EXHIBIT 47

Colorado Consumer Health Initiative

March 27, 2018

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

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

To Whom it May Concern:

The Colorado Consumer Health Initiative (CCHI) is writing in response to the request for public comment regarding the proposed rule entitled, "Protecting Statutory Conscience Rights in Health Care" published January 26, 2018. CCHI is a state-based nonprofit, nonpartisan membership organization dedicated to ensuring access to quality, affordable, and equitable health care for all Coloradans. Through our forty-five member organizations, CCHI represents about 500,000 Coloradans.

This proposed regulation would exacerbate the challenges that many patients—especially women, LGBTQ people, people of color, immigrants and low-income people—already face in getting the timely and affordable health care they need. This rule would expose vulnerable patients to increased discrimination and denials of medically-indicated care by broadening religious health care provider exemptions. Moreover, while protecting health providers who deny care, the rule would provide *no protections for patients who are being denied care—even in emergencies.* As drafted, the rule would not even require that patients be informed of all their potential treatment options and referred to alternative providers of needed care.

This proposal is in direct opposition of the pursuit of "patient-centered care." We urge the administration to put patients first, and withdraw the proposed regulation because of the serious problems enumerated below.

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1. **Expanding religious refusals can exacerbate the barriers to care that LGBTQ Coloradans already face and potentially allow denial of any health care service based on a provider's personal beliefs or religious doctrines.**

LGBTQ people, along with other vulnerable groups around the country, already face enormous barriers to getting the care they need.[1] Accessing quality, culturally competent care, and overcoming outright discrimination is an even greater challenge for those living in areas with already limited access to health providers. The proposed regulation threatens to make access to care even harder, and for some people nearly impossible.

For example, a nationwide 2015 survey of nearly 28,000 transgender adults found that respondents needed to travel much further to seek care for gender dysphoria, than for other services.[2] This means if these patients are turned away or refused treatment, it is much harder—and sometimes simply not possible—for them to find a viable alternative. In a recent study, nearly one in five LGBTQ people, including 31% of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away. That rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider.[3] For these patients, being turned away by a medical provider is not just an inconvenience: it often means being denied care entirely with nowhere else to go.

Existing refusal of care laws (such as for abortion and sterilization services) are already being used across the country to deny patients the care they need[4]. The

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[1] See, e.g., Institute of Medicine, The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding (2011), http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx; Sandy E. James et al., The Report of the U.S. Transgender Survey 93–126 (2016), www.ustranssurvey.org/report; Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* (2010), http://www.lambdalegal.org/publications/when-health-care-isnt-caring; Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2016), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

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

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

[4] *See, e.g., Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/;

proposed rule attempts to expand on these laws. Specifically, the Department and its Office for Civil Rights (OCR) are attempting to require a broad swath of entities to allow individuals to refuse "any lawful health service or activity based on religious beliefs or moral convictions."[5]

This expansive interpretation could lead to provider denials based on personal beliefs that are biased and discriminatory, such as objections to providing care to people who are transgender or in same-sex relationships. In Colorado, 21% of surveyed LGBT Coloradans reported health care workers refused services, and 28% reported their sexual orientation prevented them from receiving needed care. [6]

We are concerned about further enabling care denials by providers based on their non-scientific personal beliefs about other types of health services.

2. **The proposed rule conflicts state and local government efforts to protect patients' health and safety, including their nondiscrimination laws.**

By claiming to allow individuals and institutions to refuse care to patients based on the providers' religious or moral beliefs in such a sweeping way, the proposed rule creates conflicts with hundreds of state and local nondiscrimination laws around the country that apply to health care, including Colorado's own anti-discrimination laws[7]. Moreover, the proposed rule invites states to further expand refusals of care by making clear that this expansive rule is a floor, and not a ceiling, for religious exemption laws.[8]

3. **The regulation lacks safeguards to protect patients from harmful refusals of care, especially in emergency situations.**

The proposed regulation is dangerously silent in regards to the needs of patients and the impact that expanding religious refusals can have on their health. The proposed regulation includes no limitations to its sweeping exemptions that would protect patients' rights under the law and ensures that they receive medically

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Uttley, L., et al, *Miscarriage of Medicine,* MergerWatch and the ACLU (2013), https://www.aclu.org/report/miscarriage-medicine.

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

[6] http://www.one-colorado.org/wp-content/uploads/2012/01/OneColorado_HealthSurveyResults.pdf

[7] http://www.ncsl.org/research/civil-and-criminal-justice/state-public-accommodation-laws.aspx

[8] *See, e.g.*, Rule, *Supra* note 1, at 3888-89.

warranted treatment. Any extension of religious accommodation should always be accompanied by equally extensive protections for patients to ensure that their medical needs remain paramount, and that they are able to receive both accurate information and quality health services.

