

June 3, 2014

Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II [CMS-3267-F]

Dear Administrator Tavenner:

On behalf of the physician and medical student members of the American Medical Association, I write to express our extreme disappointment with the Centers for Medicare & Medicaid Services (CMS) final rule entitled *Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II [CMS-3267-F]*. This rule makes unprecedented changes to the Medicare hospital Conditions of Participation (CoPs) that will dramatically alter the make-up and efficacy of hospital medical staffs nationwide.

As we evaluate the lawfulness of CMS' significant new regulatory actions, revisions, and interpretations in this final rule, we strongly urge CMS to delay the effective date of July 11, 2014. This date does not allow adequate time for CMS to clarify its ruling nor for medical staffs to be educated about the major ramifications of the rule and duly amend their bylaws.

According to CMS' discussion and the final regulations in CMS-3267-F, CMS has adopted what amounts to a sea change in the manner by which medical staffs nationwide are allowed to operate under the hospital CoPs, compared with longstanding rules in force since the inception of the hospital CoPs. Specifically, multi-hospital systems may now have a single, integrated medical staff for the hospital system at large, and are no longer required to have a medical staff structure at each individual hospital.

As the AMA has repeatedly emphasized in past communications to CMS on this issue, we think that this is an ill-conceived policy that will disenfranchise physicians and hinder their input into hospital programs, especially for those physicians in rural or geographically distant hospitals.¹ We have also expressed

¹ December 23, 2011 Letter to CMS regarding "Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation" [CMS-3244-P] signed by AMA and 34 national medical specialty and 47 state medical societies; April 8, 2013 AMA Letter to CMS regarding "Medicare and Medicaid Programs; Part II—Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction" [CMS-3267-P].

serious concerns about the negative effects that this structure may have on patient care as well as the negative repercussions for system-wide care coordination activities.

The AMA is deeply concerned that CMS' timeline to implement these changes is woefully inadequate. In addition, a number of issues remain unclear and require further interpretation. **As CMS mulls these issues, we strongly request that CMS delay enforcement of this rule until at least May 12, 2015, one year after publication of the final rule:**

- (1) **Initiation.** CMS provides that medical staffs may opt-in or opt-out of the single integrated medical staff structure at the behest of the multi-hospital system.² The question of whether a medical staff may self-initiate the formation of a single integrated medical staff remains unclear. While the AMA strongly disagrees with CMS' new policy to allow a single integrated medical staff structure for a multi-hospital system, we think it is unconscionable to permit the medical staff to opt-in or opt-out solely at the behest of the multi-hospital system. We wonder why, if CMS thinks there are many good reasons for a medical staff to integrate upon the initiation of the multi-hospital system, medical staffs may not also be positioned to self-initiate an integrated structure. Clarity on this point is needed.
- (2) **Licensure.** Some medical staffs require that each member of the medical staff be licensed in the state in which the hospital provides services. In large, multi-state hospitals, will physicians who become a part of a single integrated medical staff be required to be licensed in each state in which the hospital provides services? As state licensure conveys rules, responsibilities, and legal standards unique to each state, this could create significant logistical issues and add to physicians' administrative burden and is an issue that requires clarification.
- (3) **Peer review.** CMS' new policy permitting a system-wide medical staff for a multi-hospital system creates the possibility that a physician could be subject to peer review by a system-wide medical staff that has little familiarity with the standard of care or needs in the physician's community. In addition, states differ as to protections they provide governing peer review. Has CMS considered the question of which state's peer review laws will prevail in cases where there is such a disparity? Could an integrated system pick and choose peer review laws it will comply with from among all the states where it has hospitals?
- (4) **Opt-in/opt-out.** We appreciate that CMS sought to create a middle-ground approach by requiring that multi-hospital systems have medical staffs at each individual hospital either opt-in or opt-out to a single integrated medical staff model. We wonder how this will work in practical terms. Must the hospital seek the participation of each medical staff within the system? Or can they pick and choose which medical staffs they want to work with, and leave the others out? Can a medical staff opt-in, in January 2016, and then opt-out in July 2016? What is the process for opting in and opting out? What manner of majority is needed? Opting in would require substantial revisions to the medical staff bylaws, which generally requires a two-thirds vote. So will it actually take more than a majority to opt-in in these cases? Or does CMS propose to invalidate or allow governing bodies to override medical

² 42 CFR § 482.22(b)(4).

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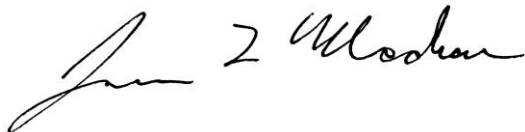
staff bylaws (which in many states are considered a legally binding contract between the hospital and the medical staff)?

CMS' current timeline for implementation gives a significant advantage to the multi-hospital systems. It does not allow for adequate time to educate medical staffs around the country of the new changes. While the AMA recognizes that the rule allows, but does not require, implementation on July 11, 2014, it is certain that many multi-hospital systems will aggressively pursue the implementation of a single integrated medical staff model at the earliest hour. Most medical staffs are unaware of or unprepared for the impending decision to either integrate into a single model or opt-out, and will undoubtedly be ill served by the expediency of these requests. CMS should give medical staffs both clarifying guidance as well as more time to understand and explore these issues.

It is of the utmost urgency, therefore, that CMS act immediately to delay the implementation of this final rule until May 12, 2015 to give medical staffs adequate time to ascertain the legal and practical ramifications of this rule.

Thank you for the opportunity to express our serious concerns about these issues. Should you have any questions about this letter, please contact Cybil Roehrenbeck, Assistant Director, Federal Affairs at cybil.roehrenbeck@ama-assn.org or 202-789-8510.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large initial "J" and a stylized "M".

James L. Madara