

December 23, 2011

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

Re: Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital  
Conditions of Participation [CMS-3244-P]

Dear Acting Administrator Tavenner:

On behalf of the undersigned organizations, we appreciate the opportunity to provide comment on the proposed *Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation [CMS-3244-P]*. We support the efforts of the Centers for Medicare and Medicaid Services (CMS) to identify and eliminate burdensome regulations. However, we strongly oppose CMS' proposed revisions to the medical staff and governing body conditions of participation (CoPs). These revisions would cause serious harm to patients by diluting the authority of the medical staff to set professional and clinical standards for patient care, and by extracting the governing body from the local setting, rendering it incapable of assessing the acute clinical needs of the hospital's patient population. We offer further comment on our concerns below.

#### Statutory Authority

As CMS states in the proposed rule, Sections 1861(e)(1)-(8) of the Social Security Act (the Act) prescribe specific requirements that hospitals must meet to participate in Medicare. In addition, Section 1861(e)(9) of the Act provides that a Medicare-participant hospital must:

“meet[s] such other requirements as the Secretary finds necessary *in the interest of the health and safety of individuals who are furnished services in the institution.*”<sup>1</sup>

It is under the authority conferred by this provision that CMS has promulgated the CoPs for hospitals. And, it is under this provision that CMS now seeks to revise the CoPs as set forth in the proposed rule.<sup>2</sup>

However, the required nexus between the proposed changes to the medical staff and governing body CoPs and “the interest of the health and safety of individuals who are furnished services” in hospitals

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<sup>1</sup> 42 USC § 1395x(e)(9).

<sup>2</sup> 76 Fed. Reg. 65892.

is absent from the proposed rule. Instead, CMS' stated rationale is to reduce regulatory burden for hospitals and, in the case of the medical staff CoP, to address "healthcare workforce shortages."<sup>3</sup>

While CMS may wish to address regulatory reduction or access to care through revision of the CoPs, it is not statutorily authorized to do so. The statute limits CMS' authority to promulgate the CoPs in furtherance of the health and safety of hospital patients.

To the contrary, as discussed herein, the proposed changes to the medical staff and governing body CoPs would be detrimental to the health and safety of patients in the hospital setting.<sup>4</sup> Therefore, we believe CMS' proposed revisions exceed its authority under the Act.

### Single Medical Staff

We are strongly opposed to CMS' proposal to clarify that existing language at 42 CFR 482.22 does not require a single and separate medical staff for each hospital within a multi-hospital system.<sup>5</sup>

### *Self-governance*

The medical staff is responsible for medical professionalism, including clinical and quality standards for physicians and non-physicians. The fundamental idea behind a medical staff is that it is *self-governing*. This means that the medical staff is familiar with the physicians whom it governs and is comprised of, understands the unique needs of the hospital in which those physicians work, and can nimbly respond to health and safety issues that arise with respect to *those* patients and *that* hospital.

Medical staff self-governance is a basic requirement for Joint Commission accreditation,<sup>6</sup> and is mandated by some States.<sup>7</sup> CMS' proposal would undermine these already established requirements by giving rise to a scenario wherein a multi-hospital system could have a single medical staff for an unlimited number of hospitals, regardless of physical proximity, and without the meaningful input of the physicians at each member hospital.

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<sup>3</sup> 76 Fed. Reg. 65894.

<sup>4</sup> CMS states in the proposed rule, "we do not believe that any requirement we propose to eliminate achieved any consequential improvements in patient safety." (76 FR 65905). We request more information from CMS regarding what research CMS conducted to reach this conclusion. We believe that the existing CoPs we discuss herein, such as the medical staff CoP, do have a direct positive impact on patient safety.

<sup>5</sup> 76 Fed. Reg. 65899.

<sup>6</sup> Joint Commission Standard LD 01.01.01 Element of Performance 2 states, "(t)he organized medical staff is self-governing."