The expanded religious exemptions in the proposed regulations also conflict with many patient protections in federal laws like the Affordable Care Act and the Emergency Medical Treatment and Active Labor Act. Because the proposed rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

4. **Health care institutions would be required to notify employees that they have the right to refuse care, *but would not be required to notify patients about the types of care they will not be able to receive at that hospital, pharmacy, clinic or doctor's office*.**

The rule sets forth extensive requirements for health care institutions, such as hospitals, to notify employees about their refusal rights, including how to file a discrimination complaint with OCR. The rule requires posting of such notices on the employer's website and in prescribed physical locations within the employer's building. The rule also sets forth the expectation that OCR would investigate or do compliance reviews of whether health care institutions are following the posting rule.[9]

By contrast, the rule contains no requirement that patients be notified of institutional restrictions on provision of certain types of care. Such notification is essential because research has found that patients are often unaware of service restrictions at religiously-sponsored health care institutions. [10]

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

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

Conclusion

The proposed rule goes far beyond established law and most importantly will put the health and potentially even the lives of patients at risk. We urge you to withdraw the proposed rule. The proposed rule will allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care. The proposed rule is discriminatory, violates multiple federal statutes and the Constitution, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons the Colorado Consumer Health Initiative calls on the Department to withdraw the proposed rule in its entirety.

Sincerely,

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survey, Contraception, Volume 96, Issue 4, 268-269,accessed here: http://www.contraceptionjournal.org/article/S0010-7824(17)30235-4/fulltext; a

EXHIBIT 48

California Medical Association
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March 27, 2018

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

Submitted electronically via http://www.regulations.gov

RE: Comments of the California Medical Association: Department of Health and Human Services, Office for Civil Rights RIN 0945-ZA03

Dear Secretary Azar:

On behalf of more than 43,000 physician members and medical students of the California Medical Association (CMA), we appreciate the opportunity to provide comments on the Department of Health and Human Services' (the "Department") proposed rule ("Proposed Rule") on Protecting Statutory Conscience Rights in Health Care.[1] Through a comprehensive program of legislative, legal, regulatory, economic and social advocacy, CMA promotes the science and art of medicine, the care and well-being of patients, the protection of the public health, and the betterment of the medical profession.

CMA supports the comments of the American Medical Association on the Conscience Protections Proposed Rule and offer further comments that address issues that are of particular concern to California physicians. While CMA is a strong advocate for the conscience rights of physicians, we do not believe this Proposed Rule accomplishes its purported aims. We are concerned that the implementation of this Proposed Rule may lead to discrimination that is prohibited under both federal and California law, adversely impact patient access to comprehensive care, and inappropriately insert politics into the patient-physician relationship. Moreover, current federal and California law provide extensive protections for the conscience rights of health care providers, and the supplemental administrative burdens imposed by this rule do not add any meaningful benefit.

By issuing the Proposed Rule and creating a new division within the Office of Civil Rights ("OCR") – the new "Conscience and Religious Freedom Division" – the Department would inappropriately use OCR's limited resources to encourage discrimination in health care and undermine the ability of states to enforce their own conscience and anti-discrimination

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

provisions. For these reasons, CMA urges the Department to withdraw the Proposed Rule in its entirety.

1. **The Proposed Rule Expands the Scope of Existing Conscience Protections to Negatively Affect Access to Care.**

CMA is concerned with the overly broad application of existing conscience protection laws and the expansion of the definitions in the Proposed Rule. The language of the Proposed Rule would allow any entity involved in a patient's care—from a hospital board of directors to the receptionist that schedules procedures to use their personal beliefs to dictate a patient's access to care. The Proposed Rule defines common phrases and words used throughout existing refusals of care laws and civil rights laws in ways that stretch their intended meaning beyond recognition. For example, the definition of "assist in the performance" greatly expands the types of services that can be refused to include "any program or activity with an articulable connection to a procedure, health care service, health program, or research activity."[2] In fact, merely "making arrangements for the procedure," no matter how tangential, would be included in the reach of the Proposed Rule.[3] This means individuals not "assisting in the performance" of a procedure within the ordinary meaning of the term, such as the office scheduler, the technician charged with cleaning surgical instruments, and other medical office and hospital employees, can now assert a new right to refuse care based on their religious and moral convictions. Such an interpretation is potentially disruptive to the normal operations of a medical office or other health care facility and impede the provision of necessary care to patients.

