American Hospital Association

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Submitted Electronically

Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: Final Rule on Conditions of Participation Published May 16, 2012

Dear Ms. Tavenner:

The May 16 final rule making changes to the hospital and critical access hospital (CAH) Medicare & Medicaid Conditions of Participation (CoP) included two revisions that surprised and greatly concern hospitals and other interested stakeholders. These revisions – the new governance requirement to include a member of the medical staff on the governing board of the hospital and the reinterpretation of the existing medical staff provision to prohibit a health system from having a single, integrated medical staff serving more than one hospital – represent substantive policy changes in the CoP.

CMS did not include either of these changes in the notice of proposed rulemaking (NPRM) issued October 24, 2011. As a result, hospitals and other stakeholders had no notice that CMS was considering adopting these revisions and could not adequately comment on them. Therefore, CMS's inclusion of these substantive policy changes only in the Final Rule violated the *Administrative Procedure Act* (APA). The APA promotes public participation in the rulemaking process to facilitate more informed agency decision making by establishing notice and comment procedures which an agency typically meets by publication in the *Federal Register* of a notice of proposed rulemaking. However, under the APA, the notice is adequate only if it "apprises interested parties of the issues to be addressed in the rulemaking proceeding with sufficient clarity and specificity to allow them to participate in the rulemaking in a meaningful and informed manner." (*Am. Med. Ass'n v. United States*, 887 F.2d 760, 767 (7th Cir. 1989)).

Had these substantive changes been proposed properly, they would have generated significant opposition from hospitals during the public comment process. Accordingly, **we urge you to immediately rescind from hospitals the requirement that a member of the medical staff serve on the hospital board. We also urge you to retract the final rule's preamble statement interpreting the current CoP medical staff requirement to mean that every hospital, regardless of whether it is a part of a multi-hospital system, must have its own, independent medical staff.**

REQUIRING A MEDICAL STAFF MEMBER ON THE GOVERNING BOARD

CMS for the first time in the May 16 final rule added new regulatory language that requires a hospital's governing body to include at least one medical staff member. By adding the new requirement solely in the final rule, CMS violated the APA requirement to provide adequate notice of the issues to be addressed in the rulemaking. Through an adequate notice of the change and a proper invitation for public comment, CMS would have learned that, although many hospitals already have a member of their medical staff on their governing board, others – for important reasons – do not. And, in some cases, by law, they cannot.

CMS's October 2011 proposed rule failed to provide sufficient clarity and specificity about potential changes to the composition of the governing body, as the APA requires. The new requirement coming solely in the final rule is not the "logical outgrowth" of any statement made in the proposed rule and could not have been anticipated as an issue for comment by anyone reading the proposed rule. The NPRM proposed no changes in the language of the regulatory text, nor did CMS make any statement that would have hinted that the agency was contemplating any change to dictate the specific composition of a governing body, including that a member of the medical staff be a member of the governing board of every hospital or health system. In the proposed rule, CMS stated only its intent to "revise and clarify the governing body requirement to reflect current hospital organizational structure, whereby multi-hospital systems have integrated their governing body functions to oversee care in a more efficient and effective manner" and, accordingly, proposed specific regulatory language to precisely – and only – do that. CMS itself characterizes its governing body proposal from the proposed rule as "allow[ing] for a single governing body within a multi-hospital system," in the final rule's preamble discussion, effectively acknowledging the real limits of the notice provided by the October rule.

CMS specifically states in the final rule that it added the requirement for medical staff representation on the governing body at the suggestion of several commenters. However, CMS's reliance on comments from a third party on a proposed rule does not satisfy the APA's requirement for federal agencies to provide appropriate notice and opportunity for comment. Rather, the agency itself must satisfy the notice requirement. (*Small Refiner Lead Phase-Down Task Force* v. *EPA*, 705 F.2d 506,549 (D.C., Cir. 1983) (explaining that "the EPA must itself provide notice of a regulatory proposal. Having failed to do so, it cannot bootstrap notice from a comment.")).