<sup>7</sup> For example, under Oregon Revised Statutes §441.055, "[t]he physicians organized into a medical staff pursuant to [Oregon law] shall propose medical staff bylaws to govern the medical staff." Under Mississippi Hospitals, Minimum Standards of Operation Regulations, Title 15, Part III, Chapter 41 §106.16, "the medical staff shall develop and adopt bylaws and rules and regulations to establish a framework for self-government and a means of accountability to the governing body, such bylaws and rules and regulations to be approved by the governing body." Georgia Regulation 290-9-7-.11(c) states, "The medical staff of the hospital shall adopt and enforce bylaws and rules and regulations which provide for the self-governance of medical staff activities and accountability to the governing body for the quality of care provided to all patients." California law has also has codified medical staff self-governance within Business and Professions Code §2282.5 (S.B. 1325).

We posit the following example: a rural hospital that is owned by a multi-hospital corporation is at least one hundred miles away from its sister hospitals, and currently has a medical staff comprised of physicians who live and practice in the community. The medical staff has first-hand knowledge about the rural hospital that informs its decisions and empowers its self-regulation. The medical staff has specific expertise regarding the rural hospital's local patient population and resources, can respond quickly to emergent quality concerns, and possesses an understanding of the rural hospital's historic strengths and weaknesses.

Under CMS' proposal, the rural hospital's medical staff could be disbanded by the unilateral decision of the multi-hospital corporation. That corporation could then establish a single medical staff to oversee an unlimited number of satellite hospitals. Divorced physically and in perspective from the rural hospital, the single medical staff could do its business without a meaningful understanding of the rural hospital's clinical needs, rendering it incapable of setting appropriate professional standards to protect the health and safety of the rural hospital's patients.

This troubling scenario would likely not be limited to rural hospitals. CMS' proposal could similarly disenfranchise the patients of any hospital within a multi-hospital system that is unique among its member hospitals for any reason, including geographic location, suite of services rendered, patient demographic, etc. For example, an underserved urban hospital may be marooned in a multi-hospital system of profitable suburban hospitals. The same could be true for a specialty hospital, geriatric hospital, children's hospital, rehabilitation hospital, etc. At issue are the distinctive clinical needs of each hospital's patients, and the relative power of each hospital within a multi-hospital system. CMS' proposal would put any hospital that is unique among its sister hospitals in the disadvantageous position of trying to explain and assert the needs of its patients to the other members of the at-large medical staff, whose interests may be divergent.

Hospital-specific medical staffs also play an important role in today's changing health care environment. As hospital consolidation continues to rise, multi-hospital systems have increasingly expansive geographic footprints and provide a wider range of services to diverse patient populations. For example, the Healthcare Corporation of America owns hospitals in 20 states across the United States.<sup>8</sup> A hospital-specific medical staff is an important check on a multi-hospital system, as it allows the multi-hospital system to remain responsive to the safety and health needs of each member hospital's unique patient population.

#### *Peer Review and the Single Medical Staff*

We strongly urge CMS to consider that medical staffs perform the important function of peer review. At present, peer review is conducted by a physician's *peers* who have first-hand knowledge about the local standard of care, and can therefore review that physician based on that standard. CMS' proposal would likely create a situation where a physician could be subject to peer review by a single medical staff that has little familiarity with the standard of care in that physicians' community.

The following example is illustrative: All Children's Hospital is located in St. Petersburg, Florida, but is part of Johns Hopkins Medicine, a multi-hospital system. All of Johns Hopkins Medicine's other member hospitals are within the Baltimore-Washington area. Johns Hopkins Medicine could opt, under CMS' proposal, to have a single medical staff, and may desire to do so because all of its other member hospitals are within a closer physical proximity.

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<sup>8</sup> See <http://hcahealthcare.com/about/facilities.dot>.