Similarly, the Proposed Rule's definition of "referral" goes beyond any understanding of the term, allowing refusals to provide any information, "by any method, pertaining to a health care service, activity, or procedures[.]" This include information "related to availability, location, training, information resources, private or public funding or financing, or directions" that could help an individual to get the health care service they need.[4] Such an expansive definition could prevent patients from getting information about the availability of comprehensive health care options in their state. CMA believes that these overly broad definitions will result in denial of care and miscommunication to patients without meaningfully advancing physicians' rights of conscience.

Furthermore, the Proposed Rule's new and expanded definitions often exceed, or are not in accordance with, existing definitions contained within the existing laws OCR seeks to enforce. For example, "health care entity" is defined under the Coats and Weldon Amendments to include a limited and specific range of individuals and entities involved in the delivery of health care.

[2] Proposed Rule, 83 Fed. Reg. at 3923.
[3] *Id.*
[4] *Id.* at 3924.

However, the Proposed Rule attempts to combine separate definitions of "health care entity" found in different statutes and applicable in different circumstances into one broad term by including a wide range of individuals, e.g., not just health care professionals, but any personnel, and institutions, including not only health care facilities and insurance plans, but also plan sponsors and state and local governments. This impermissibly expands statutory definitions and will create confusion, impeding patients' access to needed health care services and information.

2. CMA Opposes Discrimination in the Provision of Health Care and Supports Patient Access to Comprehensive Health Care.

CMA is concerned that the Proposed Rule undermines anti-discrimination protections, particularly with regard to reproductive health, sexual orientation, and gender identity. Since 2012, the Office for Civil Rights has interpreted Section 1557 of the Affordable Care Act's[5] sex discrimination prohibition to extend to claims of discrimination based on gender identity or sex stereotypes and accepted such complaints for investigation. Section 1557's protections assist populations that have been most vulnerable to discrimination, including lesbian, gay, bisexual, and transgender individuals, and help provide those populations equal access to health care and health coverage. Such individuals experience discrimination in obtaining health care which lead to lack of preventative care or delayed care.[6] Section 1557 seeks to address factors that impact access to care for certain populations but does not force physicians to violate their medical judgment. Rather, covered entities, including insurers, must "apply the same neutral, nondiscriminatory criteria [used] for other conditions when the coverage determination is related to gender transition."[7]

California law explicitly prohibits discrimination based on sex, sexual orientation, or gender identity,[8] among other factors. California law provides that persons holding licenses under the provisions of the Business & Professions Code, such as physicians, are subject to disciplinary action for refusing, in whole or in part, or aiding or inciting another licensee to refuse to perform the licensed services to an "applicant" (patient) because of any characteristics under the Unruh Civil Rights Act, that is, the applicant's race, color, sex, religion, ancestry, disability, marital

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[5] 45 C.F.R. §§92.2, 92.206, 92.207.

[6] LAMBDA LEGAL, WHEN HEALTH CARE ISN'T CARING: LAMBDA LEGAL'S SURVEY ON DISCRIMINATION AGAINST LGBT PEOPLE AND PEOPLE LIVING WITH HIV (2010). *Forum: How Discrimination Damages Health Care in LGBTQ Communities*, NPR (March, 21, 2018), https://www.npr.org/sections/health-shots/2018/03/21/594030154/forum-how-discrimination-damages-health-in-lgbtq-communities

[7] Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31435 (proposed May 18, 2016) (to be codified at 45 C.F.R. pt. 92).

[8] *See generally*, CAL. CIV. CODE §51 (The Unruh Civil Rights Act) ("All persons within the jurisdiction of this state are free and equal, and no matter what their sex, race, color, religion, ancestry, national origin, disability, medical condition, genetic information, marital status, sexual orientation, citizenship, primary language, or immigration status are entitled to the full and equal accommodations, advantages, facilities, privileges, or services in all business establishments of every kind whatsoever."_

status, national origin, medical condition, sexual orientation, or genetic information.[9] The California Supreme Court has held that physicians' religious freedom and free speech rights do not exempt physicians from complying with the Unruh Act's prohibition against discrimination based on a person's sexual orientation.[10]

California law also prohibits discrimination by any person under any program that receives any financial assistance from the state.[11] Additionally, the California Insurance Gender Nondiscrimination Act (IGNA) prohibits a health plan and insurer from "refusing to enter into, cancel or decline to renew or reinstate a contract because of race, color, national origin, ancestry, religion, sex, marital status, sexual orientation, or age."[12] Sex includes both gender identity and gender expression.[13] The Proposed Rule lays the groundwork to preempt California laws that have been put into place to ensure that patients in the state have access to comprehensive health care. In addition, the Proposed Rule may also conflict with policies of agencies that accredit health care institutions. For example, the Joint Commission, which accredits and certifies nearly 21,000 facilities in the U.S., has required since 2011 that the nondiscrimination policy of every accredited facility protect transgender patients.[14] The Proposed Rule would conflict with existing state laws and accreditation requirements, creating legal confusion for California physicians.

