHS is "to enhance and protect the health and well-being of all Americans." Yet, the NPRM elevates the religious and moral objections of health care providers over the health care needs of the patients who HHS is obligated to protect. The NPRM appears to allow individuals to refuse to provide health care services or information about available health care services to which they object on religious or moral grounds, with virtually no mention of the needs of the patient who is turned away. Patients should not be forced to bear the brunt of the objector's religious or moral beliefs, particularly to the detriment of their own health. In fact, legal and ethical principles of informed consent require health care providers to tell their patients about all of their treatment options, including those the provider does not offer or favor, so long as they are supported by respected medical opinion. As such, health care professionals must endeavor to give their patients complete and accurate information about the services available to them.

Furthermore, the NPRM fails to address serious questions as to whether its purpose is to upset the careful balance struck in current federal law between respecting employee's religious and moral beliefs and employers' ability to provide their patients with health care services. Title VII provides a balance between health care employers' obligations to accommodate their employees' religious beliefs and practices (including their refusal to participate in specific health care services to which they have religious objection) with the needs of the patients they serve. Under Title VII, employers have a duty to reasonably accommodate an employee or applicant's religious beliefs, unless doing so places an "undue hardship" on the employer. This law provides protection for individual belief while still ensuring patient access to health care services. The NPRM provides no guidance about how, if at all, health care

employers are permitted to consider patients' needs when faced with an employee's refusal to provide services.

The NPRM ignores the needs of patients and fails to consider whether an employer can accommodate such a refusal without undue hardship. In so doing, the NPRM invites health care professionals to violate their legal and ethical duties of providing complete, accurate, and unbiased information necessary to obtain informed consent. The failure of health care professionals to provide such information threatens patients' autonomy and their ability to make informed health care decisions.

Title VII is an appropriate standard that protects the needs of patients and strikes an appropriate balance. At a minimum, HHS should clarify that any final rule does not conflict with Title VII.

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The NPRM vastly underestimates the financial burden it would impose on federally funded health care providers who already operate with limited resources.

NFPRHA is particularly well positioned to comment upon the extremely burdensome effect the NPRM will have on the variety of public and private entities awarded federal dollars to provide health services to underserved communities.

As an initial matter, for a non-lawyer to simply read and understand the regulatory language and the lengthy preamble of the NPRM requires numerous hours – much longer than the roughly "10 minutes per law" estimated by HHS. (See 83 Fed. Reg. at 3913). A Final Rule, which would respond to prior comments and provide explanation and commentary elaborating on the Regulation, would require the same at minimum. Moreover, given the magnitude of funds at stake, the complexity and ambiguity of the NPRM's employment provisions, and the diverse staffing arrangements among recipients of federal funds, many NFPRHA members will need to pay for the time of legal counsel to review and consult with them on how to adjust their policies and practices prior to certifying compliance. This will also require time and cost for legal counsel to research and advise how, or if, it is possible for an entity to achieve compliance with the rule as well as with potentially conflicting obligations under State or other Federal laws. A reasonable estimate of these tasks alone would include at least several hours of attorney as well as multiple hours of executive and management staff time – not just the average of 4 hours (total) per year of lawyer and staff time estimated by HHS. (See 83 Fed. Reg. at 3913).

In particular, it appears that policies and practices to comply with the Department's articulated standard will be different than those necessary to comply with existing federal laws such as Title VII. Thus, in estimating an average of 4 hours (total) per year to update policies and procedures *and* retrain staff (see 83 Fed. Reg. at 3913), the NPRM utterly fails to account for:

- Time and cost for legal and human resources or executive staff to review and revise job postings, job descriptions, job application materials, interview and hiring policies and practices, and other employment recruitment and hiring materials.

- Time and cost for legal and human resources or executive staff to review and revise employee manuals and handbooks, and other employment related policies and documents.

- Time and cost to devise and provide trainings for managers and other supervisory staff on interviewing, hiring, and responding to accommodation requests from employees and volunteers who object to participating in the provision of certain health care services.

- Time and cost of hiring and training additional employees and/or paying and retraining existing employees for additional hours to accommodate other employees who refuse to provide services.