Under this example, a pediatrician practicing at All Children's Hospital could undergo formal proceedings in the Baltimore-Washington area. Patients and staff involved in the proceedings could be compelled to travel from Florida to the Baltimore-Washington area to testify if the physician or the medical staff were counseled by their attorneys that immunity or privilege may not attach to testimony given remotely. The physician at issue could be reviewed by physicians who are members of the single medical staff of Johns Hopkins Medicine, but who have no first-hand experience with All Children's Hospital or its medical care. This situation could be even more extreme in larger systems like the Healthcare Corporation of America.

CMS' proposal may also confound state law governing peer review.<sup>9</sup> All 50 states and the District of Columbia have enacted immunity statutes. State statutes vary significantly regarding the extent of immunity provided and which parties may enjoy immunity.<sup>10</sup> CMS' proposal could create a choice of law problem. To follow the example above, would the All Children's Hospital pediatrician enjoy the immunity protection of Florida or Maryland peer review law? We are cognizant that this issue may be decided in the bylaws of the single medical staff, but submit that this would inevitably create a situation where a physician who formerly enjoyed the robust immunity protections of State A could now, under a single medical staff structure, be less protected under the laws of State B. We think this could have a chilling effect on peer review, thwarting a process that is meant to buttress clinical oversight.

CMS must reexamine its proposal to clarify existing language at 42 CFR 482.22 to allow a single medical staff for a multi-hospital system. For the reasons explained above, we ask that CMS instead amend 42 CFR 482.22 to require a single and separate medical staff for each hospital within a multi-hospital system.

#### Privileging without appointment to the Medical Staff

We are adamantly opposed to CMS' proposal to revise 42 CFR 482.22 to allow a hospital to grant privileges to physicians regardless of whether they are also appointed to the hospital's medical staff. This proposal would divide the hospital's physicians into two, distinct groups: those who are members of the medical staff, and those who are not.

#### *Participation*

CMS' proposal would allow a hospital, by virtue of its privileging authority, to exclude some physicians from the medical staff. This proposal would undermine the medical staff's chief function: self-governance. A physician's participation in the medical staff enables that physician to have a

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<sup>9</sup> The Health Care Quality Improvement Act (HCQIA) immunity for entities and participants engaged in peer review activities is limited to damages, and provides neither privilege nor confidentiality protections for peer review deliberations or records.

<sup>10</sup> While every state provides immunity from civil damages, many states extend immunity beyond civil damages—for example, by providing immunity from injunctive or equitable relief. Some statutes confer immunity from both civil and criminal liability on peer review participants. State law also differs widely regarding which parties may enjoy peer review immunity. While all states immunize peer review committee members, most statutes extend immunity to a wider class of individuals, e.g., persons providing consultation to the committee. Some statutes confer immunity on the entities within which review communities operate. Most statutes also provide immunity for entities and/or individuals providing information to peer review committees.

voice in the crafting of that governance, including feedback regarding the specific needs of that physician's patient population and attendant professional standards.

Further, appointment to the medical staff engenders a mutual responsibility for the activities and work of the medical staff—such as quality improvement—promoting a mutual objective to oversee and protect the health and safety of patients. This mutual objective gives rise to coordination of both professional standards and care—both key policy goals of CMS.

Through their participation in the medical staff, physicians also have a forum for quality innovation. This forum is unique in that it also has the role of overseer and regulator. As CMS seeks to design innovative approaches to care delivery, we suggest that the medical staff is a built-in mechanism for the delivery of accountable, coordinated care.

#### *Judicial Relief*

By allowing hospitals to grant privileges to physicians who are not appointed to the medical staff, CMS would effectively allow hospitals to preclude physicians from participating in the medical staff. This could allow hospitals to avoid lawsuits by physicians who would otherwise be protected by the contractual relationship created by virtue of their appointment to the medical staff.

