

September 23, 2008

Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Building, SW
Washington, DC 20201

RE: RIN 0991-AB48, Provider Conscience Regulation

Dear Secretary Leavitt:

On behalf of the American Hospital Association (AHA) and our more than 5,000 member hospitals, health systems and other health care organizations, and our 38,000 individual members, we appreciate the opportunity to comment on the Department of Health and Human Service's (HHS) proposed rule on provider conscience protections.

The AHA firmly believes that health care workers should not be required to provide services that run counter to their personal convictions. As employers, we have a responsibility to ensure that our employees' beliefs and convictions are respected in the workplace. We have an obligation to make reasonable accommodations to protect our employees' fundamental liberty in exercising those personal beliefs and convictions. At the same time, we as providers have an obligation to our patients; patients must be able to get the care they need, when they need it. It is therefore imperative that, to achieve this important balance, health care professionals work together to ensure that alternatives are provided so patients have access to the services they need.

Subsequently, as to the proposed rule, we have identified several issues that cannot be properly analyzed in the short 30-day comment period. Because these issues are of such significance to the hospital field and the patients we serve, we request that the proposed rule be withdrawn to allow for a longer, deliberative process. This letter outlines several of the issues that have raised concern.

Administrative Burden

The proposed rule requires a new written certification process for any entity, such as a hospital, and any sub entity of that hospital that receives HHS funds. The written documentation certifies compliance with the Church Amendments, Public Health Service



Act Section 245, and the Weldon Amendments which, taken as a bloc, allow for the protection of individuals refusing to conduct health care procedures to which they have a moral objection. The hospital must collect, maintain, and submit written certifications for themselves and all sub entities that receive HHS funds through them.

This proposed rule does not provide sufficient analysis, in terms of staff time and cost, to fully assess the administrative burden this new certification process would impose on hospitals.

False Claims Act

The preamble language of the proposed rule suggests that the agency is considering explicitly tying payment to compliance with the certification requirement. Hospitals' experience, however, is that such requirements bring the False Claims Act and its whistleblower provisions to bear on enforcement of rules otherwise enforced by the agency. As a result, the introduction of the False Claims Act into this new certification process opens hospitals to the possibility of unnecessary yet costly litigation. Even where the Department of Justice (DOJ) would not pursue an action based on a mere mistake or temporary non-compliance with a rule or regulation, the *qui tam* provisions of the statute empower whistleblowers to pursue these same cases. As such, any certification requirement, and particularly one tied directly to payment, substantially increases the opportunity for lawsuit abuse and creates an environment for contingent fee attorneys to force hospitals to defend against additional frivolous and burdensome lawsuits. We strongly urge HHS to coordinate the analysis of any new certification requirement with DOJ and, to the extent that requirement would be intended to implicate any payment or payments received by a hospital or other provider of health care services, that the affected payments be identified specifically in a proposed rule subject to notice and comment in the ordinary course. Punitive False Claims Act litigation in federal court is too costly and blunt an instrument to decide such policy questions.

Access to Needed Services Defined

The definitions of "health care service program" and "health care service," to which an individual can find a moral objection, are very broad and potentially impinge on a patient's access to needed health care services. The preamble states that "health care service program" should be understood to include any activity related in any way to providing medicine, health care, or any other service related to health or wellness, and that "health care service" means any service so provided.

The preamble also defines, very broadly, the types of individuals that may be involved in an objectionable procedure. The preamble provides an example of a health care worker who autoclaves (sterilizes) surgical instruments used in an objectionable procedure as someone that "assists in the performance" and is thereby protected under the provider conscience clause. The preamble language further defines that any activity with a reasonable connection to the objectionable procedure, such as referrals and training, can also be considered objectionable. This broad definition of "assist in the performance"

suggests that any individual invoking the conscience clause protections is under no obligation to refer the patient to other practitioners, pharmacists or hospitals from whom the patient could receive care. The AHA objects to any proposal that releases a practitioner, for any reason, from an obligation to provide or assist patients with a referral or other information that would allow the patient to receive needed health care services.

The definitions for objectionable health care services and individuals that assist in objectionable procedures is so broad that hospitals have no reasonable way of planning to ensure that patients have access to the health care services they need. Hospitals and their emergency departments are complex entities; as the proposed rule is written, it would be extremely difficult for hospitals to anticipate all the scenarios under which a health care worker might invoke the provider conscience clause. As a result it would be impossible for hospitals to make the staffing arrangements needed to ensure access to those services. The AHA is concerned that access to services for patients may be significantly hampered by the current definitions of this rule.

Compliance with State and Federal Laws

The proposed rule does not speak to the many state and federal laws that require hospitals to provide certain services. For example, several states have passed laws that require hospital emergency departments to administer Plan B drug treatment for victims of rape. How does the new certification process intersect with such a mandate? In addition, the Medicaid program provides coverage for prescription contraceptives. How does the written certification anticipate hospitals' efforts to comply with such federal Medicaid requirements?

Loss of Federal Funds

This proposed regulation creates a new certification process to enforce the myriad of federal provider conscience protections. Compliance failures bring with it severe penalties – loss of federal funds. The AHA believes that the loss of federal funds is too high a price to pay, particularly for a certification process that is not well defined or articulated. Hospitals and the patients they serve would potentially be put at risk.

Conclusion

We strongly believe that policies addressing provider conscience clause issues are best left to local health care leaders at the local hospital level. However, if new enforcement policies are deemed necessary at the national level then they should be debated in a far more deliberative process than the 30-day comment period allows. Additional time is critical to addressing the issues raised in this letter, so that the proposed policy changes are not made without consideration of how they will affect patients' access to the care they need.

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We therefore, again, request that this proposed rule be withdrawn to allow for a more deliberative process so that these many and significant issues can be fully analyzed.

I look forward to working with you and your staff on the issues we have identified. Please feel free to contact me or Molly Collins Offner at mcollins@aha.org or 202-626-2326.

Sincerely,

Rick Pollack
Executive Vice President