While these comments do not attempt to identify and detail each of the likely costs that NFPRHA members and other regulated entities would face if the NPRM was finalized, they demonstrate the qualitatively and quantitatively substantial costs overlooked by HHS in its NPRM. In light of these burdens and the HHS's inability to demonstrate a countervailing need for the rule, NFPRHA strongly urges HHS to withdraw the NPRM. Failure to do so will result in substantial resources being diverted away from providing critical health care to patients in an already underfunded family planning safety net.

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NFPRHA appreciates the opportunity to comment on the NPRM, "Protecting Statutory Conscience Rights in Health Care." If you require additional information about the issues raised in these comments, please contact Robin Summers at rsummers@nfprha.org or 202-552-0150.

Sincerely,

Clare M. Coleman

Clare Coleman
President & CEO

Exhibit 90

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

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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.**

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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

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Roger Severino, 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.

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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 and 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

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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 91

AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

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."

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 in any way 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.

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 92

Kaiser Foundation Health Plan
Program Offices

Submitted electronically to: *www.regulations.gov*

March 27, 2018

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

RE: *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, Docket No. HHS–OCR–2018–0002*

Dear Sir or Madam:

Kaiser Permanente offers the following comments in response to the proposed rule, *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority* (the Proposed Rule) issued in the Federal Register (83 FR 3880) on January 26, 2018, which intends to promulgate regulations to ensure that the Department of Health and Human Services (the Department) funds do not support discriminatory practices or policies.

Kaiser Permanente is the largest private integrated health care delivery system in the United States, delivering health care to nearly 12 million members in eight states and the District of Columbia. Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii (Health Plan); the not-for-profit Kaiser Foundation Hospitals (Hospitals), which operates 39 hospitals and 680 other clinical facilities; and the Permanente Medical Groups (Medical Groups), independent physician group practices that contract with Kaiser Foundation Health Plan to meet the health needs of Kaiser Permanente's members.

This Proposed Rule will broadly impact Kaiser Permanente – as a provider of health care, through its Medical Groups, Hospitals and pharmacy system; as a health plan; and as a large employer of approximately 290,000 persons, including 22,100 physicians and 58,000 nurses.

Kaiser Permanente recognizes the importance of protecting the religious or moral beliefs of our workforce. We adhere to strict policies and practices that protect our workforce from religious and moral compromise and related discrimination. However, Kaiser Permanente also recognizes the importance of ensuring our members equitable access to high quality, affordable care. The Proposed Rule fails to acknowledge that conscience objections may conflict with patient rights

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Oakland, CA 94612

and professional obligations and fails to suggest or even allow for acceptable practices that balance the rights of the workforce with the needs of patients. A Final Rule should interpret the statutory language to balance the conscience protections of the health care workforce with the needs and rights of patients.

The Proposed Rule is at odds with numerous Department policies that place the patient at the center of health care delivery and focus on measurable quality of care, patient satisfaction, and access. Examples of this can be seen in the Department's strategic goals and movement towards value-based payment that rewards providers for improved patient outcomes and satisfaction. Similarly, the Rule is at odds with numerous state efforts to protect patients and improve their care experience. Additional guidance is needed to understand the intersection of the Proposed Rule with existing federal and state policies.

Kaiser Permanente's greatest concerns with the Proposed Rule are:

- The Department's proposed definitions for "assist in the performance" and "referral or refer" permit providers to withhold not just needed services, but information or referral to another provider or source of information, eliminating options for ensuring patients' access to needed care.
- The Proposed Rule's broad interpretation of the federal statutes appears to create conflicts with other federal and state laws and the Rule provides limited guidance on how to resolve such conflicts.
- The Proposed Rule's broad interpretation of the authorizing statutes creates confusion in several key areas that impact the business operations of physicians, hospitals, pharmacists, laboratories, health plans and others in the health care sector, including the rules governing relationships with employees, contracts with other entities, and systems of compliance. This will lead to significant administrative and financial burdens for health care businesses that will further strain health care resources.