A majority of jurisdictions have held that medical staff bylaws constitute a contract between the hospital and the medical staff.<sup>11</sup> To wit, the Joint Commission also prohibits unilateral amendment of bylaws by the medical staff or the hospital governing body, recognizing the relationship as contractual.<sup>12</sup> Typically, cases involve an aggrieved medical staff member who sues the hospital and/or medical staff leaders to obtain judicial enforcement of the procedural rights enumerated in the bylaws.

CMS' proposal would allow hospitals to circumvent the medical staff bylaws—and the protections that they afford to physicians vis-à-vis the hospital—by privileging physicians without appointing them to the medical staff.

#### *Peer Review and Physicians privileged outside the Medical Staff*

Like CMS' single medical staff proposal, we think that CMS' proposal to allow hospitals to grant privileges outside the medical staff could have a negative impact on peer review. The following questions arise: Would physicians who are not appointed to the medical staff enjoy the due process protections of peer review? Might they instead be subject to a hospital-driven review process dictated solely by hospital administrators? Or, in states where the peer review committee is statutorily required to also be a committee of the medical staff, would physicians who are not on the medical staff be subject to review by the few hospital-selected physicians who do sit on the medical staff? We seek further clarification from CMS on these points, and strongly urge CMS to ensure that this proposal would not confound peer review efforts.

#### *Fraud and Abuse*

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<sup>11</sup> Physician's Guide to Medical Staff Organization Bylaws, 5th Addition. (June 2011) American Medical Association. See <http://www.ama-assn.org/resources/doc/omss/x-ama/omss-bylaws/index.html>.

<sup>12</sup> Joint Commission Standard MS.01.01.03 of the *Comprehensive Accreditation Manual for Hospitals*.

We urge CMS to review the possible fraud and abuse implications of their proposal to allow hospitals to privilege physicians without also making them members of the medical staff. The appointment to the medical staff of some physicians who have been granted privileges and not others may implicate the Anti-Kickback statute, which prohibits the knowing and willful solicitation or receipt of any remuneration in return for referring individuals or arranging for the acquisition of goods or services.<sup>13</sup> Remuneration has been interpreted very broadly by the courts, and includes anything that can be viewed as a ‘quid pro quo’ for a referral. In most cases, appointment to the medical staff would be viewed by the courts as remuneration because it has value. Therefore, if the hospital conditions a physician’s membership on the medical staff on that physician’s referral volume, the Anti-Kickback statute may be violated.<sup>14</sup>

### *Categorical Membership*

We also urge CMS to consider that appointment to the medical staff is not an “either / or” proposition. For example, the American Medical Association (AMA) has long given guidance to its members that medical staffs may have categories of membership, including “active,” “affiliate,” “administrative,” “call coverage,” “telemedicine,” and “temporary” membership.<sup>15</sup> These categories differ in their level of responsibility and oversight, but share the comity of membership in the medical staff, which we believe engenders a shared accountability. Categories of medical staff membership allow the hospital and medical staff to be responsive to the particular needs of that hospital and staff while still including all privileged physicians in the medical staff.

We note that CMS offers an alternative to their proposal in the preamble, namely, that a hospital could establish categories of practitioners who have full membership and those that have an “associate,” “special,” or “limited” membership.<sup>16</sup> While we strongly support CMS’ proposal not to require a specific categorical framework for membership in the CoPs, we urge CMS to consider that most medical staffs do already employ membership categories, as specified in their bylaws. Therefore, we request that CMS abandon its proposal at 42 CFR 482.22 to effectively exclude some physicians from the protections of, and participation in, the medical staff.

### *Oversight*

We point out CMS’ assertion in the preamble that physicians and non-physicians who have been granted privileges, but are not appointed to the medical staff, would be subject to medical staff bylaws and oversight.<sup>17</sup> While we oppose the privileging of physicians outside of the medical staff, we share CMS’ belief that all physicians and non-physician practitioners should in all instances be subject to the medical staff bylaws and oversight. We strongly urge CMS to review its proposed regulatory language on this point, as it makes no specific mention of the applicability of the medical staff bylaws and oversight to such physicians and non-physicians, and instead refers broadly to medical staff “requirements,” which may not affect CMS’ intent.<sup>18</sup>

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<sup>13</sup> 42 U.S.C. § 1320a-7b(b).