CMS's failure to provide adequate notice of the change effectively prevented the agency from hearing from the many public and private sector hospitals that are adversely affected by the new requirement and properly considering their comments. For example, the governing boards of many public hospitals are directly elected and would not meet the requirement unless a physician decides to run for the hospital's board/commission and is successful in that campaign. In other cases, the county council or other elected officials are empowered to appoint the trustees of their publicly owned hospitals or hospitals that were once publicly owned, but are now not-for-profit. They have the responsibility to choose individuals who can best fulfill the fiduciary responsibilities for these important public hospitals based on a variety of characteristics, but may not choose an individual from the hospital medical staff as the person to fulfill those duties. In Iowa, the trustees of county public hospitals are elected, but Iowa law specifically prohibits "[a] person or spouse of a person with medical or special staff privileges in the county public hospital" from serving as a trustee for a county public hospital. In other instances, the regents of public universities are empowered to serve as the governing board of the associated university hospitals and are chosen for that role based on their ability to oversee that entire university, not just for their expertise in providing hospital care. Further, investor-owned hospitals have governing boards selected by their investors; it is a right and responsibility of the owners to select those who govern the organization and not appropriate for an agency to interfere with the choices made by the investors in a privately held company. Because these hospitals would fail to meet a CoP by not having a medical staff member on their governance bodies, they could inappropriately lose their status as Medicare-participating hospitals, leaving Medicare and Medicaid beneficiaries without access to important sources of hospital care in their communities.

CMS suggests that it has adopted the new requirement to ensure open lines of communication between the governing board and the medical staff leadership. However, an adequate notice and comment process would have uncovered that there are many other effective strategies for ensuring communication. We agree that having an open and effective method of communication between the medical staff and the organizational leadership is critically important to the organization and its patients. But we believe that CMS's substitution of its own judgment about how to accomplish this goal without thorough and considered public comment has resulted in a significantly ill-informed policy with which many hospitals will be unable to comply.

Had CMS properly informed the public of such a contemplated change, the agency would have been deluged with reasons why this change is either unworkable or ill-advised for hospitals and health systems. Affected hospitals could have raised a number of important policy considerations, such as:

- Whether CMS has the authority and understanding of individual hospitals' organization and circumstances to be able to dictate who should be on the organizational board that has the fiduciary responsibility for guiding it;
- The impediments for organizations that have boards that are elected, appointed or otherwise selected by the members of the communities they serve, the duly elected officials of those communities or other public sector officials, or the private shareholders who own the company;

- The challenges for organizations whose medical staffs are composed of individuals who are employed by the organization in dealing with the inherent conflicts of interest that would arise from having an employee on the board;
- The challenges organizations whose medical staff members practice at competing hospitals would have in dealing with the inevitable conflicts of interest; and
- The impediments to communication between the board and the medical staff leadership in places where sunshine laws preclude any two members of a board from conversing about hospital business without appropriate public notice and access.

The governing body requirement for medical staff participation should be rescinded immediately.

THE MEDICAL STAFF PROVISION ABOUT-FACE

In a surprising and impermissible about-face, CMS concludes in the final rule's *preamble* discussion that the unchanged language of the medical staff CoP "will continue to [be interpreted] to require that each hospital, regardless of whether it is a part of a multi-hospital system, have a single and separate medical staff, as a matter of CMS policy." This interpretation contradicts the entirely lucid discussion in the proposed rule, which stated:

> We do not believe that the current language Medical Staff CoP language implies that we require a single and separate medical staff for each hospital within a multi-hospital system. Therefore, we have retained the current requirement without revision.

At no time has CMS proposed or made any changes to the *actual* language of the CoP for medical staff, which does *not* prohibit the use of a unified medical staff.

In an attempt to explain this about-face in the final rule, CMS first expresses surprise that "many of the comments [on the proposed rule] reflected some confusion over our discussion of this issue," noting specifically that "[s]ome commenters interpreted our discussion as a proposal to allow a single medical staff for a multi-hospital system." Then, in a dissembling explanation, CMS contends that the proposed rule statement was intended <u>*solely*</u> "to point out the current language's potential ambiguity, not to propose a change in our interpretation of it." The agency then "apologize[s] for any confusion that may have been caused by the ambiguous statement in the preamble to the proposed rule."