Our detailed recommendations for clarifying or modifying the Proposed Rule follow.

Section 88.2. Definitions

Issue:
The Proposed Rule creates sweeping definitions for statutory terms that broaden the reach of those statutes and diminish health care entities' ability to ensure that the needs and rights of patients are met without compromising the moral or religious beliefs of the workforce. Additionally, several vague definitions create operational difficulties for health care entities required to comply with the regulations.

Recommendations:
Assist in the Performance. The Department would define "assist in the performance" to include participation "in any program or activity with an articulable connection to a procedure, health service, health program, or research activity." This includes but is not limited to "counseling, referral, training, and other arrangements for the procedure, health service, health program, or research activity." The definition encompasses an inappropriately broad scope of activities in

using the open-ended "articulable connection." The Proposed Rule provides examples of an "articulable connection" – counseling, referral, training, and other arrangements – but these examples only broaden the scope of the definition and create additional ambiguity.

Defining "assist in the performance" to include counseling and referral could conflict with physicians,' hospitals' and health plans' obligations and regulatory requirements to provide patients access to health care services and could potentially endanger patient health and safety in certain circumstances. For example, this definition would allow a provider with religious or moral objections to blood transfusions to refuse to offer that treatment to a patient with a life-threatening condition and fail to refer the patient to a provider who does not have an objection. As another example, the Proposed Rule would allow a provider with religious or moral objections to refuse to vaccinate a newborn or provide parents with information about recommended childhood vaccinations. Both situations could lead to immediate and irreparable harm to patients.

The Department should replace the open-ended "articulable connection" with language that directly connects the assistance to the objectionable procedure or service and limit it to the clinical setting. This definition should include a complete, not illustrative, description of the activities subject to the rule (i.e., providing, training, or ordering a procedure) and should not include counseling or referral.

Referral or Refer for. The Proposed Rule defines "referral or refer for" to include "the provision of any information… by any method…pertaining to a health care service, activity, or procedure..."[1] This definition would create an overly broad scope by allowing a single individual interacting with a patient to block access to information about medically necessary care. This definition would conflict with health care providers' legal and professional ethical obligations to refer patients who need medically necessary services.

This definition also eliminates an effective process for health care entities, particularly entities like Kaiser Permanente that use an integrated model of care, to protect the religious rights of our workforce. Referral allows providers to refrain from performing or assisting in the performance of an activity, while allowing organizations like ours to meet our legal obligations to provide access to services and treatment guaranteed under contract and frequently mandated under state law. The proposed language creates a dichotomy in which a health plan may be obligated to provide or arrange for a covered service but be unable to do so if a provider has a religious or moral objection to performing or referring for that service. The Department should permit and encourage providers to refer or otherwise arrange for patient care if they cannot provide it themselves due to religious or moral objections. In a Final Rule that includes "referral," we suggest narrowing the definition of "referral" to active facilitation of access.

Discriminate or Discrimination. The Proposed Rule's definition of "Discriminate or Discrimination" is also overly broad and creates operational challenges for employers. The definition appears to preclude an employer from denying employment to an applicant who objects on moral or religious grounds to performing the primary job responsibilities, even where no reasonable accommodation exists and the applicant's inability to perform the responsibilities

[1] 83 FR 3924

would disrupt business operations. Similarly, if a current employee expresses an objection to performing primary job responsibilities on religious grounds, removing the employee from the position and reassigning them to a comparable position could run afoul of the Rule.

Federal Financial Assistance. The Proposed Rule defines "Federal Financial Assistance" to include "[a]ny Federal agreement, arrangement, or other contract that has as one of its purposes the provision of assistance."[2] The inclusion of any "arrangement" and the "provision of assistance" make this particularly challenging for business entities that provide health care and coverage to interpret. The Final Rule's definition of "Federal Financial Assistance" should not include the ill-defined category "arrangement" and should clarify whether this definition includes any claim for payment, payments in exchange for health care services, or applications to participate in a federal program through which payment would be made.