<sup>14</sup> Evolving Relationship between Hospitals and Medical Staff. Brian M. Peters, Esq. (2001). AHLA Seminar Materials. Post & Schell, PC.

<sup>15</sup> Physician’s Guide to Medical Staff Organization Bylaws, 5th Addition. (June 2011) American Medical Association. See <http://www.ama-assn.org/resources/doc/omss/x-ama/omss-bylaws/index.html>.

<sup>16</sup> 76 Fed. Reg. 65894.

<sup>17</sup> 76 Fed. Reg. 65894.

<sup>18</sup> 76 Fed. Reg. 65907.

*Non-Physician Practitioners*

We object to CMS' explicit endorsement of the replacement of physicians with non-physician practitioners throughout the rule. For example, CMS states: "one third [of hospitals] are willing to make such medical staff substitutions" and projects that "33 percent of physician per patient time would now be covered by non-physician practitioners."<sup>19</sup> CMS proffers a cost savings of \$330 million annually based on the replacement of physicians with non-physicians in the hospital setting; we request further clarification on the methodology behind this analysis. CMS provides no indication of what services it anticipates would now be covered by non-physician practitioners, nor does CMS outline the cost differential for the non-physician provision of these services. Indeed, CMS states in its regulatory impact statement that CMS has "no precise basis for calculating potential savings, which would in any event depend on future staffing and management decisions." Therefore, we think that the projected cost savings may be in error. We urge CMS to review this analysis, and to confer with a wider range of stakeholders than those consulted prior to the promulgation of the proposed rule.

CMS' stated intent to affect the replacement of physicians with non-physicians is contrary to the purpose of the CoPs, namely, to provide a safe hospital setting. While we recognize that non-physician practitioners are a valuable component of a health care team, physicians are best qualified to lead that team. Further, any scope of practice expansions should be carefully tailored based on a review of the evidence and training of non-physician practitioners and a determination that allowing non-physician providers to expand their scopes of practice is in the best interest of patient health and safety. The sweeping replacement of physicians with non-physicians that CMS advances in the proposed rule is especially troubling in the hospital setting, where patients are treated for complex and critical illnesses and injuries. While we are cognizant of CMS' desire to address access to care issues, revision of the CoPs is not the appropriate—or statutorily permitted—avenue to advance these policies.

We also object to CMS' explicit effort to encourage states to widen their scope of practice laws. CMS states that the proposed rule would "facilitate the ability of States to reform their scope of practice laws without Federal requirements reducing the effectiveness of such reforms. We understand that about half of the States are considering such reforms, and we support such efforts."<sup>20</sup> This conflicts with the express language of the proposed rule, which appropriately defers to existing state scope of practice laws.<sup>21</sup> Moreover, revisions to the CoPs are not the appropriate vehicle for such policy assertions. For these reasons, and we strongly urge CMS to omit this language and similar commentary in the preamble of the final rule.

Privileging in accordance with Hospital Policies and Procedures

We are opposed to CMS' proposal to revise 42 CFR 482.22 to allow a governing body to grant privileges in accordance with hospital policies and procedures. This is a clear change in policy that

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<sup>19</sup> 76 Fed. Reg. 65903.

<sup>20</sup> 76 Fed. Reg. 65906.

<sup>21</sup> See 76 Fed. Reg. 65907 ("(i) Drugs and biologicals may be prepared and administered...only if such practitioners are acting in accordance with State law, including scope of practice laws...;(iii) Orders for drugs and biologicals may be documented and signed by other practitioners...only if such practitioners are acting in accordance with State law and scope of practice...").

we are not sure CMS intended. Currently, although the hospital grants privileges, it does so upon recommendation of the medical staff, in accordance with medical staff bylaws, rules, and regulations, not hospital policies and procedures.