3. CMA Supports Conscience Protections that Promote the Rights of Providers without Negatively Impacting Patient Care.

CMA policy has always sought to balance the rights of patients to access needed health care with the rights of physicians to exercise their conscience. Conscientious refusals occur most commonly in the field of reproductive medicine, and in many areas of the country patients face challenges in accessing reproductive healthcare.[15] Though CMA advocates for access to abortion

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[9] CAL. BUS. & PROF. CODE §125.6

[10] *North Coast Women's Care Medical Group, Inc. v. San Diego County Superior Court* (Benitez) 189 P.3d 959 (Cal. 2008).

[11] CAL. GOV. CODE §11135.

[12] CAL. HEALTH & SAFETY CODE §1365.5; CAL. INS. CODE §10140. *See also,* Dep't. of Managed Health Care, Gender Nondiscrimination Requirements, Letter No. 12-K (April 9, 2013), *available at* http://www.dmhc.ca.gov/Portals/0/LawsAndRegulations/DirectorsLettersAndOpinions/dl12k.pdf; CAL. CODE REGS. tit 10, § 2561.2.

[13] CAL. HEALTH & SAFETY CODE §1365.59(e).

[14] Joint Commission Standards RI.01.01.01, EP29.

[15] *See, e.g.* (2017), NAT'L WOMEN'S LAW CTR., REFUSALS TO PROVIDE HEALTH CARE THREATEN THE HEALTH AND LIVES OF PATIENTS NATIONWIDE (2017), *available at* https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/08/Refusal-to-Provide-Care.pdf; CATHERINE WEISS ET AL., AM. CIVIL LIBERTIES UNION, RELIGIOUS REFUSALS AND REPRODUCTIVE RIGHTS (2002), *available at* https://www.aclu.org/report/religious-refusals-and-reproductive-rights-report; JULIA KAYE ET AL., AM. CIVIL LIBERTIES UNION HEALTH CARE DENIED (2016), *available at* https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf; KIRA SHEPHERD ET AL., PUB. RIGHTS PRIVATE CONSCIENCE PROJECT, BEARING FAITH THE LIMITS OF CATHOLIC HEALTH CARE FOR WOMEN OF COLOR, 1 (2018), *available at* https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

under accepted ethical medical standards, CMA policy provides that no physician should be required to act against their moral principles. Similarly, while CMA supports the training of all OB/GYN residents and appropriate other residents in primary care specialties in the basic skills of performing abortions, CMA also supports the concept of choice for residents in training, allowing each resident to choose whether or not to participate in elective abortions. CMA has prioritized the physician-patient relationship, and seeks to ensure that health care systems do not interfere with physician-patient communications on reproductive health care, and that access to reproductive health care services is preserved. These principles properly preserve the conscience rights of physicians and their role in providing patient care.

American Medical Association (AMA) policy also recognizes that "at times the expectation that physicians will put patients [sic] needs and preferences first may be in tension with the need to sustain moral integrity and continuity across both personal and professional life."[16] However, it recognizes that this freedom is not unlimited: "[p]hysicians are expected to provide care in emergencies, honor patients informed decisions to refuse life-sustaining treatment, and respect basic civil liberties and not discriminate against individuals in deciding whether to enter into a professional relationship with a new patient."[17] Physicians must consider the harm to patients from refusing to provide treatment and whether the patient will be able to access needed treatment from another physician. The AMA also recognizes that physicians must clearly communicate to the patient which services a physician will or will not provide before entering into a physician-patient relationship, as well as inform patients about all relevant options for treatment, even those to which the physician has conscientious objections.[18]

The Committee on Ethics of American College of Obstetricians and Gynecologists (AGOG) has adopted a number of recommendations that "maximize respect for health care professionals' conscience without compromising the health and well-being of the women they serve."[19] Similar to the AMA opinion, the ACOG opinion recommends that physicians give patients accurate and unbiased information, as well as clearly communicate any moral objections they may have. The ACOG opinion further recognizes that physicians have a duty to refer their patients to other providers for services they cannot provide due to reasons of conscience, and to provide such services in an emergency situation where a referral is impossible. ACOG concludes: "Lawmakers should advance policies that balance protection of providers' consciences with the critical goal of ensuring timely, effective, evidence-based and safe access to all women seeking

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[16] American Medical Association, Policy E-1.1.7, "Physician Exercise of Conscience." *Code of Medical Ethics.* Adopted 2016.
[17] *Id.*
[18] *Id.*
[19] American College of Obstetricians and Gynecologists (ACOG*), The Limits of Conscientious Refusal in Reproductive Medicine*, ACOG Committee on Ethics Opinion Number 385, 5. Adopted November 2007. Reaffirmed 2016).

reproductive services."[20] The Proposed Rule falls short of this aim and the principles of CMA and AMA policies by expansively interpreting existing protections without properly balancing the needs of patients and physicians.