Health Care Entity. The Proposed Rule states that the definition of "health care entity" includes health care professionals and health care personnel, among other categories. The Department should specifically define "health care professional" or "health care personnel" in the definition of "health care entity." Health care businesses should know specifically which employees are included under this definition.

Sub-Recipient. The definition for "Sub-Recipient" is overly broad and has the potential to bring into scope individuals and entities that indirectly receive any amount of federal financial assistance. Administrative and operational costs to health care businesses to identify subrecipients and to track their compliance with the Proposed Rule would be significant. The Final Rule should specifically limit sub-recipients to those for whom there is a direct pass-through of federal financial assistance and who are identified as sub-recipients of such dollars in contracts with the direct recipient. This definition should not subsume every contracting party of a recipient of federal financial assistance.

Workforce. The Proposed Rule includes "volunteers" and "contractors" in the definition of "workforce." The Department should modify this definition to include only volunteers or contractors performing or assisting the performance of health care activities. If the Rule maintains a broader definition of "volunteers" and "contractors," it should clarify the statutory basis to support the decision to use such a broad definition.

Religious or Moral Objections. The Final Rule should define "Religious or Moral Objections" and thereby clarify the group of individuals who can object to performing or assisting in the performance of services. The Final Rule should adopt similar definitions of these terms as provided in the employment and First Amendment context when religious accommodations and protections are sought.

[2] 83 FR 3924

Requirements for Conscience Objections

Issue:
The Proposed Rule does not provide guidance about the processes that should be in place to enable a health care provider to raise a conscience objection, making it more challenging for health care businesses to ensure quality and patient satisfaction.

Recommendations:
The Proposed Rule fails to create an obligation for the objecting provider or employee to notify, in advance or otherwise, the employer of what services they object to providing. Without a duty to inform employers, an individual could be hired into and remain in a job he or she cannot fully perform. There are no guardrails that enable employers to take advance steps to ensure patients get the care they need. Likewise, there are no guardrails to ensure that employers are informed at the time when patients do not receive medically necessary services or information about those services. Particularly in an emergency, notice is critically important to patient safety.

Without appropriate notification requirements, the Rule will introduce inconsistencies in the quality of care patients receive, as it would depend on their providers' religious and moral beliefs. This limits health care entities' ability to ensure high-value coordinated care, patient safety and patient satisfaction and is inconsistent with numerous other Department policies.

The Final Rule should establish processes that an individual should follow when raising a conscience objection. Health care workers with a religious or moral objection to performing a service should have a duty to notify their employer or putative employer so that reasonable accommodations can be considered to respect the workers' beliefs, as well as the needs and rights of the patient. Under current law, employees are required to provide notice and request accommodation of disabilities and religious beliefs. The Final Rule should specify how a provider should exercise a conscience objection if an individual is in an emergency and in need of health care services.

Section 88.4 Assurance and Certification

Issue:
The Proposed Rule conditions the continued receipt of Federal financial assistance or Federal funds on an assurance and certification. Payment conditioned on assurance and certification goes beyond the intent of the underlying statutes. The broad enforcement remedies allow the Office for Civil Rights to choose an appropriate and effective means of enforcement, which is sufficient to increase awareness of and compliance with the requirements of the regulation. As drafted, the proposed Rule could result in health care entities being subject to both civil litigation and regulatory action.

Recommendations:
Section 88.4 of the Proposed Rule describes, as a condition of receipt of Federal financial assistance or Federal funds, the requirement that applicants or recipients provide written assurance and certification of compliance with federal conscience laws. The Department has stated that certifications "provide a demonstrable way of ensuring that applicants for such funding

know of, and attest that they will comply with, applicable Federal health care conscience and associated anti-discrimination laws" and that assurances and certifications "would provide an important vehicle for increasing awareness of [those] laws and thereby increas[e] compliance."[3]

Tying certification to payment is not necessary to accomplish the Department's stated goals, which can be met through the submission process for the proposed attestations and certifications themselves. Payment conditioned on certification is additionally unnecessary given the broad remedies proposed in Section 88.7 (Enforcement). Section 88.7 delegates to the Office for Civil Rights the authority to enforce the federal conscience laws, including handling complaints, conducting investigations, referring to the Department of Justice, and "tak[ing] other appropriate remedial action as the Director of OCR deems necessary and as allowed by law…."[4] The Proposed Rule also grants the Office for Civil Rights the authority to temporarily withhold cash payments, deny and/or terminate use of federal monies, refer matters to the Attorney General, and "tak[e] any other remedies that may be legally available."[5] The proposed remedies allow the Office for Civil Rights to choose an appropriate means of enforcement, bounded by law and the intent of the underlying statutes.

