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
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...” 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

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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.” 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.

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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.”

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….“ 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.” 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

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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.”\textsuperscript{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.”\textsuperscript{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.

\textsuperscript{6} 88.7(b)\textsuperscript{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. 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.

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

• State laws may require that patients receive notice about providers or hospitals that do not cover certain services.

• 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                      Stephen M. Parodi, MD
Senior Vice President                Associate Executive Director
Government Relations                 The Permanente Medical Group
Kaiser Permanente                    Executive Vice President, External Affairs
                                      The Permanente Federation LLC