



**American Hospital
Association**

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December 16, 2011

Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

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

Dear Ms. Tavenner:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed regulation to reform the hospital and critical access hospital Conditions of Participation (CoPs) for the Medicare and Medicaid programs.

Overall, the AHA is pleased by the proposed rule, which represents the first comprehensive review and revision of the CoPs in more than 25 years. The proposed changes will allow hospitals and critical access hospitals (CAHs) to deliver more efficient, higher quality care by removing several antiquated regulatory burdens. The AHA urges CMS to consider additional revisions outlined in our comments below that will provide the strongest possible support to hospitals in maintaining high levels of service in a frequently changing health care environment.

GOVERNING BODY: § 482.12

The AHA supports CMS's intention to clarify that multi-hospital systems may have one governing body, thus eliminating the expectation that each hospital in a multi-hospital system must have its own governing body. This change recognizes the more integrated organizational model adopted by many hospitals. However, the proposed language does not specifically delineate CMS's stated position that multi-hospital systems can be effectively led by a single governing body. We urge CMS to adopt clearer language in the regulations. Specifically, we propose the following language:



There must be an effective governing body that is legally responsible for the conduct of the hospital. Hospital systems with more than one CMS Certification Number may have a single governing body. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

This kind of clarification in the final rule will provide better support for hospitals to create the most efficient and effective operating structures.

On a related note, we agree with CMS's position that a multi-hospital system may have a single organized medical staff responsible for the quality of the medical care provided by every hospital in the system. However, we urge CMS to update the language of the Medical Staff Conditions of Participation to make it consistent with proposed changes for the Governing Body requirements. As CMS has affirmed its belief that multi-hospital systems should be able to operate with one governing body and with one medical staff, the language for both sections should be uniform to reflect the consistency in the two policies.

As with the AHA's suggestion for the Governing Body requirements, we urge CMS to clearly state its position that multi-hospital systems may operate with a single integrated medical staff. The AHA proposes the following language for the Medical Staff provision:

There must be an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital. Hospital systems with more than one CMS Certification Number may have one medical staff.

Current language in both the Medical Staff regulations and the interpretive guidance directly addresses the circumstances of *individual* hospitals, and we believe the language suggested above will better achieve CMS's desired flexibility for multi-hospital systems.

PATIENT'S RIGHTS: § 482.13

The AHA supports the modification of reporting requirements for patient deaths involving the use of soft two-point wrist restraints and no seclusion. We also believe that allowing for fax and electronic reporting of deaths associated with other types of restraint and seclusion will assist hospitals in meeting their requirements.

However, it is problematic that CMS did not clarify the overall requirement for death reporting. The act of reporting all deaths while restrained does not truthfully indicate the number of deaths *caused* by restraints. For example, some patients may be near death when they are put into restraints. We recommend CMS clarify in the final rule that these individuals should not be included in the reporting requirement.

MEDICAL STAFF: § 482.22

The AHA applauds CMS's proposal to clarify that a hospital may grant privileges to both physicians and non-physicians to practice within the scope of practice allowed by state law. This move will allow practitioners to be granted privileges even if they are not a member of the medical staff. The AHA believes this change will allow hospitals to fully utilize the training, skills and potential of practitioners such as advanced practice registered nurses.

In addition, the AHA supports expanding the list of practitioners who may be given the responsibility for the organization and conduct of the medical staff to doctors of podiatric medicine.

NURSING SERVICES: § 482.23

The AHA supports CMS's proposals regarding the Nursing Services CoPs. Specifically, we endorse:

- More flexible requirements to let hospitals integrate a nursing care plan into a more comprehensive interdisciplinary plan of care. Many hospitals use an integrated plan of care that includes a variety of different health care disciplines, including respiratory care, pharmacy, and more. This change will promote quality by ensuring all relevant patient information is readily available in one location. This change also will foster efficiency by enabling hospitals to integrate all aspects of care into one all-inclusive and cohesive plan of care.
- Revisions to the CoPs that would allow for drugs and biologicals to be prepared and administered, as well as documented and signed, on the orders of practitioners other than those specified under § 482.12(c).
- CMS's proposal to allow for the preparation and administration of drugs and biologicals on the orders contained within pre-printed and electronic standing orders, order sets and protocols for patient's orders.
- The elimination of current regulations mandating that non-physicians who administer blood transfusions and intravenous medications must have special training. These duties have been nursing care functions for more than 20 years.
- CMS's proposal to allow hospitals to develop policies to enable a patient and/or the patient's caregivers to administer specific medications (other than controlled drugs and biologicals). Self-administration of many medications is an acceptable practice. This change also will make the rules consistent with interpretive guidelines for §482.25(b)(2)(i). For example, the guidelines recognize that items such as nitroglycerine tablets, inhalers, rewetting eye drops and other medications are already given to patients at bedside. The AHA also supports CMS's inclusion of safeguards for this policy, such as requirements for a practitioner to issue an order allowing self-administration, for

hospitals to ensure that caregivers have been given adequate instructions and for hospitals to make sure that documentation exists as to the administration of each medication.

MEDICAL RECORD SERVICES § 482.24

CMS currently requires all orders, including verbal orders, to be dated, timed and authenticated promptly by the ordering practitioner. The AHA supports CMS's plan to permanently adopt a five-year exception to this rule that allows another practitioner to authenticate orders as long as that practitioner is one who is responsible for the patient's care under § 482.12(c) and who has authority to write orders. In addition, we are pleased with the proposal to eliminate the requirement to authenticate all verbal orders within 48 hours absent a state law mandating another timeframe.

