December 21, 2011

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3244-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: Medicare and Medicaid Programs: Reform of Hospital And Critical Access Hospital Conditions of Participation (CoPs) (File No. CMS-3244-P)

To Whom It May Concern:

The California Medical Association (CMA) appreciates the opportunity to comment on the Department of Health and Human Services (HHS) proposed rule regarding revising the requirements that hospitals and critical access hospitals must meet to participate in Medicare and Medicaid Programs. CMA is a not-for-profit, professional association of approximately 35,000 California physicians and medical students. For more than 150 years, CMA has promoted the science and art of medicine, the care and well-being of patients, the protection of the public health, and the betterment of the medical profession. CMA’s physician members practice medicine in all specialties and settings, including in hospitals throughout the State.

Our comments originate from the principle that medical staff self-governance is a vital part of the carefully crafted system designed to ensure the delivery of quality patient care. This system recognizes that the hospital's medical staff is the only body with the medical expertise and daily experience with the factors unique to a particular hospital necessary to conduct the quality assurance activities integral to the health and welfare of the public.

In response to the proposed rule, CMA offers the following comments:

1. Each hospital, including hospitals in a multi-hospital system, should have its own governing body. Multiple hospitals cannot be effectively governed by a single governing body.

The proposed rule includes a revision to § 482.12 which states that “There must be an effective governing body that is legally responsible for the conduct of the hospital.” The CMS analysis states that the intent of this revision is to reflect the concept that hospitals in a multi-hospital
system can be effectively governed by a single governing body. CMA is concerned that this revision would result in the elimination of community-based hospital governing bodies. Hospital governing bodies should be comprised of physician and public members who can communicate all of the benefits that the community derives from the hospital: 24-hour care, a variety of community services and programs, education of health professionals, medical research, employment and purchase of goods and services. Community hospital boards are also critical for communicating the needs of the community to hospital administration. Further, Joint Commission Standard LD.01.03.01, EP 9 requires that "the governing body provide the organized medical staff with the opportunity to be represented at governing body meetings (through attendance and voice), by one or more of its members, as selected by the medical staff." Allowing multi-hospital systems to establish single governing boards would drastically reduce, if not completely eliminate, input from each hospital’s medical staff and local community, and result in lower quality patient care that does not reflect the local needs of each hospital. There are numerous multi-hospital systems in California operating in dozens of communities that would feel negative impact of the proposed revision to § 482.12. Catholic Healthcare West, for instance, operates 30 hospitals in California between Mount Shasta in Northern California to Long Beach, six hundred miles away in Southern California. One single governing body could not adequately ensure that all of these hospitals serve the needs of their communities. Additionally, Catholic Healthcare West also owns and operates four other hospitals in Arizona and four in Nevada. Would the revised § 482.12 allow a single governing board to manage across state lines? The proposed revision to allow one single governing body to govern all hospitals in a multi-hospital system is unwise.

RECOMMENDATION: CMA recommends not amending the regulation in the manner proposed.

2. Credentialing and granting privileges to physicians and non-physicians are medical staff functions. Allowing hospitals to grant privileges to physicians and non-physicians who have not been duly appointed to the medical staff will have a negative impact on patient safety and quality of care.

The proposed rule includes a revision to § 482.22 which would allow a hospital to grant privileges to both physicians and non-physicians to practice within their scope of practice regardless of whether they are also appointed to the hospital’s medical staff. Pursuant to the revision, medical staff membership would not be a prerequisite for a hospital’s governing body to grant privileges. The analysis of the proposed rule states that the intent of the revision is to provide hospitals with “the clarity and flexibility they need under federal law to maximize staffing opportunities for all practitioners, and particularly for non-physician practitioners…” CMA has concerns about the intent of the revision, because the focus appears to be on reducing costs for hospitals, potentially at the expense of patient safety and quality patient care.
The responsibilities imposed upon medical staffs pursuant to federal and California law, and Joint Commission standards, recognize that patient welfare depends on medical staffs providing the ongoing review, evaluation, and monitoring of the quality of patient care and treatment rendered in hospitals. Accordingly, the medical staff is primarily responsible for credentialing (i.e. assuring the initial and ongoing competence of every physician and, where lawful and applicable, other licensed healthcare practitioners admitted to the staff). Health care services must be regularly monitored and evaluated in order to resolve problems and to identify opportunities to improve patient care. Protocols and procedures must be continuously analyzed and revised to reflect new information and technologies. The clinical performance of physicians and other health care providers must be repeatedly assessed so that appropriate educational information and training may be provided, and impaired or incompetent individuals may be identified before patients may be seriously injured.

