EXHIBIT 11

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Chicago Office
233 North Michigan Avenue, Suite 240
Chicago, IL 60601

Kansas City Office
601 East 12th Street, Room 353
Kansas City, MO 64106

Office for Civil Rights
Midwest Region
Website: http://www.hhs.gov/ocr
Voice - (800) 368-1019
TDD - (800) 537-7697

April 18, 2017

[redacted]

OCR Transaction Number: 17-259696

Dear [redacted]

Thank you for your letter received on January 19, 2017 by the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR). In your complaint, you state that CVS Caremark discriminated against you when it continuously sent you literature describing contraceptives after you advised CVS Caremark that your sincerely held religious beliefs and practices don't allow for the funding of, or association with, contraceptives.

Among other things, OCR enforces Federal civil rights laws that prohibit discrimination in the delivery of health and human services because of race, color, national origin, age, disability, and, under certain circumstances, sex and religion. OCR has also been designated to receive complaints brought pursuant to the Federal health care provider conscience protection statutes, which prohibit recipients of certain HHS FFA from discriminating against health care providers and health care personnel because of their refusal or willingness to participate in certain health care services they find religiously or morally objectionable.

We have carefully reviewed your complaint and we are closing this case without further investigation because you have not raised facts sufficient to support a claim of discrimination on the basis of your religious beliefs or moral convictions under the laws OCR enforces.

OCR's determination as stated in this letter applies only to the allegations in this complaint that were reviewed by OCR. Under the Freedom of Information Act, we may be required to release this letter and other information about this case upon request by the public. In the event OCR receives such a request, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

We regret we are unable to assist you further. Thank you.

Sincerely,

Steven M. Mitchell
Acting Regional Manager

EXHIBIT 12

DEPARTMENT OF HEALTH & HUMAN SERVICES

Voice - (404) 562-7886, (800) 368-1019
TDD - (404) 562-7884, (800) 537-7697
(FAX) - (404) 562-7881
http://www.hhs.gov/ocr/

OFFICE OF THE SECRETARY

Office for Civil Rights, Region IV
61 Forsyth Street, Suite 3B70
Atlanta, Georgia 30303

January 26, 2011

Matthew Bowman, Esq
Alliance Defense Fund
801 G Street N.W., Suite 509
Washington, D.C. 20001

Julia Caldwell Morris, Deputy General Counsel
Sheree Wright, Sr. Associate General Counsel
Vanderbilt University
Office of General Counsel
2100 West End Ave., Suite 750
Nashville, TN 37203

Re: Transaction - 11-122388
Ann Marie Dust v Vanderbilt University

Dear Mr. Bowman, Ms. Morris, and Ms. Wright:

The Office for Civil Rights (OCR) has completed its investigation of the complaint filed against Vanderbilt University. The OCR has jurisdiction over programs and entities that receive Federal financial assistance from HHS in cases involving discrimination based on race, color, national origin, age, disability and, under certain circumstances, sex and religion. OCR also has been designated to receive complaints of discrimination and coercion that violate the Church Amendments, 42 U.S.C. §300a-7, and its implementing regulation, 45 C.F.R. Part 88. As a recipient of Federal financial assistance Vanderbilt University is obligated to comply with 42 U.S.C. § 300a-7 and its implementing regulation.

Issue Presented

The Alliance Defense Fund (Complainant) filed a complaint on behalf of [redacted] (Affected Party) against Vanderbilt University (Covered Entity) on January 11, 2011. The complaint alleged a violation of the Alleged Party's federal rights of conscience under 42 U.S.C. § 300a-7 and was filed with this office pursuant to 45 C.F.R. Part 88. Specifically, the complaint alleges that as a condition to admission to Vanderbilt University's Nurse Residency Program, applicants must in writing, promise that they will assist in termination of pregnancy procedures during their employment in the residency program, or their application for the program will be denied.

Discussion

On January 19, 2011, OCR notified the Covered Entity of the complaint filed against it by telephone. The Covered Entity provided OCR with assurances that it does not require nurses or

others to perform or participate in the performance of termination of pregnancy procedures if it is inconsistent with their religious or moral beliefs. The Covered Entity explained that if an employee raises an objection to participating in the performance of a termination of pregnancy, the employee may request an accommodation.

