

April 8, 2009

Charles E. Johnson
Acting Secretary
Department of Health and Human Services
200 Independence Building, SW
Washington, DC 20201

RE: RIN 0991-AB48, Rescission of Provider Conscience Regulation

Dear Acting Secretary Johnson:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 38,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Department of Health and Human Services' (HHS) rescission of the final 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 are respected in the workplace and an obligation to make reasonable accommodations to protect our employees' fundamental liberty in exercising those personal convictions. At the same time, we have an obligation to our patients – patients must be able to get the care they need, when they need it. Therefore it is imperative that, to achieve this important balance, health care professionals work together to ensure that alternatives are provided so that patients can access the services they need.

We have several serious concerns with the final rule. This letter outlines those issues. Because these issues are of such significance to the hospital field and the patients we serve, we request that the final rule be withdrawn to allow for a longer, more deliberative process to determine if rulemaking is necessary.

ADMINISTRATIVE BURDEN

The final 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 various federal statutes that allow for the protection of individuals refusing to conduct health care procedures to which they have a moral objection. For hospitals, the new



certification requirement means they must collect, maintain and submit written certifications for themselves and all sub-entities that receive HHS funds through them. The final 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 and the discussion of written comments in the final rule suggest HHS' interest in explicitly tying payment to compliance with the certification requirement. In our experience, requirements of this nature bring with it 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 and 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(s) received by a hospital or other health care provider, 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 final rule addresses these concerns in its review of written public comments, but HHS chose not to mitigate them in any way. The final rule defines the scope of "health care service program" to include "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded by the Department, which may include components of programs operated by State or local governments." The final rule notes that a definition for "health care services" is unnecessary since it is self-explanatory.

The proposed rule preamble defines, very broadly, the types of individuals that may be involved in an objectionable procedure. It provides a further 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. And the proposed rule preamble language defines that any activity with a reasonable connection to the objectionable procedure, such as referrals and training, can also be considered objectionable. While the final rule addresses concerns raised regarding the broad definition of "assist in the performance," it affirms the proposed rule stance by stating that "the definition would require a health care facility to apply protections to all of its employees and contractors no matter how far removed..."

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 final rule notes that “Providers who object to... a particular health service may provide information on other options, if asked, but are under no obligation to do so.” We object to any proposal that releases a practitioner, for any reason, from an obligation to provide or assist a patient 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 are 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 final 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. We are 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 final 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 rape victims. 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? The final rule addresses these questions by stating: “The Department does not operate its programs in conflict with the existing federal protections being further implemented by this rule.” With regard to state law, the final rule avoids a direct response by stating the following: “This rule does not change federal policy regarding the conscience rights of health care providers, or create new rights, but simply seeks to ensure that recipients of Department funds are aware of the existing conditions that apply to the receipt of these funds. As such, States should already be aware of these existing protections, and should ensure that they do not take actions that would violate these established federal protections.” For the hospital, that must comply with a myriad of state and federal laws regarding patient care, the final rule simply offers no clarity as it relates to meeting the dual responsibilities of the new requirements imposed by this final rule and existing state and federal laws. Hospitals are largely left on their own to figure it out.

LOSS OF FEDERAL FUNDS

This regulation creates a new certification process to enforce myriad federal provider conscience protections. Failure to comply can bring severe penalties – the loss of federal funds. We believe 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 potentially would be put at risk.

Charles E. Johnson

April 8, 2009

Page 4 of 4

CONCLUSION

We strongly believe that policies addressing provider conscience clause issues are best left to local health care leaders at the 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 to ensure that any policy changes are made with the full consideration of how they will affect patients' access to needed care.

Therefore, we again request that this final rule be withdrawn to allow for a more deliberative process so that these issues can be fully analyzed.

I look forward to working with you and your staff on the issues we have identified. If you have any questions about our comments, please feel free to contact me or Molly Collins Offner at mcollins@aha.org or (202) 626-2326.

Sincerely,

Rick Pollack
Executive Vice President