In contrast, requiring that certification be tied to payment does not effectuate the intent of the underlying statutes, and potentially provides an avenue for third party litigation outside of the Office for Civil Rights' purview. Under the Proposed Rule, a health care entity could be found to have violated the assurance and certification requirement, potentially subjecting it to two separate processes: one pursued by the Office for Civil Rights and civil litigation filed and pursued by a *qui tam* plaintiff. A health care entity would be required to defend against the litigation regardless of whether the Office for Civil Rights found an assurance and certification violation or otherwise pursued a remedy against the entity.

The Final Rule should not include an assurance or certification requirement tied to payment.

Section 88.5 Notice

Issue:
The notice requirements of the Proposed Rule will be administratively and financially burdensome to health care entities. The notice text in Appendix A may be misleading.

Recommendations:
The Proposed Rule requires the Department and all recipients to post the notice text in Appendix A within 90 days of the publication of the Final Rule on websites and in conspicuous physical locations.

Kaiser Permanente's experience with ACA Section 1557 Nondiscrimination and Language Assistance Notices (1557 Notices) leads us to believe that the notice requirements will create significant administrative and financial burdens on health care entities and that the Proposed Rule underestimates that burden. Various regulators required the publication of multiple versions

[3] 83 FR 3896
[4] Section 88.7(a)
[5] Section 88.7(j)

of the 1557 Notices with variations in content. The Department's recommended 1557 content for commercial plans differed from that required by the Centers for Medicare and Medicaid Services' for Medicare and/or Medicaid plans, and that required by state regulators based on state code requirements for nondiscrimination disclosures. For an integrated health system operating in eight states and the District of Columbia, this resulted in approximately 20 different versions of the 1557 Notices and an unexpected and ongoing operational impact to manage numerous versions of notices used with different types of documents based on line of business, region of operation, and medium. The varying requirements of both federal and state agencies created confusion and uncertainty. Without clarifying the notice requirements, we anticipate health care businesses and government agencies spending considerable time and resources responding to employees' inquiries.

We do not believe the notice requirements in the Proposed Rule will be any less burdensome. As written, the rule requires use of the exact text in Appendix A and claims that this approach maximizes efficiency and economies of scale, but the Department also authored ACA Section 1557 notices and the benefits were not realized due to the variations in regulatory guidance.

The Final Rule should reduce the burden on health care businesses by seeking ways to streamline notice requirements. The Department should coordinate with other federal and state agencies to align on the content of the Notice in the Final Rule's Appendix A. Additionally, the notice language in Appendix A may be overbroad in stating that "you" may decline to "refer for" or "pay for" "certain health care-related treatments, research, or services." Not all individuals have the right, in all circumstances, to refuse to refer for or pay for treatments. The text of the Notice in the Final Rule's Appendix A should be adjusted to more accurately reflect the scope and coverage of individual rights.

Section 88.6 Compliance

Issue:
If the Proposed Rule is adopted, health care entities will require additional guidance for implementing or modifying organizational compliance policies.

Recommendations:
The Proposed Rule states that recipients and sub-recipients must maintain records evidencing compliance. The Department should delineate what records must be retained and how an entity affirmatively demonstrates compliance or this provision should be deleted.

The Proposed Rule requires recipients and sub-recipients to inform Departmental funding components if they are subject to an Office for Civil Rights compliance review, investigation, or complaint related to a religious or moral objection. The Proposed Rule does not describe the process through which covered entities would inform Departmental Components. Health care businesses would benefit from more detail on these requirements and some limitations. Since large organizations may receive federal financial assistance from many different sources and for many different purposes, it is far too sweeping to require that recipients notify funding sources of any investigation into compliance.

