

March 27, 2018

Alex Azar
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, SW.
Washington, DC 20201

Re: RIN 0945-ZA03

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Secretary Azar:

On behalf of more than 37,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the draft rule relating to protecting conscience rights in health care, as it affects our practice of emergency medicine and the patients we serve.

While we believe that enforcement of existing federal conscience protections for health care providers is important, we strongly object to this proposed rule and do not believe it should be finalized. As written, it does not reflect nor allow for our moral and legal duty as emergency physicians to treat everyone who comes through our doors. Both by law¹ and by oath, emergency physicians care for all patients seeking emergency medical treatment. Denial of emergency care or delay in providing emergency services on the basis of race, religion, sexual orientation, gender identity, ethnic background, social status, type of illness, or ability to pay, is unethical².

ACEP has specific comments on multiple sections of the proposed rule, which are found below.

Application of Proposals in Emergency Situations

As emergency physicians, we are surprised and concerned that the proposed rule does not in any way address how conscience rights of individuals and institutions interact

¹ 42 U.S. Code § 1395dd - [Examination and treatment for emergency medical conditions and women in labor](#)

² ACEP Code of Ethics for Emergency Physicians; Approved Jan 2017;

<https://www.acep.org/clinical---practice-management/code-of-ethics-for-emergency-physicians>

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with the mandated provision of emergency services. The Emergency Medical Treatment and Labor Act (EMTALA) requires clinicians to screen and stabilize patients who come to the emergency department. Such patients have every right to expect the best possible care and to receive the most appropriate treatment and information about their condition.

Patients with life-threatening injuries or illnesses may not have time to wait to be referred to another physician or other healthcare professional to treat them if the present provider has a moral or religious objection. Likewise, emergency departments operate on tight budgets and do not have the staffing capacity to be able to have additional personnel on hand 24 hours a day, 7 days a week to respond to different types of emergency situations that might arise involving patients with different backgrounds, sexual orientations, gender identities, or religious or cultural beliefs. The proposed rule seems to demand that, in order to meet EMTALA requirements, an emergency department anticipate every possible basis for a religious or moral objection, survey its employees to ascertain on which basis they might object, and staff accordingly. This is an impossible task that jeopardizes the ability to provide care, both for standard emergency room readiness and for emergency preparedness. Emergency departments serve as the safety-net in many communities, providing a place where those who are most vulnerable and those in need of the most immediate attention can receive care. By not addressing the rights and needs of patients undergoing an emergency, the legal obligations of emergency physicians, and the budget and staffing constraints that emergency departments face, this rule has the potential of undermining the critical role that emergency departments play across the country.

Definition of Referrals

Under the proposed rule, health care providers could refuse not only to perform any given health care service, but also to provide patients access to information about or referrals for such services. The Department of Health and Human Services (HHS) defines a referral broadly in the rule as “the provision of any information... by any method... pertaining to a service, activity, or procedure, including related to availability, location, training, information resources, private or public funding or financing, or direction that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity, or procedure, 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.”

Such a broad definition of referral as referenced under the proposed rule’s prohibition could create unintended consequences, such as preventing patients from getting appropriate care now or even in the future. For example, this definition would allow a primary care physician with a moral or religious objection to abortion to deny referring a pregnant woman (who may not have any immediate intentions or desire for an abortion) to a particular obstetrician-gynecologist out of fear that the woman could eventually receive an abortion from that obstetrician-gynecologist, whether at some point in the future of this pregnancy or even for a future pregnancy.

Another situation where this definition could lead to an undesirable outcome for a patient is when a provider has an objection to a patient’s end-of-life wishes expressed in an advance directive. Emergency physicians often treat patients with advanced illness, and ACEP strongly believes that providers should respect the wishes of dying patients including those expressed in advance directives. Most States today allow for a conscience objection and the right to refuse to comply with a patient’s advance directive, but they all impose

an obligation to inform such patients and, more importantly, to make some level of effort to transfer the patient to another provider or facility that will comply with the patient's wishes. However, under this proposed rule, providers with a religious or moral objection to their patients' end-of-life or advanced care wishes would have no obligation to either treat these patients in accordance with their wishes or refer them to another provider who would. Unfortunately, it is unclear how such State laws would interact with or be impacted by the federal enforcement aspects of this proposed rule, were it to be finalized. What is clear however, is that if this proposed rule is finalized, the patient's wishes could be ignored and the patient ultimately loses.

In all, the proposed rule's far-reaching definition of referral will likely cause confusion about when a referral may or may not be appropriate, thereby increasing the chances that patients do not receive accurate or timely information that may be critical to their overall health and wellbeing. The proposed rule therefore threatens to fundamentally undermine the relationship between providers and patients, who will have no way of knowing which services, information, or referrals they may have been denied, or potentially whether they were even denied medically appropriate and necessary services to begin with. Additionally, given that many insurance plans such as HMOs require referrals before coverage of specialty services, the proposed rule could place patients at financial risk based on the refusal of their primary care physician to provide a referral.

The definition of referral is representative of one of the major, unacceptable flaws in the rule: it does not focus on the needs of patients or our responsibility as providers to treat them. The rule does not mention the rights of patients even once or seek comment on how patients can still be treated if providers have a moral and religious objection to their treatment. It seems to imply that these providers have no responsibility to their patients to make sure they receive the best possible care when they are unable to provide it themselves, and there is no process or guidance in place for these providers to still try to serve their patients. The lack of attention to protecting and serving patients is one of the major reasons we believe that the rule should be withdrawn.