4. Current Federal and State Law Protect the Rights of Physicians and Patients

Existing federal and state laws protect the rights of physicians by allowing states to take nuanced positions on the protecting the conscience rights of health care workers, particularly with regard to abortion, sterilization, and aid-in-dying. Section 88.3 of the rule incorporates the extensive existing law protecting the conscience rights of health care providers and institutions, including, among others, the Church Amendments,[21] the Coats-Snowe Amendment[22] and the Weldon Amendment.[23] In addition, the Affordable Care Act includes health care provider conscience protections within the health insurance exchange system. The law provides that "no qualified health plan offered through an exchange may discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions."[24] Regulations implementing the Act further provide that existing laws protecting religious freedom and belief, including provider conscience laws, the Religious Freedom Restoration Act, the ACA's provisions regarding abortion services, and the ACA's preventive health services regulations, continue to apply.[25]

The Proposed Rule's provisions are not only redundant but will have a chilling effect on the enforcement of and passage of state laws that protect access to health care. The preamble of the Proposed Rule discusses at length state laws that the Department finds objectionable, including California's Department of Managed Health Care's requirement that health insurers must cover abortion services.[26] As mentioned in the Proposed Rule, California law requires most health

[20] *Id.*
[21] The Church Amendments, 42 U.S.C. § 300a-7 (2018).
[22] Public Health Service Act, 42 U.S.C. § 238n (2018).
[23] The Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009).
[24] 42 U.S.C. §18023 (2018).
[25] 45 C.F.R. §92.2(b)(2).
[26] *See* Proposed Rule, *supra* note 1, at 3888-89. The health insurers filed a complaint, and OCR found there was no violation of the Weldon Amendment. Letter from OCR Director to Complainants (June 21, 2016), *available at* http://www.adfmedia.org/files/ CDMHCInvestigationClosureLetter.pdf.

plans to cover abortion services,[27] as well as all FDA-approved methods of contraception without cost-sharing.[28]

California law already properly balances the rights of physicians and their patients. California has extensive protections for health care providers that do not want to participate in abortion for moral, ethical, or religious reasons, while protecting women who need emergency care.[29] While religiously affiliated hospitals can also exercise their rights under this provision, they must post a notice of their refusal policy so that patients are properly informed about the care they will receive.[30] California law protects the rights of physicians to "decline to comply with an individual health care instruction of health care decision for reasons of conscience"[31] Additionally, California law allows a religious employer to request an exemption from generally applicable requirements for contraceptive coverage in health plans.[32] Increasing the number of federal rules in this area is both unnecessary and will create confusion for providers and their patients.

CMA has sought to ensure that physicians' rights are protected even in an evolving health care landscape. For example, the End of Life Option Act, passed in 2015, permits individuals suffering from a terminal disease to request life-ending medication under certain circumstances.[33] This bill contains extensive provisions ensuring that health care providers with conscientious objections are not subject to any professional sanctions or legal liability for refusing to participate in actions related to the Act's activities.[34] Adding a confusing and unnecessary layer of federal regulations may prevent states from successfully passing and implementing their own conscience protections. The Proposed Rule would impede the ability of states to craft nuanced solutions, such as those found in the End of Life Option Act, that protect the rights of providers in accordance with states' own values.

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[27] See, e.g., Letter from Michelle Rouillard, Director, Dep't of Managed Health Care, to Mark Morgan, Cal. President, Anthem Blue Cross (Aug. 22, 2014), *available at* https://www.dmhc.ca.gov/portals/0/082214letters/abc082214.pdf. *See also* Cal. Dep't of Health Care Servs., Letter to all Medi-Cal Managed Care Health Plans, All Plan Letter No. 15-020: Abortion Services (Sept. 30, 2015), http://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2015/APL15- 020.pdf; Cal. Dep't of Health Care Srvs., Medi-Cal Medical Services Provider Manual Ch. Abortions at p. 1.
[28] CAL. WELF. AND INST. CODE §14132; CAL. INS. CODE §10123.196; CAL HEALTH AND SAFETY CODE § 1367.25.
[29] CAL. HEALTH & SAFETY CODE §123420.
[30] *Id.*
[31] CAL. PROBATE CODE §4734.
[32] CAL. HEALTH & SAFETY CODE §1367.25
[33] Cal. S.B. 128, Stats. 2016, ch. 1.
[34] CAL. HEALTH AND SAFETY CODE §§ 443.14-443.15.