CMS' proposal provides that privileges would be granted "in accordance with State law and *hospital policies and procedures*." We submit that, for the reasons discussed herein, privileges should continue to be granted in accordance with medical staff bylaws, rules, and regulations, not hospital policies and procedures. Therefore, we propose that CMS modify the proposed regulatory text to read:

"(5) ... and will make recommendations to the governing body for the appointment of these candidates and the approval of these in accordance with State law and *medical staff bylaws, rules, and regulations*."

We note generally that CMS does not defer to medical staff bylaws, rules, and regulations throughout its proposal. Specifically, CMS' proposed amendments at 42 CFR 482.23(c)(1)(i), (c)(3) introductory text, and (c)(3)(i) do not appropriately defer to medical staff bylaws, rules, and regulations, and we ask that CMS include such reference. We also urge CMS to rescind its proposed amendment to 42 CFR 485.639 to allow a "responsible individual" to grant clinical privileges in the critical access hospital setting.

#### *Economic Credentialing*

Should CMS modify the CoPs as proposed to defer to hospital policies and procedures, hospitals could more easily employ 'economic credentialing,' a practice we oppose. Economic credentialing is the use of economic criteria unrelated to quality of care or professional competence to determine a physician's qualifications for initial or continuing privileges. If the decision to grant privileges is ultimately in the hands of the hospital, and based only on hospital policies and procedures, as opposed to those established by the medical staff, hospitals may take the opportunity to grant privileges based on which physicians or non-physicians can generate the most revenue for the hospital through increased referrals.

#### *Horse Trading*

Privileging without deference to medical staff policies and procedures could give rise to "horse trading" whereby two or more hospitals informally agree on the privileging status of physician applicants based on the hospitals' mutual interests. For example, Hospital A could agree not to privilege a physician applicant that Hospital B would like to retain exclusively in exchange for Hospital B's commitment to privilege another physician who would increase referrals to Hospital A. This scenario also implicates CMS' single governing body proposal discussed forthwith, which would provide a ready-made forum for such agreements. While hospitals could be dissuaded from horse trading for fear of violating the antitrust laws, without the input and oversight of the medical staff on privileging, CMS would have to keep a more vigilant eye on hospital privileging.<sup>22</sup>

#### Single Governing Body

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<sup>22</sup> Evolving Relationship between Hospitals and Medical Staff. Brian M. Peters, Esq. (2001). AHLA Seminar Materials. Post & Schell, PC.

We are opposed to CMS' proposal to revise 42 CFR 482.12, which currently requires that each hospital facility have a separate governing body, to instead allow hospitals in a multi-hospital system to be governed by a single governing body.

#### *Coordinated Governance*

As a threshold matter, we remind CMS that a hospital's governing body is usually a hospital's Board of Trustees. As such, the governing body is generally made up of a diverse group of individuals, including corporate executives, attorneys, civic leaders, and others. Even in the most robust multi-hospital systems, very few, if any, physicians typically serve on the Board of Trustees. The governing body / Board of Trustees therefore relies heavily on the clinical expertise of the hospital medical staff. While the governing body decides hospital policy, the medical staff sets the standard for medical professionalism, including clinical and quality standards for both physicians and non-physicians.

Bringing together those distinct roles, the hospital's medical staff and governing body are mutually responsible for the provision of quality care and a safe environment for patients. While this responsibility is primarily vested with the medical staff, the governing body is relied upon to be an accountable partner in addressing the unique needs of the hospital's patient population.

This symbiotic relationship—which serves as the “check and balance” to ensure the health and safety of the hospital's patients—would be damaged by CMS' proposal to allow a multi-hospital system to have a single governing body. Ongoing, timely communication between the governing body and the medical staff is essential for the practical coordination of care between physicians, the hospital, and patients.

