National Association of Public Hospitals and Health Systems

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Ms. Marilyn Tavenner
Acting 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: CMS-3244-F: Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation

Dear Ms. Tavenner:

The National Association of Public Hospitals and Health Systems (NAPH) is generally very pleased with and appreciative of the final rule revisions to the hospital and critical access hospital conditions of participation in the Medicare and Medicaid programs. However, we are deeply troubled by the unexpected requirement—added to the final rule introductory text of the regulations at §482.12 (governing body standards)—that would mandate the inclusion of a member of the hospital medical staff on the governing body of a hospital. The language reads as follows: "The governing body (or the person legally responsible for the conduct of the hospital and carrying out the functions specified in this part that pertain to the governing body) must include a member, or members, of the hospital's medical staff." This addition, which was neither raised nor contemplated as a policy proposal in the proposed rule (CMS-3244-P, 76 FR 65891 et seq.), is highly problematic both on policy and procedural levels. **We urge the Centers for Medicare & Medicaid Services (CMS) to either rescind this provision because its promulgation violates Administrative Procedures Act (APA) notice and comment rulemaking requirements (section 553 of title 5, United States Code), or, in the alternative, treat this new policy addition as a proposed rule under the process established in section 1871(a)(4) of the Social Security Act for which comment must be sought**. CMS must act with far greater deliberation before advancing any final regulatory policy proposal on this issue.

I. This new proposal is in direct conflict with many state and local law requirements for public hospital governing board membership.

This final rule requirement poses substantial legal issues for public hospitals. As these hospitals are public institutions, their governance rules are specifically set forth under statute in many states or political subdivisions of states. In many cases, these rules define who may be or is

required to be appointed to the governing board. Or, they may stipulate that the governing board be directly elected by constituents. Compliance with the conditions of participation final rule requirement would in many cases place our hospitals in direct violation of state or local law. If CMS intended to preempt state and local law, CMS should have indicated this in its rulemaking, both proposed and final regulations, through a formal statement and a legal justification. This inclusion would have provided public hospitals a viable legal defense to claims that they are violating state or local law in regard to their governing body. Absent such a legal statement and justification, public hospitals will either face substantial state-level compliance complications or fail to comply with this new federal-level requirement.

In particular, this new requirement will pose a significant challenge to many public hospitals that have governing bodies that are directly elected, appointed by governing officials, overseen by a state university board of regents or supervisors, or held to other requirements by law. In California alone, 140 hospital districts have directly elected boards, and this new requirement conflicts with otherwise applicable legal requirements for public hospitals in these circumstances. In Iowa, the board members of county hospitals also are directly elected, and in addition, Iowa law prohibits any person with medical staff privileges at the county hospital, and his or her spouse, from serving on the hospital's board. Likewise, Ohio state law specifically precludes county hospitals from placing on their boards any physician who is employed by the hospital. As many of these institutions employ all of their physicians, they would be unable to comply with the new rule.

Many states and local jurisdictions have enacted laws vesting in elected officials the authority to appoint members of the governing bodies of public hospitals. In Florida, more than 30 hospital or health care taxing districts are responsible for the operation of hospitals, and these hospitals' board members are appointed by the governor. Finally, many state university medical centers are overseen directly by a universitywide board of regents, given the medical centers' role as just one part of a much larger institution.

These legislative decisions are premised in part on ensuring these institutions' accountability to the communities they serve as well as their responsiveness to those communities and elected officials. The state or local legislatures and elected officials who currently choose the governing body best suited to ensuring these hospitals' accountability, vigilance, and operations represent the very communities being served, which often provide significant funding for these hospitals. The final rule's new requirement substitutes a removed federal agency's judgment for theirs. **A change in policy of this magnitude certainly should not be made without an opportunity for the public to fully discuss the policy implications and submit meaningful comments after notice of the proposed change.**

II. This new proposal is in violation of requirements for notice and comment rulemaking, as it is not a logical outgrowth of any policy expressed in the proposed rule.

The APA, specifically section 553(c) of title 5, United States Code, requires an agency, in the case of notice and comment rulemaking, to afford the public adequate notice and a meaningful opportunity to comment on the content of a proposed rule. While it is common for a final rule to differ in some aspects from the proposed rule, generally if new issues, persuasive new data, or

policy arguments are raised in response to the proposed rule, an agency may terminate the rulemaking or continue the rulemaking and change aspects of the rule to reflect these comments. If the change is major, the agency will publish a supplemental proposed rule. If the change is a logical outgrowth of the issues and solutions discussed in the proposed rule, the agency may proceed with a final rule without the need for additional notice and comment. **This new requirement for membership on the governing board cannot be considered a logical outgrowth of the proposed rule because 1) members of the public could not have reasonably anticipated inclusion of this policy in the final rule and 2) interested parties have not yet been given an opportunity to comment on this newly proposed policy; only a new notice and comment period will give them their first opportunity to do so.**

The main tenet of the logical outgrowth test is one of fair notice. In a proposed rule, an agency must describe the range of alternatives or policy proposals being considered with reasonable specificity, otherwise interested parties will not know the subject and substance of the proposals on which they should comment. Interested parties should not have to guess what an agency might be contemplating; rather, they should be able to reasonably anticipate the change in question in order to offer comments on the change. **Further, an agency cannot rely on a comment submitted in response to a proposed rule to serve as notice to the public for a regulatory proposal or change that is included in the final rule.**[1] If the proposed rule makes no mention of an important component of the final rule, then the final rule, or the change in question, is not a logical outgrowth of the proposed rule.