5. CMA Opposes Unnecessary Administrative Burdens on Physicians

Finally, sections 88.4 through 88.6 of the Proposed Rule impose significant new requirements on physicians, who already face an increasing number of administrative burdens due to federal law and various existing federal program requirements. Under the Proposed Rule, physicians must submit certifications and assurance, post lengthy required notices on their website and in conspicuous physical locations, maintain detailed records, and generally ensure compliance with the new rule.[35] The Department conducts an analysis of the estimated burdens for the Proposed Rule[36] in which it looks at the implementation costs for providers. The estimate includes time for providers to familiarize themselves with the Rule and the cost to hire an attorney to review it; at least four hours of staff time to review the assurance and certification language and underlying laws; four hours of staff time to review policies and procedures and the cost of hiring an attorney to assist in the review; and the costs of printing the notice in any paper documents. These costs are burdensome enough in themselves; this analysis fails to fully consider, moreover, the significant time and resources it takes to continuously implement and enforce such a Proposed Rule, and the numerous other administrative and regulatory burdens physicians already face and the degree to which each additional burden detracts from a physician's clinical practice.[37] Excessive administrative tasks imposed on physicians divert time and focus from providing actual care to patients and improving quality, and may prevent patients from receiving timely and appropriate care. CMA opposes adding additional burdens to physicians that do nothing to improve the quality of patient care and create yet more regulatory hurdles for the practice of medicine.

As discussed above and in the Proposed Rule, federal and state laws already protect health care provider conscience rights.[38] These long-standing provisions of federal law provide sufficient protection to physicians seeking to exercise their conscience rights. Instead of guaranteeing additional protection, this Proposed Rule would negatively impact patient access to care, sanction discrimination in health care settings, and impose increased administrative burdens on physicians, including paperwork requirements and significant staff time with no demonstrable benefit to the provision of health care.

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[35] Proposed Rule, *supra* note 1, at 3928-30.
[36] *Id*. at 3912-15.
[37] *See, e.g* Jessica Davis, *JAMA: EHRs fail to reduce administrative billing costs,* HEALTHCARE IT NEWS (Feb. 21, 2018), http://www.healthcareitnews.com/news/jama-ehrs-fail-reduce-administrative-billing-costs; Alexi A. Wright and Ingrid T. Katz. *Beyond Burnout – Redesigning Care to Restore Meaning and Sanity for Physicians*, 378 NEW ENG. J. OF MEDICINE 308 (Jan. 2018), http://www.nejm.org/doi/full/10.1056/NEJMp1716845
[38] The Church Amendments, 42 U.S.C. §§300a-7 *et seq.* (2018); Public Health Service Act, 42 U.S.C. §236(n)); and the Weldon Amendment (Consolidated Appropriations Act, 2012, Pub.L. No. 112-74, 125 Stat. 786).

Conclusion

Thank you for your consideration. If you have questions, please contact me at jrubenstein@cmanet.org or (916) 551-2554.

Sincerely,

Jessica Rubenstein
Associate Director
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EXHIBIT 49

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March 26, 2018

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

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

Dear Mr. Severino:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DUE PROCESS PROTECTIONS SHOULD BE EXPLICITLY INCLUDED IN THE REGULATIONS.

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

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

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

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

REGULATORY BURDEN SHOULD BE EASED WHEREVER POSSIBLE.

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

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

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

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President

EXHIBIT 50

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Director
Office for Civil Rights
Washington, D.C. 20201

June 21, 2016

SENT VIA U.S. MAIL AND ELECTRONIC MAIL

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Michelle (Shelley) Rouillard, Director
California Department of Managed Health Care
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Re: OCR Transaction Numbers: 14-193604, 15-193782, & 15-195665

Dear Ms. Short, Mr. Bowman, Mr. Mattox, Mr. Sweeney, and Ms. Rouillard:

The Office for Civil Rights (OCR) of the U.S. Department of Health and Human Services (HHS) has concluded its investigation of allegations that the California Department of Managed Health Care (CDMHC) engaged in discrimination under the Weldon Amendment[1] by issuing letters to several health insurers directing them to amend their plan documents to remove coverage exclusions and limitations regarding elective abortions. OCR received three complaints challenging the CDMHC letter, filed on behalf of a religious organization, churches and a

[1] Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, Div. H, Sec. 507(d) (Dec. 18, 2015).

church-run school, and employees of a religiously-affiliated university. The following sets forth the results of our investigation of these complaints.