In order to resolve this matter, the Covered Entity has provided OCR with documentation that it has voluntarily taken the following corrective actions:

1. The Covered Entity emailed a clarification to all active nurse residency candidates [candidates who already submitted an online application and who met the basic qualifications for the position] concerning its policies regarding participation in termination of pregnancy and accommodations for religious beliefs or moral convictions.
2. The Covered Entity has eliminated the previous acknowledgment form from its Nurse Residency Program Application Packet and replaced it with a notice form that clarifies its policies regarding participation in termination of pregnancy and accommodations for religious beliefs or moral convictions.
3. Revised information packets and the clarification were sent to new candidates, including the Affected Party, on January 13, 2011.

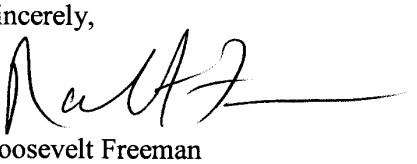
On January 25th, OCR contacted the Complainant. The Complainant, who had expressed satisfaction with the measures taken by the Covered Entity in the [redacted] edition of *The Tennessean,* informed OCR that the Complainant had withdrawn the complaint based on those steps. The Complainant faxed to OCR a copy of the withdrawal letter dated January 12th, which OCR had not previously received.

Based on the foregoing voluntary corrective action, OCR is closing this matter. The closure of this case is not intended and should not be construed to cover any other issues regarding compliance with 45 C.F.R. Part 88 that may exist but were not specifically addressed during our investigation.

OCR shall place no restriction on the publication of the contents of this letter and may release this document and related materials consistent with the Freedom of Information Act, 5 U.S.C Section 522, and its implementing regulation 45 C.F.R. Part 5.

Thank you for your cooperation. If you have any questions, please do not hesitate to contact [redacted].

Sincerely,



Roosevelt Freeman
Regional Manager

EXHIBIT 13

STATE OF WASHINGTON
DEPARTMENT OF HEALTH

March 26, 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, D.C. 20201

The Washington State Department of Health (DOH) appreciates the opportunity to comment on the proposed rule, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," printed in the Federal Register on January 26, 2018 (83 FR 3880). We are specifically responding to the request for feedback on the rule's potential to improve or worsen health outcomes.

The proposed rule significantly broadens the criteria by which people or entities can claim conscience objections to deny patients care, the types of entities that must accommodate their employees' or volunteers' objections, and the types of activities to which an entity can object. This threatens to directly reduce access to essential health care services, especially for vulnerable populations—including those living in rural areas—and thereby worsen health outcomes. In addition, the proposed rule conflicts with program requirements in existing successful HHS programs (e.g., immunizations and family planning) that have been shown to improve outcomes. This change will jeopardize the integrity of and funding for these programs. This would further reduce access to care and lead to poorer health outcomes and wider inequities.

The proposed rule does not appropriately balance the conscience rights of providers with health outcomes of their patients or the public health system's role to ensure access to health care services for *all* people.

For these reasons, we recommend HHS withdraw the proposed rule.

If not withdrawn, we strongly urge HHS to revise the language to:

- Allow entities, including states, health systems, clinics, providers, and insurers, to consider significant public health concerns, such as patient access to care, when managing conscience objections.
- Remove requirements for accommodations when they directly conflict with the statutory requirements of HHS programs as determined by the U.S. Congress.

The rule proposes definitions that broaden the type of entity who can claim a conscience objection and the types of activities for which a moral or religious objection could be made, including referrals. The proposed definitions for "assist in the performance," "health care entity,"

and "referral/refer for," taken in conjunction with one another, significantly broaden the number of entities or persons who have a basis to file a complaint and will lead to significant unintended consequences.

First, the broadening of these definitions will make it difficult for some organizations to manage conscience objections without harming their business operations. Small clinics cannot afford multiple schedulers, billers, or assistants who may raise moral or religious objections, which previously were accommodated only for healthcare providers.