In the conditions of participation proposed rule (CMS-3244-P), CMS communicated its intent to revise the governing body requirements as follows: “There must be an effective governing body that is legally responsible for the conduct of the hospital.” This point was intended to clarify that the governing body requirement would reflect current hospital organizational structure whereby multihospital systems have integrated their governing body functions to oversee care in a more efficient and effective manner. CMS also proposed to retain a similar requirement that the persons legally responsible for the hospital’s conduct must carry out the regulatory functions that pertain to the governing body if the hospital does not have an organized governing body. Nowhere in the proposed rule, with respect to a hospital’s governing body, did CMS indicate any intention to impose specific membership requirements with respect to the hospital’s governing body, such as the inclusion of a member of the medical staff (see 76 FR 65893 through 65894). CMS’ proposal to revise the governing body requirements intended to ensure there was a governing body, or person, legally responsible for the conduct of the hospital. NAPH agrees with this intention and expressed support for it in our comment letter to CMS in response to the proposed rule.

CMS indicated in the final rule that this new membership requirement is a response to comments on the proposed rule. Those commenters supported the clarifications and revisions to the governing body requirements expressed in the proposed rule (comments which were clearly within the scope of the proposed rule) and also asked that CMS impose this medical staff

[1]See e.g., American Fed'n of Labor and Congr. of Indus. Orgs. v. Donovan, 757 F.2d at 340 (D.C.Cir.1985) “As a general rule, [an agency] must itself provide notice of a regulatory proposal. Having failed to do so, it cannot bootstrap notice from a comment.”; see also see also Nat'l Black Media Coalition v. Fed. Communications Comm'n, 791 F.2d at 1023 (2d Cir.1986) (“[T]he comments of other interested parties do not satisfy an agency's obligation to provide notice.”); see also National Wildlife Federation v. Norton, 386 F.Supp.2d 553 (D. Vt. 2005) citing American Fed'n of Labor and Congr. of Indus. Orgs. v. Donovan.

governing body membership requirement (see 77 FR 29038). That request was outside the scope of the policies included in the proposed rule, which focused on eliminating redundant or obsolete regulatory requirements in the conditions of participation. Even if those comments could be considered within the scope of the proposed rule, the comments alone cannot and did not constitute adequate notice of this new requirement to interested parties.

Had it been clear from the proposed rule that CMS intended to add this new requirement, NAPH, hospitals, health systems, and other hospital associations would have submitted comments discussing the legal complications that would result from this requirement, as well as the added burdens on hospitals in order to comply with it. For example, in those cases where following this rule would place a hospital out of compliance with applicable state or local laws or regulations, the hospital would face potential additional costs defending in court or administratively its compliance with this new requirement. This additional burden was not contemplated or considered under the proposed rule, which is another indication that this particular policy was not ripe for inclusion in a final rule as a logical outgrowth of the proposed rule. As CMS gave no indication in the proposed rule that it was contemplating the addition of this new requirement, NAPH was not granted the requisite notice to share our concerns with CMS as is intended under section 553(c) of the APA. Our first opportunity to submit comments is now—after publication of the final rule—which violates fundamental fairness and procedural due process, which are the hallmarks of the APA. This situation is also a clear violation of the principles of the logical outgrowth standard.

Section 1871(a)(4) of the Social Security Act was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 in response to concerns that matters that had not been the subject of public comment were included in final regulations, and therefore, interested parties did not have sufficient notice to meaningfully comment on them. This law treats provisions that are not a logical outgrowth of a previously published proposed rule or interim final rule, yet are included in a final regulation, as proposed regulations that may not take effect as final regulations until after the end of a period of public comment.

Therefore, we urge CMS to rescind the provision in question because it violates section 553 of the APA. To the extent CMS determines that section 1871(a)(4) applies in this instance, the agency must treat the matter as a proposed rule and conduct proper notice and comment rulemaking, after which it may publish in final form a regulation, if any, with respect to membership requirements on hospital governing bodies. Obviously, no legal effect would be given to the new requirement during the period the agency conducted proper notice and comment rulemaking under section 1871(a)(4). Because of the complexities around the organization of hospital governance structures and the myriad governance arrangements that exist, it is critical that CMS address this issue through the proper notice and comment process. **Any attempt to resolve this issue through subregulatory means, such as guidance or manual instructions, will not afford hospitals their due process right to inform CMS as to how this provision may affect their unique organization before the implementation of the new requirement. Nothing short of proper, revised regulatory text that specifically addresses the issue as it relates to public hospitals will constitute legally sufficient clarification for hospitals, states, and their political subdivisions with respect to any final regulatory requirement on this issue.**

NAPH appreciates your attention to this very important matter. We look forward to working with the agency to craft a solution that will benefit all relevant stakeholders. If you have any questions, please contact Beth Feldpush, vice president for policy and advocacy, at bfeldpush@naph.org and (202) 585-0111.

Sincerely,

Bruce Siegel, MD, MPH
President and Chief Executive Officer
NAPH

Cc: Patrick Conway, MD, Director of the Office of Clinical Standards and Quality, CMS
William Schultz, Acting General Counsel, U.S. Department of Health and Human Services