Background

On August 22, 2014, the Director of CDMHC notified seven California health insurance plans[2] that it had come to CDMHC's attention that each of them had issued insurance contracts that limited or excluded coverage for termination of pregnancies. CDMHC regulates health care service plans under the Knox-Keene Health Care Service Plan Act of 1975 (Act), Cal. Health & Safety Code Sections 1340-1399.864, and its letter directed each health insurer to ensure that its health plans complied with the Act's requirement to cover legal abortions. CDMHC required the insurers to amend plan documents to remove coverage exclusions and limitations for "voluntary" or "elective" abortions and any limitations on coverage to only "therapeutic" or "medically necessary" abortions and to file revised documents within 90 days. A footnote in the letter stated that "no individual health care provider, religiously sponsored health carrier, or health care facility may be required by law or contract in any circumstance to participate in the provision of or payment for a specific service if they object to doing so for reason of conscience or religion."

Implementing regulations of the Federal Health Care Provider Conscience Laws designate OCR as the office to receive complaints alleging discrimination under the Weldon Amendment. 45 C.F.R. § 88.2. OCR investigated each of the three complaints it received about the CDMHC letter, including requesting, receiving, and analyzing a written response to the complaints from CDMHC; collecting additional information from the complainants; interviewing each of the seven health insurers contacted by CDMHC, some on several occasions; and engaging in follow-up conversations with CDMHC.

OCR's investigation found that each of the insurers that received the CDMHC letter had, at the time it received the letter, included coverage for voluntary abortions in plans that it offered; upon receipt of the letter, each amended its plan documents by CDMHC's deadline to eliminate the subject exclusions from any plans that contained them. None of the insurers asserted any objection to offering coverage for voluntary abortion services and none identified any religious or moral objection that it had to such coverage.

OCR's investigation also found that Blue Cross of California (dba Anthem Blue Cross) subsequently sought and received from CDMHC an exemption to allow it to offer a plan excluding elective abortion services for religious employers as defined under California law. Cal. Health & Safety Code Section 1367.25(c)(1). As a result, CDMHC has demonstrated its willingness to authorize insurers to offer products that exclude coverage for elective abortion to such religious employers.

[2] The seven health insurance plans were Aetna Health of California, Inc.; Blue Cross of California, dba Anthem Blue Cross; California Physicians' Service, dba Blue Shield of California; GEMCare Health Plan, Inc., dba ERD, Inc., Physicians Choice by GEMCare Health Plan; Health Net of California, Inc.; Kaiser Foundation Health Plan, Inc., dba Kaiser Foundation, Permanente Medical Care Program; and United Healthcare of California. OCR understands that GEMCare is no longer participating in the commercial insurance marketplace.

The Weldon Amendment

The Weldon Amendment provides:

> (d)(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.
>
> (2) In this subsection, the term "health care entity" includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.[3]

The amendment was passed to protect health care entities covered by the amendment from discrimination where those entities object to abortion on religious or moral grounds. *See State of California v. Lockyer*, 450 F.3d 436, 441 (9th Cir. 2006) ("Congress passed the Weldon Amendment precisely to keep doctors who have moral qualms about performing abortions from being put to the hard choice of acting in conformity with their beliefs or risking imprisonment or loss of professional livelihood").

The amendment applies only to health care entities as defined therein. As the primary sponsor of the amendment, Representative Weldon himself made clear in discussing its scope:

> This provision is intended to protect the decisions of physicians, nurses, clinics, hospitals, medical centers, and even health insurance providers from being forced by the government to provide, refer, or pay for abortions. . . . It explicitly clarifies existing law to state that a health care entity includes a hospital, a health professional, a provider-sponsored organization, a health maintenance organization, a health insurance plan or any other kind of health care facility. It goes on further to state that existing law protects health care entities from discrimination based on three kinds of participation in abortion: performing, training and referring.[4]

Representative Weldon further stated that the health care entities that are protected are those that "choose not to provide abortion services."[5] In making clear that the amendment protects those who object to the provision of abortions, he stated, "[t]he Hyde-Weldon amendment . . . simply states you cannot force the unwilling" to participate in elective abortions. "The amendment does not apply to willing abortion providers."[6]

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[3] Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, Div. H, Sec. 507(d) (Dec. 18, 2015).
[4] 150 Cong. Rec. H10090 (Statement of Rep. Weldon) (Nov. 20, 2004).
[5] *Id.*
[6] 151 Cong. Rec. H177 (Statement of Rep. Weldon) (Jan. 25, 2005).