We envision a scenario under CMS' proposal where a single governing body for a multi-hospital system is working in a virtual vacuum, unaware of the specific needs and challenges of its many physicians and myriad patient populations, without an informed understanding of the acute and emergent care coordination challenges of each of its member hospitals.

We are cognizant that as we move toward coordinated health care delivery, governance must be coordinated. However, in the context of hospital governance, we believe that a hospital-specific governing body plays an important role in care delivery that promotes, rather than detracts from, care coordination. We also note that there is nothing to deter governing bodies in a multi-hospital system from working together on issues of care coordination and quality.

Rather than enact the proposed revision, which would dilute coordination between the governing body and the medical staff, CMS should include language in the CoPs that would require a member of the medical staff to serve on the governing body. This requirement would ensure that the governing body would have a common member who also sits on the medical staff, promoting greater coordination between the medical staff and the governing body, and further informing patient health and safety initiatives within the hospital.

#### *Nonprofit Hospitals*

We offer the following practical example of one way in which CMS' proposal to allow a single governing body could prove problematic: Section 9007(a) of the Affordable Care Act (ACA) included new requirements for non-profit hospitals to earn and retain their tax-exempt status.

Specifically, non-profit hospitals must conduct a community health needs assessment every three years that “takes into account input from persons who represent the broad interests of the community served by the hospital facility, including those with special knowledge of or expertise in public health.”<sup>23</sup>

Should CMS’ proposal go forward, a nonprofit hospital would not be able to conduct this community health needs assessment through its own governing body, because it may no longer have one. A hospital-specific governing body would otherwise be the natural convener of this activity in conjunction with the medical staff. Instead, a nonprofit hospital would likely have to create a wholly distinct body to conduct the community needs assessment, as it is unlikely that a Board of Directors at a multi-hospital system would possess the statutorily required expertise.

In addition to requirements under the ACA, nonprofit hospitals must satisfy requirements under Section 501(c)(3) of the Internal Revenue Code to be granted tax-exemption, including a demonstration that the hospital provides a “community benefit.” The Internal Revenue Service, in guidance in effect since 1969, has defined a hospital’s provision of “community benefit” based on part on whether a wide range of members of the community have a seat on the governance board.<sup>24</sup> This requirement, and other state-specific requirements, for tax-exempt status would be confounded by CMS’ proposal to allow a single governing body for a multi-hospital system that is divorced from the very community that it is meant to represent.

We believe that CMS does not intend to confound the process by which nonprofit hospitals may seek tax-exempt status, or the myriad of other negative consequences that this proposal, in its current form, would produce. We suggest that CMS take a more nuanced view of the issue and consider that governing bodies in a multi-hospital system, under the current governing board CoP, may work together to address issues of care coordination and clinical integration. Rather than the ‘top-down’ model that CMS proposes, the current CoPs allow hospital-specific governing bodies to highlight their own hospital’s unique strengths and weaknesses in furtherance of a ‘bottom-up’ effort to achieve the care coordination goals of the multi-hospital system.

#### Delegation of Leadership

We are opposed to CMS’ proposal at 42 CFR 482.22 to allow podiatrists to hold leadership positions within the medical staff of any hospital. Our understanding is that this proposal was prompted by a situation where a podiatrist at a podiatric hospital was unable to hold a leadership position at that hospital. CMS’ proposed revision goes beyond this scenario, however, by allowing a podiatrist to hold a leadership position at any hospital.

We are concerned about the precedent that this proposal sets. Practitioners who are not medical doctors or doctors of osteopathy should not be authorized by the CoPs to hold leadership positions on the medical staffs of all hospitals. We are particularly troubled by a practice taking place in many hospitals whereby a “Chief Medical Officer,” someone hired by the hospital who is not a physician, is

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<sup>23</sup> § 501(r)(3) of the Internal Revenue Code of 1986, as amended by § 9007(a) and § 10903 of the Affordable Care Act.