Requirement to Submit Written Assurances and Certifications of Compliance

HHS would require certain recipients of federal funding (including hospitals that provide care to patients under Medicare Part A) to submit annual written assurances and certifications of compliance with the federal health care conscience and associated anti-discrimination laws as a condition of the terms of acceptance of the federal financial assistance or other federal funding from HHS. There are several exceptions from the proposed requirements for written assurance and certification of compliance, including physicians, physician offices, and other health care practitioners participating in Part B of the Medicare program. However, "excepted" providers could become subject to the written certification requirement if they receive HHS funds under a separate agency or program, such as a clinical trial.

ACEP finds the lack of clarity around this requirement extremely concerning, as we believe that it will pose a significant burden on health care professionals including emergency physicians.

First, the rule does not account for all the possible circumstances or arrangements that would potentially force "excepted" physicians to file certifications. For example, some emergency physicians who are participating in Medicare Part B also have joined an accountable care organization (ACO) led by a hospital where they see patients. In many cases, the ACO has entered into a contract with the Centers for Medicare

& Medicaid Services (CMS) to be part of the Medicare Shared Savings Program or a Center for Medicare & Medicaid Innovation (CMMI) ACO model. Since the ACO includes both physicians and a hospital and therefore receives payments from both Parts A and B of Medicare, it is unclear whether emergency physicians who are part of the ACO would lose their exemption status. Numerous other alternative payment models besides ACO models are operated by CMS and involve participation from both hospitals and physicians. HHS should clarify whether physicians who are part of these models would still be exempted from the certification requirement.

Second, it is unclear whether clinicians who treat Medicaid patients are exempt from the requirement. In the rule, HHS includes Medicaid in the list of examples for why some exemptions may be appropriate³, but does not actually list reimbursement from the program as one of the exceptions. Some of our members may see only patients with Medicaid, so this lack of clarity is of great concern to them.

Third, ACEP is concerned about the cost-burden that this proposal will have on the hospitals, free-standing emergency departments, and emergency physicians who are subject to the requirement. CMS estimates that the assurance and certification requirement alone could cost health care entities nearly \$1,000 initially and \$900 annually thereafter to sign documents, review policies and procedures, and update policies and procedures and conduct training. This substantial cost is on top of the cost of posting a notice, which is estimated to be \$140 per entity. Since emergency physicians by law must provide services to patients regardless of their insurance status, their total reimbursement, if any, rarely covers the full cost of providing the services. By adding more burdensome government mandates that emergency departments must cover out of their own constrained budgets, the proposed rule could potentially jeopardize the financial viability of the emergency care safety net. While we believe the proposed rule should be withdrawn because it is so problematic, in the event the rule is finalized, ACEP requests that at minimum emergency departments, and the physicians and other health care providers that furnish care within them, be exempt from the written assurances and certifications of compliance requirement.

Notice Requirement

The proposed rule requires all health entities to post a notice on their websites and in locations in their organizations where public notices are typically posted. This notice advises people about their rights and the entity's obligation to abide by federal health care conscience and associated anti-discrimination laws. The notice also provides information about how to file a complaint with the Office of Civil Rights within HHS. The rule requires entities to use a prescribed notice, found in "Appendix A" of the rule, but seeks comment on whether to permit entities to draft their own notices.

ACEP objects to this posting requirement. Beyond our concerns with the burden of having to adhere to another government-imposed mandate as discussed above, we also are troubled by the fact that the notice in no way addresses the needs of patients or our responsibilities as providers to treat them. It does not provide any information about the fundamental rights of patients to receive the most accurate information and best available treatment options for their conditions. We therefore have grave concerns about posting the notice as currently drafted.

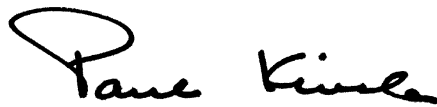
³ On pages 73- 74 of the proposed rule, HHS states "Furthermore, the Department believes that, due primarily to their generally smaller size, several of the excepted categories of recipients of Federal financial assistance or other Federal funds from the Department are less likely to encounter the types of issues sought to be addressed in this regulation. For example, State Medicaid programs are already responsible for ensuring the compliance of their sub-recipients as part of ensuring that the State Medicaid program is operated consistently with applicable nondiscrimination provisions."

It is also unclear whose exact responsibility it is to post the notice(s). Most emergency physicians are employed by a group independent from the hospital that houses the emergency department where they see patients. Therefore, would the hospital's posted notice be sufficient, or would the group that the hospital's emergency physicians are employed by need to also take on this responsibility as a separate entity, with a separate, additional posting in the emergency department?

If so, posting this notice in the emergency department could potentially be considered a violation of EMTALA. EMTALA requires providers to screen and stabilize patients who come to the emergency department. Therefore, notices that could potentially dissuade patients from receiving care that is mandated by Federal law cannot be posted publicly in the emergency department. Since the notice proposed in this rule explicitly states that providers have the right to decline treatment for patients based on their conscience, religious beliefs, or moral convictions, some patients may become concerned that they would not be treated appropriately and decide to leave before they treated—a violation of EMTALA.

In light of the above concerns, ACEP urges the Department to withdraw the proposed rule. We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at jdavis@acep.org.

Sincerely,

A handwritten signature in black ink that reads "Paul D. Kivela". The signature is written in a cursive, flowing style.

Paul D. Kivela, MD, MBA, FACEP
ACEP President