To be effective, this monitoring function must be performed by individuals who have both the expertise necessary to conduct these quality-assurance activities and the ability to implement indicated changes. The maintenance of high medical standards depends on the effectiveness of the oversight of medical staff committees, and thus on the accuracy of the information which the committees can obtain concerning the operations of the facility with which they are affiliated. Moreover, it is crucial that the committees be made up of health care professionals of the highest possible qualifications.

To ensure that these activities are performed in a manner that best protects patients, the medical staff – an organization comprised of members with the "highest possible qualifications" – and not the hospital should perform these critical quality of care functions, and the medical staff's judgment should be free of commercial pressure. A hospital's medical staff is a separate legal entity, an unincorporated association, which needs to be self-governing and independently responsible from the hospital for its own duties and for policing its member physicians.

The revision proposes an unworkable structure whereby the hospital would be able to grant privileges to practitioners who would not be required to meet the requirements for medical staff membership or participate in medical staff functions, but would supposedly be credentialed and overseen by the medical staff. The creation of disparate privileging processes would create significant barriers to the establishment of equitable and effective processes for quality oversight and peer review. Indeed, allowing a hospital to grant privileges to practitioners who are not on the medical staff would complicate the peer review system, which is conducted by the medical staff and intended to continuously monitor and ensure the highest safety and quality standards for patients.
CMA recognizes that medical staffs can be comprised of both physician and non-physician members. However, determining the types of non-physician practitioners who are eligible for medical staff membership and granted clinical privileges directly impacts the quality of care at the hospital and should be decided by the medical staff, not the hospital. The CMA Model Medical Staff Bylaws enables a medical staff to allow non-physicians to be members and establishes a range of medical staff membership categories that reflect varying levels of medical staff participation and eligibility for clinical privileges. However, all eligible practitioners, regardless of membership category are still members of the medical staff and required to comply with the medical staff bylaws.

RECOMMENDATION: CMA recommends not amending § 482.22 in the manner proposed.

3. A broad expansion in the types of practitioners who can order the preparation of drugs and biologicals could potentially expand this authority to practitioners who lack the clinical training and expertise to be responsible for the care of patients.

The proposed rule contains a revision to the Nursing Services Conditions of Participation at § 482.23(c) which would allow for drugs and biologicals to be prepared and administered on the orders of practitioners other than those specified under §482.12(c). While we recognize that federal law already allows some non-physicians to write orders, in accordance with Federal and State laws—under California law, a physician assistant, nurse midwife, nurse practitioner, or naturopathic doctor may administer, provide, or issue a drug order for controlled substances under physician supervision—a broad expansion of this authority to any practitioner, as allowed by State law, would be ill-advised and potentially harmful to patients.

A practitioner writing orders for drugs and biologicals normally examines the patient and writes a prescription for treatment. The proposed revision could potentially expand the ability to write orders for drugs to practitioners who do not have the appropriate training, experience or clinical expertise to write such orders, as long as they are privileged and are not prohibited by state law from doing so.

RECOMMENDATION: CMA recommends not amending § 482.23(c) in the manner proposed.

1 Current federal law specifies the following practitioners may order drugs or biologicals, subject to legal authorization by the state: A doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, a chiropractor, a clinical psychologist.
4. Removal of the sunset provision and the 48-hour timeframe requirement for authentication of verbal orders is appropriate and eliminates a burdensome regulation.