Reporting should only be required when an investigation relates to alleged non-compliance during activities conducted with the federal funding provided by the funding component. The Final Rule should require federal agencies to communicate and not to place the burden on investigated entities to inform all agencies from which they obtain funding.

The Proposed Rule requires recipients and sub-recipients to disclose, with any application for new or renewed Federal financial assistance or Departmental funding, the existence of compliance reviews, investigation, and complaints filed with the Office for Civil Rights for five years from such complaints' filing. Given that recipients are subject to enforcement actions due to violations of sub-recipients, clarification is needed on whether recipients must disclose the compliance reviews, investigations, and complaints filed on sub-recipients. The Final Rule should exempt unsubstantiated complaints from the five-year retrospective reporting obligation on applications, since they are not relevant to a consideration of an entity's eligibility for funding.

Under the Proposed Rule, funding restrictions may be imposed on recipients if their sub-recipients are non-compliant. It is excessive for recipients to lose funds because one of their sub-recipients engaged in prohibited actions. At a minimum, this should be discretionary based upon the degree of fault or non-compliance by the recipient. Additionally, the only funding that should be at risk is the funding that the primary recipient received for the project or business relationship undertaken with the sub-recipient.

The Proposed Rule creates risks for recipients related to the behavior of sub-recipients, but does not account for the limited influence a recipient may have over sub-recipients regarding compliance. To the extent the Proposed Rule encourages recipients to control the compliance activities of its sub-recipients, the Propose Rule may potentially expose recipients to joint employer liability under other federal or state labor and employment laws. The guidelines should instead address how recipients may establish processes, including contractual representations and warranties, that can be used to support sub-recipient compliance and provide information to recipients to ensure sub-recipient compliance, including disclosure of any Office for Civil Rights compliance reviews, investigations, and complaints.

The Final Rule should contain guidelines for compliance and a more thorough discussion of how the complaint system and enforcement of these nondiscrimination regulations will operate. The Rule should model guidelines after the policies and procedures in current federal and state employment discrimination laws and regulations. The guidelines should specify who in the Department should be informed of compliance reviews, investigations, or complaints, at what frequency and what information the Department wishes to receive.

Section 88.7 Enforcement

Issue:
The section of the Proposed Rule authorizing the Office for Civil Rights to enforce the Rule, inappropriately expands the class of persons who can bring complaints against health care entities.

Recommendations:

Pursuant to the Proposed Rule, anyone may file a complaint with the Office for Civil Rights, not only the person or entity whose rights have been potentially violated. The Department specifies "[t]he complaint filer is not required to be the person, entity, or health care entity whose rights under the Federal health care conscience and associated anti-discrimination laws or this part have been potentially violated."[6] Similarly, the Preamble states, "[u]nder the proposed rule, OCR would also be explicitly authorized to investigate 'whistleblower' complaints, or complaints made on behalf of others, whether or not the particular complainant is a person or entity protected by conscience and associated anti-discrimination laws."[7]

As noted above, the Office for Civil Rights has various remedies, including withholding, denying, suspending payments, awards, and Federal financial assistance, and referral to the Department of Justice. The remedies can be triggered "when there appears to be a failure" or even a "threatened" failure to comply with the underlying laws or the proposed regulation.

The Final Rule should limit those who can file a complaint to those who have suffered harm, as defined by the Rule and the statutes from which the Rule gains its authority. The Final Rule should eliminate the references to the apparent and "threatened" failures to comply with the law and reserve the remedies for those who have failed to comply.

Section 88.8 Relationship to Other Laws

Issue:
The Proposed Rule's broad interpretation of the federal statutes from which it derives its authority may create conflicts with other federal and state laws:

- Title VII of the Civil Rights Act of 1964 and other applicable federal and state laws authorize employers to engage in the interactive process with an employee to explore whether the employee's religious practices can be reasonably accommodated without incurring an undue hardship. Under Title VII, there may be instances in which a health care entity is unable to accommodate the employee's refusal to perform, or assist in performing, a health care activity because the accommodation is not reasonable or would pose an undue hardship.