<sup>24</sup> See Internal Revenue Service Rev. Rul. 69-545, 1969-2 C.B. 117 at <http://www.irs.gov/pub/irs-tege/rr69-545.pdf>. See also *PPACA’s Additional Requirements Imposed on Tax-Exempt Hospitals Will Increase Transparency and Accountability on Fulfilling Charitable Missions*. Cynthia S. Marietta, J.D., LL.M. at [http://www.law.uh.edu/healthlaw/perspectives/2010/\(CM\)%20Charitable.pdf](http://www.law.uh.edu/healthlaw/perspectives/2010/(CM)%20Charitable.pdf).

appointed to serve in a leadership position that would otherwise be held by a member of the medical staff. We think that CMS' proposal, if broadened, could result in more of this activity, and ask that CMS consider carefully the intended result of this proposal.

CMS also requests comment on whether it should revise the overall organizational structure of the CoPs to condense current requirements for departmental leadership responsibilities into a single, non-specific CoP that would allow hospitals to appoint hospital leaders based on hospital-established qualifications. This would alter the current department-specific organization of the CoPs and current specialty-department-specific leadership requirements.

We are opposed to the extraction and deletion of current department-specific leadership requirements. These requirements are in place to ensure that persons with the appropriate expertise are at the helm of their department. The deletion of these requirements, and / or the promulgation of non-specific requirements that defer broadly to hospital policy, would allow the hospital to establish qualification thresholds for leadership that are lower than what is currently required, or that are not substantively related to the department's specialty or service. We also believe that current requirements concerning who may serve as the director or leader of a department are best placed within their service-specific CoP, as their placement in the regulatory text with the other requirements of the same service binds them to the discrete and unique requirements of that specialty or service.

We request clarification from CMS regarding whether CMS is also contemplating changes to the staffing, personnel, and organizational requirements of each service, and / or to existing supervision requirements. We are unable to discern the extent of CMS' proposal from CMS' explanation in the preamble, and therefore urge CMS to issue further information on this proposal. If CMS does intend to modify these requirements, particularly those related to supervision, such modifications would be significant changes in policy and would clearly require prior notice and comment. We would likely have serious objections to such changes, and ask that CMS carefully evaluate the effect of their objectives in this arena on patient health and safety.

#### 48 Hour Rule

We support CMS' proposal to provide that all orders, including verbal orders, must be dated, timed, and authenticated *promptly* by the ordering practitioner or another practitioner who is responsible for the care of the patient. Currently, absent state law to the contrary, all verbal orders must be authenticated with 48 hours. This requirement is unduly burdensome for physicians. For example, a physician privileged at a rural hospital may have to spend several hours traveling to that hospital solely to authenticate an order within the 48 hour timeframe. CMS' proposal would instead allow another physician who is on-site and responsible for the patient's care to authenticate the order, or allow the ordering physician to authenticate the order when they are on-site later that week to treat another patient. CMS' proposal would permit physicians to appropriately organize their time and coordinate with other physicians to maximize patient care, rather than to comply with an arbitrary regulatory requirement.

#### Conclusion

While we support the spirit of the President's Executive Orders to reduce regulatory burden, we strongly oppose the proposed revisions discussed herein. The revisions to the medical staff and

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governing body CoPs do not, in our view, have a substantiated patient health or safety rationale. In fact, we believe that CMS' proposals to the medical staff and governing body CoPs would seriously harm patients by diluting the authority of the medical staff to set professional and clinical standards, and by effectively eliminating governing bodies' ties to the local patient population. We appreciate your review of our comments. Should you have any questions please contact Margaret Garikes, Director, Division of Federal Affairs, American Medical Association, at 202.789.7409 or [margaret.garikes@ama-assn.org](mailto:margaret.garikes@ama-assn.org).

Sincerely,