CMA supports the consolidation of provisions related to authentication of orders into § 482.24(c)(2), which removes the 5-year sunset on the regulation that allows all orders to be dated, timed, and authenticated by the ordering practitioner or another practitioner who is responsible for the care of the patient; and removes that requirement that all orders be authenticated within 48 hours. The current regulations are unduly burdensome and divert precious time and resources away from the delivery of quality patient care. The proposed revisions bring the regulations into line with current medical practice in an environment focused on patient safety and the delivery of quality care. CMA agrees with the other stakeholders that the current requirement is burdensome and does not have any appreciable benefit for patients with regard to safe care.

RECOMMENDATION: CMA recommends amending § 482.24(c)(2) in the manner proposed.

5. A single and separate medical staff for each hospital within a multi-hospital system improves quality oversight of patient care.

Specific comments were requested regarding whether clarifying language is needed as to whether a single and separate medical staff is required for each hospital within a multi-hospital system. The analysis of the proposed rule indicates that CMS does not believe that this requirement is necessary.

CMA strongly opposes the option of having a single organized medical staff responsible for the quality of medical care provided to patients by all of the hospitals in the system. A single medical staff for multi-hospital systems would reduce the capacity of medical staffs to establish standards of care that reflect the local needs and medical culture at each hospital. In addition, it would be difficult for the medical staff to provide appropriate oversight and perform the necessary peer review functions, not to mention select from among their peers to lead the medical staff effectively. Effective peer review could be seriously undermined if not performed by physicians who are indeed peers and who know the local practices of a hospital and its community. Requiring medical staff members to provide care pursuant to bylaws and rules established by medical staff members who do not practice in a specific hospital could have a negative impact on the quality of care at a hospital. It is vital that functions such as credentialing, privileging, and peer review be conducted by medical staff members who practice at a hospital and pursuant to medical staff bylaws that reflect the local practice environment.
Therefore, we believe that the regulation should be amended to clarify that each hospital in a multi-hospital system must have a single, separate, independent and self governing medical staff.

**RECOMMENDATION:** CMA recommends that the regulations be amended to clarify that each hospital in a multi-hospital system must have a single, separate, independent and self governing medical staff.

6. Requirements for departmental leadership directly impact patient care and should be established by the independent, self-governing medical staff.

Specific comments were requested regarding the department specific organization of the current CoPs and the specified leadership requirements for each specialty department. As stated in the CMA Model Medical Staff Bylaws, each department should have a chair and vice-chair who are members of the active staff and shall be qualified by licensure, training, experience and demonstrated ability in at least one of the clinical areas covered by the department. Department chairs must be certified by an appropriate specialty board or must demonstrate comparable competence. In addition to exercising their responsibilities, all department chairs and vice chairs should verbally disclose all actual or potential conflicts of interest in the course of each department meeting or other event where such a disclosure may be relevant. Any potential conflicts so disclosed shall be resolved as set forth in the medical staff bylaws. Department chairs and vice-chairs should be elected every two years by those members of the department who are eligible to vote for general officers of the medical staff.

**RECOMMENDATION:** CMA recommends that requirements for departmental leadership directly impact patient care and should be established by the independent, self-governing medical staff.

In conclusion, CMA supports the overall concept of proposing changes to the requirements that hospitals must meet to participate in the Medicare and Medicaid programs, such that procedural burdens on providers are reduced. However, we have serious concerns regarding the proposed revision, particularly with respect to the removal of safeguards that ensure that hospital governing bodies and organized medical staffs have the independence and authority to make decisions that will protect patient care in the local community. In addition, the shift toward providing more flexibility for hospitals to enable other health practitioners, who may lack the appropriate training and experience, to expand their scope of practice is very troubling, and we urge you to reconsider these revisions.

Thank you in advance for your consideration of our comments on the proposed rule. California’s physicians look forward to working with you to develop federal regulations that reduce procedural burdens on providers, while keeping patient care and safety a top priority.
Respectfully submitted,

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Associate Director
California Medical Association