

July 1, 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:

The undersigned organizations 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. We understand that in a recent letter to the American Medical Association (AMA), CMS declined to delay the effective date of its revisions to the medical staff CoP. We strongly disagree with this decision and urge CMS to reconsider. **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 physicians have 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 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.

We are 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**

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 81 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].

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 we strongly disagree 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 require 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 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 we recognize 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

² 42 CFR § 482.22(b)(4).

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.

Sincerely,

American Medical Association
American Academy of Dermatology Association
American Academy of Emergency Medicine
American Academy of Hospice and Palliative Medicine
American Academy of Ophthalmology
American Academy of Orthopaedic Surgeons
American Academy of Otolaryngology—Head and Neck Surgery
American Association for Hand Surgery
American Association of Neurological Surgeons
American Clinical Neurophysiology Society (ACNS)
American College of Cardiology
American College of Emergency Physicians
American College of Mohs Surgery
American College of Radiology
American College of Surgeons
American Orthopaedic Foot and Ankle Society
American Osteopathic Academy of Orthopedics
American Osteopathic Association
American Psychiatric Association
American Shoulder and Elbow Surgeons
American Society for Surgery of the Hand
American Society of Dermatopathology
American Society of Echocardiography
American Society of Interventional Pain Physicians
American Spinal Injury Association
American Urological Association
College of American Pathologists
Congress of Neurological Surgeons
J. Robert Gladden Orthopaedic Society
Musculoskeletal Tumor Society
National Association of Medical Examiners
Orthopaedic Trauma Association
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society of Critical Care Medicine
Society of Interventional Radiology

Medical Association of the State of Alabama
Arizona Medical Association
Arkansas Medical Society
California Medical Association
Colorado Medical Society
Connecticut State Medical Society
Medical Society of Delaware
Medical Society of the District of Columbia
Florida Medical Association Inc
Medical Association of Georgia
Hawaii Medical Association
Idaho Medical Association
Illinois State Medical Society
Indiana State Medical Association
Kansas Medical Society
Kentucky Medical Association
Louisiana State Medical Society
Maine Medical Association
MedChi, The Maryland State Medical Society
Massachusetts Medical Society
Michigan State Medical Society
Minnesota Medical Association
Mississippi State Medical Association
Missouri State Medical Association
Montana Medical Association
Nebraska Medical Association
Nevada State Medical Association
Medical Society of New Jersey
New Mexico Medical Society
Medical Society of the State of New York
North Carolina Medical Society
North Dakota Medical Association
Ohio State Medical Association
Oklahoma State Medical Association
Oregon Medical Association
Pennsylvania Medical Society
Rhode Island Medical Society
South Carolina Medical Association
South Dakota State Medical Association
Tennessee Medical Association
Texas Medical Association
Utah Medical Association
Vermont Medical Society
Medical Society of Virginia
Washington State Medical Association
West Virginia State Medical Association
Wyoming Medical Society