Representative Weldon also made clear that the health care entities protected under the amendment are those that have objections based on religious or moral grounds:

> [The Weldon Amendment] is a continuation of the Hyde policy of conscience protection. . . . The right of conscience is fundamental to our American freedoms. We should guarantee this freedom by protecting all health care providers from being forced to perform, refer, or pay for elective abortions.[7]

Findings

CDMHC is an agency and instrumentality of the State, and thus an entity to which the terms of the Weldon Amendment apply. The State of California receives federal funding under the Appropriations Act that includes the Weldon Amendment.[8] The seven health insurers to which CDMHC sent the August 22, 2014 letter meet the definition of "health care entity" in the Weldon Amendment, as each is a "health insurance plan." Based on the facts provided to OCR, none of the complainants meets the definition of a "health care entity" under the Weldon Amendment.

By its plain terms, the Weldon Amendment's protections extend only to health care entities and not to individuals who are patients of, or institutions or individuals that are insured by, such entities. In addition, its author, Representative Weldon, made clear both that the amendment protects only those covered health care entities that object to the provision of abortions and that its basic purpose is to protect those entities whose objections are made on religious or moral grounds.

Here, none of the seven insurers that received the CDMHC letter – the entities that are covered under the Weldon Amendment – objected to providing coverage for abortions. All modified their plan documents to cover voluntary abortion in response to the CDMHC letter, and none has indicated to OCR that it has a religious or moral objection to abortion or to providing coverage for abortion in the products it offers. Indeed, as noted above, at the time CDMHC sent the letter, all of the insurers offered plans that covered abortion, demonstrating that they have no religious or moral objection to that procedure. As a result, there is no health care entity protected under the statute that has asserted religious or moral objections to abortion and therefore there is no covered entity that has been subject to discrimination within the meaning of the Weldon Amendment.[9]

We further note that the approach described above avoids a potentially unconstitutional application of the amendment. A finding that CDMHC has violated the Weldon Amendment might require the government to rescind all funds appropriated under the Appropriations Act to

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[7] 150 Cong. Rec. H10090 (Statement of Rep. Weldon) (Nov. 20, 2004).
[8] Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, Div. H, Sec. 507(d) (Dec. 18, 2015).
[9] We reiterate that to the extent that entities whose religious beliefs are not protected under the Weldon Amendment nonetheless object to CDMHC's letter, CDMHC has demonstrated its willingness to authorize insurers to offer products that exclude coverage for elective abortion to entities that qualify as religious employers under California law. *See* discussion of Anthem Blue Cross *supra*. Some employers may also, of course, decide to self-insure; self-insured plans are not subject to the CDMHC policy.

the State of California – including funds provided to the State not only by HHS but also by the Departments of Education and Labor, as well as other agencies. HHS' Office of General Counsel, after consulting with the Department of Justice, has advised that such a rescission would raise substantial questions about the constitutionality of the Weldon Amendment. Specifically, in *National Federation of Independent Business v. Sebelius*, 132 S. Ct. 2566 (2012), the Supreme Court ruled that Congress could not condition a State's preexisting Medicaid funding on the State's compliance with an Affordable Care Act requirement to expand the program to include all low-income adults. The Court reasoned that this threat to terminate significant independent grants was so coercive as to deprive States of any meaningful choice whether to accept the condition attached to receipt of federal funds. Following accepted canons of statutory construction, OCR's approach, which is consistent with the views of the primary sponsor of the amendment, avoids this potentially unconstitutional application of the statute. *See Gomez v. United States*, 490 U.S. 858, 864 (1989).

Accordingly, OCR is closing its investigation of these complaints without further action.

Advisements

The determinations in this letter are not intended, nor should they be construed, to cover any issues regarding CDMHC's compliance with the Weldon Amendment that are not specifically addressed in this letter. It neither covers issues or authorities not specifically addressed herein nor precludes future determinations about compliance that are based on subsequent investigations.

The complainant has the right not to be intimidated, threatened, or coerced by a covered entity or other person because he or she has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing held in connection with a complaint. Please take all necessary steps to ensure that no adverse action is taken against the complainants or any other individual for the filing of this complaint, providing information to OCR, or otherwise participating in this investigation.

Under the Freedom of Information Act, it may be necessary to release this document and related correspondence and records upon request. In the event OCR receives such a request, we will seek to protect, to the extent provided by law, personal information which, if released, would constitute an unwarranted invasion of privacy.

Sincerely,

Jocelyn Samuels
Director, Office for Civil Rights

cc: Gabriel Ravel
Deputy Director, General Counsel
California Department of Managed Health Care