- 42 U.S.C. 5106i(b) requires states to permit child protective services to pursue legal remedies to provide treatment to children whose parents have objected to treatment on religious grounds in certain circumstances. The Proposed Rule interprets 29 U.S.C. 290bb-36(f) as prohibiting requiring a parent or legal guardian to provide a child any medical service or treatment against their religious beliefs or moral objections. Under the Rule, States are neither required to find nor prohibited from finding child abuse or neglect in cases in which parents or legal guardians rely solely or partially on spiritual means rather than medical treatment.

[6] 88.7(b)
[7] 83 F.R. 3898

- Federal and state laws mandate coverage for certain care and treatment. For example, providers who accept Medicare Part A and/or Medicaid must provide transgender individuals equal access to facilities and services and must treat transgender individuals consistent with their gender identity.[8] A provider may assert a religious or moral objection and deny services to transgender individuals in violation of those patients' rights.

- Public health law authorizes federal agencies to establish communicable disease control policies that may impose requirements on providers related to services, counseling or reporting.[9]

- State laws require pharmacists to fill any legal prescription, even those to which he or she has a moral or religious objection.[10]

- State laws may require that patients receive notice about providers or hospitals that do not cover certain services.[11]

- Existing state laws address the following issues: Advanced directives; abortion, sterilization, and contraception; physician assisted suicide; newborn hearing screening; vaccinations and immunizations; privacy; sexual orientation; and transgender care.

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[8] 45 C.F.R. § 92.206 (stating that healthcare services and health coverage may not be denied because a person's gender identity differs from his/her sex assigned at birth. Providers may not limit a transgender person's access to services ordinarily available to people of only one sex based on the transgender person's sex assigned at birth or gender identity).

[9] 42 U.S.C. § 264. The Public Health Services Act authorizes the Secretary of Health and Human Services to make and enforce regulations necessary "to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession."

[10] Recent state laws and proposed legislation have addressed pharmacists' rights and responsibilities in dispensing contraception/emergency contraception. Some states would allow pharmacists to refuse, on moral grounds, to fill a prescription for contraceptives; other states would require pharmacists to fill any legal prescription for birth control. *See* *http://www.ncsl.org/programs/health/conscienceclauses.htm*

[11] *See* California Health & Safety Code 1363.02 (a) The Legislature finds and declares that the right of every patient to receive basic health information necessary to give full and informed consent is a fundamental tenet of good health policy and has long been the established law of this state. Some hospitals and other providers do not provide a full range of reproductive health services and may prohibit or otherwise not provide sterilization, infertility treatments, abortion, or contraceptive services, including emergency contraception. It is the intent of the Legislature that every patient be given full and complete information about the health care services available to allow patients to make well informed health care decisions.
(b) On or before July 1, 2001, a health care service plan that covers hospital, medical, and surgical benefits shall do both of the following:
(1) Include the following statement, in at least 12-point boldface
type, at the beginning of each provider directory:
"Some hospitals and other providers do not provide one or more of the following services that may be covered under your plan contract and that you or your family member might need: family planning; contraceptive services, including emergency contraception; sterilization, including tubal ligation at the time of labor and delivery; infertility treatments; or abortion. You should obtain more information before you enroll. Call your prospective doctor, medical group, independent practice association, or clinic, or call the health plan at (insert the health plan's membership services number or other appropriate number that individuals can call for assistance) to ensure that you can obtain the health care services that you need."

Recommendations:
The Final Rule should contain guidelines and a more thorough discussion of how the provider conscience regulations will intersect with federal and state laws and discuss how situations will be evaluated when there is a federal or state law that is contrary to the provider conscience regulations. Section 88.8, governing the Proposed Rule's relationship to other laws, clarifies that the Rule is not intended to preempt any Federal, State or local law equally protective of religious freedom and moral convictions. It is not clear how it will be determined whether state laws are, in fact, "equally protective." Clarification is needed whether the Department will defer to state and local regulatory interpretation of whether their laws are equally protective of religious freedom and moral convictions.