The courts refuse to allow agencies to use the rulemaking process to inflict what one court aptly described as a "surprise switcheroo" on a regulated community. In *Environmental Integrity Project v. EPA*, the D.C. Circuit Court of Appeals held that an EPA final rule violated the APA's notice-and-comment requirements because, as the court said, "[w]hatever a 'logical outgrowth' of [the EPA's original] proposal may include, it certainly does not include the Agency's decision to repudiate its proposed interpretation and adopt its inverse." That is precisely what CMS has done here. Moreover, an agency's "final rule is a logical outgrowth of the proposed rule only if

interested parties should have anticipated that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment." (*Int'l Union, United Mine Workers of Am. v. Mine Safety and Health Admin.*, 626 F.3d 84, 94 (D.C. Cir. 2010) (internal quotation marks omitted); *see also CSX Transp., Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1079-80 (D.C. Cir. 2009)). An agency's final rule will not be deemed the logical outgrowth of the proposed rule "where the final rule was surprisingly distant from the proposed rule" and where interested parties would be required to "divine" the agency's "unspoken thoughts." (*CSX Transp.*, 584 F.3d at 1080 (internal quotation marks omitted).)

The discussion in the proposed rule establishes that **CMS <u>believes</u> its current regulatory language does not require separate medical staffs for each hospital in a multi-hospital system**. In addition, CMS said it concluded that there was no need to change the language of the provision. This followed CMS's explanation that it had considered changing the medical staff provision of the CoP in response to previous input from stakeholders (such as the AHA), indicating that some systems had unified their medical staffs to promote effective and efficient operation, just as some had unified their governing boards. The *only possible interpretation* of this section of the proposed rule is that CMS concluded that its language permits a unified medical staff, and it was not proposing to change that. Indeed, not only is that how AHA read the language, also it is how others whose comment letters we have examined understood this section of the proposed rule. Having proposed no change to the language of the CoP because the agency had concluded that provision did not preclude a specific result, CMS cannot then go back and adopt the precise opposite interpretation of what the same text means. If it were otherwise, an agency could easily evade notice and comment requirements by amending a rule under the guise of reinterpreting it." (*Molycorp, Inc. v. EPA*, 197 F.3d 543, 546 (D.C.Cir.1999); see also *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 586 (D.C.Cir.1997).)

If CMS had properly proposed a change in the language that would have prohibited the use of a unified medical staff in a multi-hospital system, it would have received many comments urging it to alter its course and continue to allow such unified staffs. The affected stakeholders would have described the enhanced ability of their medical staffs, working as a unified body, to more effectively and efficiently review, credential and privilege individuals seeking staff privileges. Their comments would have described how their systems are more reliably and completely standardizing high-quality, safe care across their systems with a unified medical staff. They also would have described how a unified medical staff enables them more effectively to discover and address knowledge gaps, skill deficits and other issues practitioners might have before patient care suffers. Their comments would have noted the importance of a unified medical staff for many of these organizations as they pursue many different types of integrated and coordinated care delivery that CMS has publicly advocated be adopted. They also would have discussed the greater opportunities for learning and practice that ensue when the medical staff is unified.

It is these patient care reasons that prompted many health systems to unify their medical staffs, a change that was made with the clear consent and involvement of the clinicians serving on the medical staff. These organizations have developed and adopted medical staff by-laws, policies and procedures, and the medical staffs themselves have established the necessary committee structures and other relationships necessary to conduct the work of the medical staff. Undoing

these arrangements and revising medical staff by-laws to create separate medical staffs for each of these hospitals would be a time-consuming, expensive, challenging and unwarranted activity.

We urge CMS to retract its reinterpretation of the meaning of the current CoP for the organization of the medical staff and continue to recognize that the current provision does not preclude a unified medical staff for health systems.

Should you have further questions, please feel free to contact Melinda Hatton, senior vice president and general counsel, at mhatton@aha.org or (202) 626-2336; Nancy Foster, vice president, quality and patient safety at nfoster@aha.org or (202) 626-2337 or Lawrence Hughes, assistant general counsel, at lhughes@aha.org or (202) 626-2346.

Sincerely,

Rich Umbdenstock
President and CEO

Cc: William Schultz, Acting General Counsel, HHS
Janice Hoffman, Associate General Counsel, HHS
Patrick Conway, MD, Director of the Office of Clinical Standards and Quality, CMS