It is also our expectation these expanded definitions would create substantial gaps in access to preventive services and limit referrals to services that are provided elsewhere. These gaps could be especially harmful for vulnerable populations such as women and families with low incomes; people who are lesbian, gay, bisexual, or transgender (LGBT); people of color; and people living in rural or otherwise underserved areas. While 20 percent of the population lives in rural areas, less than 10 percent of physicians practice in rural areas. As a result, many individuals across the U.S. already have limited options to receive medical care, including preventive services such as family planning or vaccinations. If the only provider in an area does not administer vaccines because it is against his or her personal religious beliefs, for example, entire communities could be left vulnerable to devastating infectious diseases. Similarly, all women in a given community could find themselves without access to contraception or other reproductive health care if the only provider in the area asserts moral or religious objections.

Finally, the broadening of these definitions may create confusion or be interpreted in a way that facilitates discrimination against women, low-income individuals, LGBT people, or people of color, under the guise of a conscience objection. These groups already face barriers to care and experience health inequities. The proposed rule could further decrease their access to necessary health care and worsen health outcomes and disparities. This clearly runs counter to the mission of HHS "to enhance and protect the health and well-being of all Americans," and it neglects the responsibility of our public health system to ensure access to quality health services.

The proposed rule conflicts with existing requirements in HHS programs.

Definitions in the proposed rule allow for refusals that conflict with the requirements of some existing HHS programs. These programs have a documented history of providing quality preventive health care services, improving health outcomes, and saving costs. This proposed rule will jeopardize the integrity and continued success of these programs, funding for them, and the delivery of the quality services they provide.

- The Vaccines for Children program requires participating healthcare providers to offer all routinely recommended vaccines to eligible at-risk children (42 USC 1396s(c)(2)(B)(i)). Under this proposed rule change, a person or entity may object to administering a vaccine. States and health care providers may struggle to comply with federal requirements for at-risk children to access and receive the recommended standard-of-care vaccines, because of an expanded number and basis for conscience objections.

- The Title X family planning projects are designed to "consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children" (42 CFR 59.1). The Title X statute specifically requires that "all pregnancy counseling shall be nondirective" (Public Law 112-74, p. 1066-1067), and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination (42 CFR 59.5(a)(5)).

The proposed rule protects individuals and entities who refuse to provide some essential services or provide complete information about all of a woman's pregnancy options. The proposed rule could force the Washington State Department of Health and Title X sub-recipients to choose between violating the Title X requirements or violating the proposed rule.

The Emergency Medical Treatment and Active Labor Act (EMTALA) requires emergency department to provide emergency treatment to *anyone* seeking treatment. The proposed rule could potentially conflict with EMTALA statutory requirements. For example, a hospital or provider could decline service to a woman with possible complications following an abortion. These proposed rules could jeopardize patient lives.

Preserving religious freedom in the U.S. is important, and so is our responsibility as government leaders to ensure access to health care services for all people. Existing laws have sought to preserve balance between conscience objections based on sincerely held religious beliefs and moral convictions, and the needs of patients and the public health. It is imperative to the nation's health and well-being that this rule does the same. Unfortunately, the rule as written fails to strike an appropriate balance, clearly placing the health of patients and the public at risk. I urge you to withdraw it.

Sincerely,

John Wiesman, DrPH, MPH
Secretary of Health

EXHIBIT 14

AAMC

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

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

March 26, 2018

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

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

Dear Mr. Severino:

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

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

The Needs of Patients Should Be Put First

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

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

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

There Is No Demonstrable Need for the Proposed Rule

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

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

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

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

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

Additional requirements include the following:

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

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

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

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

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

Similarly, the ACGME states that:

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

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

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

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

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

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

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

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

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

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

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

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

The Proposed Rule Adds Burdensome Requirements That Have No Commensurate Benefit

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

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[2] Thorburn S, Bogart LM. "African American women and family planning services: perceptions of discrimination," *Women Health*. 2005;42(1):23–39.
[3] Institute of Medicine (US) Committee on Unintended Pregnancy; Brown SS, Eisenberg L, editors. "The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families. National Academies Press (US); 1995. 3, *Consequences of Unintended Pregnancy*. Available from: https://www.ncbi.nlm.nih.gov/books/NBK232137/
[4] Herd P et al., "The implications of unintended pregnancies for mental health in later life," *American Journal of Public Health*, 2016, 106(3):421–429.
[5] Cahill, S. "LGBT Experiences with Health Care," *Health Affairs* Vol. 36, No.4. 2017. Available from: https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.0277

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

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

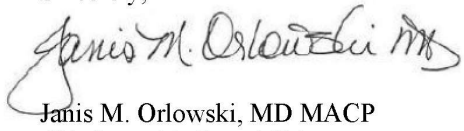
The Department also proposes notice requirements, which includes notice on the funding recipient's website, in prominent and conspicuous physical locations where other notices to the public and notices to the recipient's workforce are customarily posted. The notice is to be posted by April 26, 2018,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

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

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

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

Sincerely,



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

EXHIBIT 15

XAVIER BECERRA
Attorney General

State of California
DEPARTMENT OF JUSTICE

1300 I STREET, SUITE 125
P.O. BOX 944255
SACRAMENTO, CA 94244-2550
Public: (916) 445-9555

March 27, 2018

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

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

Dear Secretary Azar:

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

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

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

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

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

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

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

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

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

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

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

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

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

b. The Proposed Rule Exceeds Congressional Authority

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

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

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

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

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

c. The Proposed Rule is Contrary to Law

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

XAVIER BECERRA
Attorney General of California

EXHIBIT 16

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

March 27, 2018

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

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

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

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

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

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

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

I. Background

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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[5] 42 U.S.C. § 18113(a).

[6] 83 Fed. Reg. at 3923.

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

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

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

[7] 83 Fed. Reg. at 3923.

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

[9] 42 U.S.C. §§ 300a-7(b)-(d).

[10] 42 U.S.C. § 300a-7(e).

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

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

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

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

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

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

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

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

[14] 83 Fed. Reg. at 3923.

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

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

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

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

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

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

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

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

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

[18] 83 Fed. Reg. at 3924.

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

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

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

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

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

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

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[19] 42 U.S.C. § 1395dd.

[20] 42 U.S.C. § 1395dd(e)(1)(A).

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

[22] 42 U.S.C. § 18023(d).

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

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

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

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

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

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

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

[23] 42 U.S.C. § 18114.

[24] *Id.*

[25] *See infra* Section V.

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

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

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

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

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

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

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

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

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

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

[30] 42 U.S.C. § 2000e-2(a).

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

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

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

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

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[31] 29 C.F.R. § 1605.1.

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

[33] 42 U.S.C. § 18023(c)(3).

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

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

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

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

(C) The Proposed Rule Violates the Establishment Clause.

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

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

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

[37] *Id.*

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

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

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

[41] *Id.*

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

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

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

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

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

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[42] 83 Fed. Reg. at 3918.

[43] *See supra* Section III.

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

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

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

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

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

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

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

[49] 83 Fed. Reg. at 3913.

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

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

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

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

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

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

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

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

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

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

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

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

[57] 83 Fed. Reg. at 3905.

[58] 83 Fed. Reg. at 3889.

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

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

(B) The Proposed Rule Violates the Spending Clause.

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

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

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[59] 42 U.S.C. §§ 300a-7(b)-(c)(1).

[60] 42 U.S.C. §§ 300a-7(c)(2)-(e).

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

[62] 83 Fed. Reg. at 3931.

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

[64] *Id.*

[65] 83 Fed. Reg. at 3929.

[66] 83 Fed. Reg. at 3931.

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

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

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

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

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

[68] *Id.* at 576.

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

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

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

[72] 83 Fed. Reg. at 3905.

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

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

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

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

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

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

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

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

[76] 83 Fed. Reg. at 3903.

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

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

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

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

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

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

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

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

[82] *See supra* Section II.

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

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

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

VIII. Conclusion

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

Respectfully submitted,

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

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