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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 babies³, 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 health 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

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.

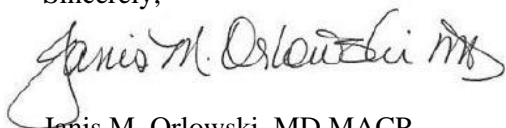
The Department also proposes notice requirements, which includes notice on the funding recipient's website, in prominent and conspicuous physical locations where other notices to the public and notices to the recipient's workforce are customarily posted. The notice is to be posted by April 26, 2018, 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,

A handwritten signature in cursive script, appearing to read "Janis M. Orlowski".

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