The preemption standard seems to create the undesirable consequence of preempting state laws that are protective of patients when those protections conflict with the religious freedom and moral convictions of the health care workforce. The Department should discuss how provider conscience objections can be exercised without taking away the ability of states to regulate areas that are traditionally the subject of state jurisdiction.

The Final Rule should clarify how a health care entity should respond to an employee's refusal to participate or assist in participating in a health service in circumstances addressed by an applicable collective bargaining agreement. Where a health care entity has reached a bargained agreement with a union that addresses how to respond to a represented employee's objection to participating in a medical procedure, the Proposed Rule does not clarify whether that bargained agreement can continue to be enforced.

We appreciate the opportunity to comment on these important issues. Please contact Leah Newkirk at (510) 271-5938 or leah.g.newkirk@kp.org with any questions.

Sincerely,

Anthony Barrueta
Senior Vice President
Government Relations
Kaiser Permanente

Stephen M. Parodi, MD
Associate Executive Director
The Permanente Medical Group
Executive Vice President, External Affairs
The Permanente Federation LLC

Exhibit 93

ALAMEDA COUNTY
HEALTH CARE SERVICES
AGENCY
COLLEEN CHAWLA, Director

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TEL (510) 618-3452
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March 27, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Subject: Docket Number: HHS-OCR-2018-0002
Conscience NPRM: RIN 0945-ZA03
Proposed Rule: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Secretary Azar:

On behalf of the County of Alameda, California, I write today regarding the Department's Notice of Proposed Rule Making (NPRM) that would allow for the Conscience and Religious Freedom division to handle investigations of religious freedom complaints, compliance, and enforcement.

The County of Alameda is committed to providing and supporting services that promote healthy and thriving populations. Our County values and strives to increase access to equity, fairness, and inclusive health services. We appreciate and support efforts to prevent discrimination of health workers, but we are concerned that the proposed rule language could be misinterpreted, allowing for discrimination of those needing essential medical services who could be denied care based on moral or religious convictions of the provider. This denial of care would ultimately perpetuate health care inequalities and health disparities. Additionally, this will deteriorate patient care and puts the health and wellbeing of our residents at risk.

Specifically, our concerns with the proposed rule are the following:

1. **Financial implications –** Our County and community health providers strive to develop effective and efficient ways to provide services at a low cost because adequate health care funding is not provided and oftentimes funding is threatened and/or cut for low-income and indigent individuals. If enacted, the proposed rule would allow for the denial of care and would increase health costs to our County and our providers. Health needs persist. Those who are denied treatment would seek care in emergency rooms and other higher-cost venues. The proposed rule would cause staff shortages. It must also be recognized that many of our community health providers operate on a tight budget and do not have the additional staff on hand to fill in should a colleague refuse to provide care under these regulations. If this rule is implemented, approximately 430,000 individuals in Alameda County enrolled in Medi-Cal could be negatively impacted.
2. **Destroys trust –** Our County and community health providers serve the most in need and vulnerable populations. To effectively serve them, relationships are built and trust is fostered. This proposed rule would destroy the relationships we have developed with individuals that are hard to reach and are unlikely to obtain health services. For example, the County's Health Care for the Homeless Program provides health services to over 9,000 homeless individuals. These clients are facing difficult physical and mental health challenges and denying services will have catastrophic consequences especially those who are suicidal, have substance use disorders (such as opioids), etc.

3. **Endangers public health –** The proposed rule could be a barrier that leads to delays in controlling communicable diseases and endangering public health. For example, recently, there was a Hepatitis A virus outbreak in California and a State of Emergency was declared. Quick response, education, and immunizations are necessary to prevent and control current and future outbreaks. If health workers decline to provide immunizations, containment efforts would be impacted.

The County of Alameda urges the Department of Health and Human Services, Office for Civil Rights to seriously consider our concerns and revise the proposed rule so that it does not restrict access to health care and allow for discrimination that can ultimately cause financial burdens, destroy community trust, and endanger public health.

Sincerely,

Colleen Chawla, Director
Alameda County Health Care Services Agency