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Hospitals

Attorneys, AHA React to CMS's Conditions On Hospital Staffing, Governance Rules

ttorneys contacted by BNA joined the American Hospital Association in criticizing a new rule for hospitals and critical access hospitals, scheduled to take effect July 16, that requires hospitals to include a medical staff member on their governing board and prohibits multi-hospital systems from having a single, integrated medical staff.

AHA, in a strongly worded letter June 5, urged the Center for Medicare & Medicaid Services (CMS) to immediately rescind the new conditions of participation (CoPs), which were part of a final rule issued May 16.

According to AHA President and Chief Executive Officer Rich Umbdenstock, the two revisions "surprised and greatly concern hospitals and other interested stakeholders." These revisions represent substantive policy changes in the CoP, AHA said.

AHA in the letter said CMS did not include either of the changes in the proposed rule, which was issued Oct. 24, 2011 (20 HLR 1564, 10/20/11).

According to AHA, 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 [Administrative Procedure Act (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."

CMS's failure to adequately notify stakeholders 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," AHA said. "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."

'Out of Left Field.' CMS for the first time in the May 16 final rule added language that requires a hospital's governing body to include at least one medical staff member.

Sandra M. DiVarco, a partner in McDermott Will & Emery's Chicago office, told BNA the provision "really came out of left field." DiVarco noted that CMS gave the health care industry "no notice or opportunity to comment on the change."

"It almost seems like CMS reviewed the submitted comments to the proposed revisions that mentioned the merits of such a requirement and thought, 'Hey, that sounds like a good idea,' without considering the ripple effect the change would have," she said.

If CMS had given adequate notice of the change and a proper invitation for public comment, AHA said, the agency 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.

DiVarco explained that many hospitals likely will not be able to satisfy the requirement by its July 16 effective date because they are in the middle of current terms for their board members. Additionally, she said, "compliance may be impossible" for some, especially government hospitals where the governing body is elected by the constituents in a locality or appointed by local officials.

There even are jurisdictions where the law prohibits medical staff members from serving on government hospital boards, DiVarco said.

'Not an Issue.' Two other attorneys who spoke to BNA, however, downplayed the impact of the medical staff board member requirement. Phil Zarone, a partner at Pittsburgh's Horty Springer & Mattern, said many hospitals already have medical staff members on their boards, at least as ex officio members.

Terri D. Keville, a partner at David Wright Tremaine, in Los Angeles, said this is "not an issue" in California. The main concern about the governance requirement, she said, is that it will create a conflict of interest where the medical staff board member is an employee of the hospital. Since California does not permit hospitals to employ physicians, this is "nonissue" in that state, she said.

Outside of California, hospitals can avoid the conflictof-interest issue by appointing employed medical staff members to serve as ex officio, nonvoting members of the board, Keville said. "CMS didn't say the medical staff member must have voting privileges," she noted.

Keville explained that CMS's main concern in adopting the governance provision was to ensure clear communications between the medical staff and the governing board. "An ex officio nonvoting member can be present at governing body meetings and participate in all discussions relevant to the medical staff, but be excused before a vote on any medical staff-related issue," she said.

DiVarco suggested that there are other ways to ensure the continuity and communication between the medical staff and the hospital governing board that are

essential for guaranteeing the quality of care rendered at the hospital and defining the medical staff's role in providing that care.

"Joint committee structures, reporting relationships and just good old fashioned communication between the governing body leadership and medical staff leadership," can help the board ensure there is high quality of care and patient safety, she said.

Keville agreed with DiVarco that "timing will be an issue." She told BNA "it won't be easy for hospitals to meet this requirement before the effective date of July 16"

Medical Staff Provision. AHA called the provision prohibiting a health system from having a single, integrated medical staff serving more than one hospital "a surprising and impermissible about-face."

According to AHA, the new interpretation "contradicts the entirely lucid discussion in the proposed rule. 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."

AHA noted 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. "This is precisely what CMS has done here," AHA said.

"The discussion in the proposed rule establishes that CMS believes its current regulatory language does not require separate medical staffs for each hospital in a multi-hospital system," AHA wrote. "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."

According to Zarone, however, the October discussion suggesting that the agency would accept a unified medical staff was the real surprise. CMS consistently has interpreted the CoPs as requiring a separate medical staff for each hospital in a multiple-hospital system, he said. Zarone added that his firm does not "necessarily agree with CMS's interpretation of the existing regulatory language." He said "there would be significant patient safety advantages if hospitals in a health system could have a single medical staff."

For example, Zarone said, in a multi-hospital system with a single, integrated medical staff, "peer review information could be shared more easily, and those conducting peer review would have access to a greater number and variety of specialists."

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"At the very least," Zarone said, CMS should be encouraged "to allow hospitals in a health system to have a single medical staff if they are located in close geographic proximity to one another."

Keville told BNA that the prohibition on a single, integrated medical staff probably is not as big a deal for California hospitals as it is for hospitals in other states. California already requires each separately licensed hospital to have its own medical staff—although one staff is allowed for single-licensee hospitals that have more than one campus. California's regulation is similar to CMS requirements that each hospital having its own provider number, which could include multiple campuses, have a separate medical staff.

"Depending upon size and other circumstances," Keville said, "at least some systems having multiple hospitals can achieve a high degree of functional integration even with separate medical staffs, especially if there is a single governing body." Still, the prohibition on having a unified medical staff does not make sense to the extent it requires duplication of effort by separate medical staffs, given CMS's encouragement of ways to save costs and increase efficiency, she said.

"This is an example of regulators not necessarily understanding how things work in the real world and the challenges hospitals are facing," Keville said. "If CMS truly wants hospitals to be able to reduce costs, it should allow for more flexibility to avoid duplication of efforts."

Violation of Procedural Process? In its letter, AHA said 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)," AHA said.

The APA promotes public participation in the rulemaking process to facilitate more informed agency decisionmaking by establishing notice and comment procedures that an agency typically meets by publication in the *Federal Register* of a notice of proposed rulemaking, AHA said.

Had the "substantive changes" been proposed properly, they would have generated significant opposition from hospitals during the public comment process, AHA said.

"Accordingly, we urge you to immediately rescind from hospitals the requirement that a member of the medical staff serve on the hospital board," AHA said. "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."

By Nathaniel Weixel and Mary Anne Pazanowski

AHA's letter can be found at http://op.bna.com/hl.nsf/r?Open=nwel-8v3rjq.