INFECTION CONTROL: § 482.42

The AHA agrees with CMS's proposal to eliminate the requirement that hospitals keep a separate infection control log. Offering more flexibility in how hospitals collect infection control information will lead to better and more efficient collection of relevant data.

OUTPATIENT SERVICES: § 482.54

The AHA applauds CMS's revision to allow one or more individuals to be responsible for outpatient services. As more care is delivered in an outpatient setting, this new framework will better ensure that individuals with the best expertise will direct each particular kind of care provided. The change also will remove the burden on hospitals to hire another person to oversee multiple directors in order to comply with the current mandate that one person must oversee outpatient services. Further, the AHA supports the proposed change to a requirement that a hospital have appropriate professional and non-professional employees at each location. The AHA agrees that this requirement should be based on the scope and complexity of the outpatient services.

TRANSPLANT CENTER PROCESS REQUIREMENTS: § 482.92

The AHA also agrees with CMS's proposal to remove the blood type verification requirements for transplant centers at § 482.92(a). This regulation is duplicative with regulations for Organ Procurement Organizations.

DEFINITIONS AND PROVISION OF SERVICES: § 485.602 AND § 485.635

The AHA supports removing the requirement for CAHs to provide direct services in the areas of general diagnostic/therapeutic services, radiology services, laboratory services and emergency procedures. This change will better enable smaller hospitals in more rural areas to address staffing challenges and provide high-quality care to their patients.

OTHER AREAS CMS IS SEEKING COMMENT

CMS asked for comments on several additional provisions in the CoPs. Below are the AHA's comments regarding those additional options for change under consideration by CMS.

Medical Staff Language. As noted above, CMS has stated that it does not believe that the current Medical Staff language requires a single and separate medical staff for each hospital in a multi-hospital system. **Please see our comments on page two of this letter regarding the changes the AHA believes are necessary to successfully clarify CMS's position.**

Overall Organization Structure. CMS considered revising the overall organizational structure of the CoPs to condense regulations for departmental leadership into a single non-specific regulation. However, CMS maintained that the department-specific organization and requirements of the CoPs are appropriate. **The AHA believes CMS should allow flexibility in organizational structure and requirements.**

History and Physical Exam. CMS asked for input on the current regulation requiring a hospital to update a History and Physical examination (H&P) when the H&P is completed within 30 days of admission or registration. CMS clarified that some hospitals may think that a full H&P is required when only an updated H&P for changes is required. While the AHA is generally supportive of this regulation, **we are concerned that the rigid interpretation of this requirement could create an unnecessary burden.** As the AHA and The Joint Commission previously noted, currently a patient who visits his doctor the day before or the morning of surgery and receives a H&P exam must undergo another H&P prior to surgery. **CMS should clarify the interpretive guidance with regard to exams conducted within 24 hours prior to admission or registration.**

Life-Safety Code Requirements. CMS is seeking comments with regard to the Life-Safety Code requirements. Federal regulations require hospitals to meet the standards of the 2000 version of the *Life-Safety Code* (LSC). As CMS recognizes, many accrediting bodies, as well as state and local jurisdictions, require hospitals to comply with more recent versions of the LSC, such as the 2003, 2006 or 2009 editions. **CMS should require usage of the most recent LSC available.**

Federal regulations should embrace the advances in technology and safety that can increase a patient's protection while in the hospital. For example, the 2000 edition of the LSC references more than 50 technical codes and standards, which have been updated over the years. Hospitals can be stuck using reference codes from as far back as 1995 because they are mandated by the 2000 edition of the LSC.

In addition, the use of outdated codes siphons significant resources away from patient care. New hospitals are built to comply with up-to-date codes, such as the 2012 *International Building Code* that will be used by most local municipalities and code officials to regulate the design and construction of health care facilities. But once hospitals open, they are surveyed using the outdated 2000 *Life Safety Code*. Hospitals spend significant resources and suffer lengthy delays in bringing new and updated spaces online because of conflicting codes and standards.

ADDITIONAL ISSUES CMS SHOULD REVISIT

Finally, the AHA would like to express its concern regarding three other areas of policy that affect hospitals' ability to provide high quality care to their patients.

Immediate Jeopardy. Section 3001 of the *Patient Protection and Affordable Care Act* states that hospitals cited for immediate jeopardy may not participate in the value-based purchasing program. **The AHA urges CMS to further define immediate jeopardy as well as the process in place to apply immediate jeopardy to value-based purchasing.** For example, it is unclear how many cited deficiencies are warranted for the exclusion to apply or whether degrees of severity are taken into account in deciding whether a hospital will be excluded.

Further, it is imperative to ensure that the organizations that issue immediate jeopardy citations do so in a uniform manner. **CMS should explain the process in place to guarantee that consistent standards will be used to evaluate situations in which immediate jeopardy is suspected.**

Interpretive Guidelines. As noted earlier, this proposed rule on CoPs for hospitals and CAHs marks the first attempt to comprehensively review and revise the requirements for participation in Medicare and Medicaid in more than 25 years. However, interpretive guidelines are frequently updated. Unfortunately, these guidelines often lack outside input and can appear to overreach the intent of the regulatory requirement. **CMS should revise the way in which it develops changes to interpretive guidelines to allow for meaningful stakeholder input.**

Privacy Standards. Currently, both the CoPs and the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) impose requirements related to medical record privacy on hospitals. The AHA urges CMS to eliminate what are very general medical record privacy requirements from the CoPs because the HIPAA provisions provide a more comprehensive, robust set of standards that protect both the privacy and security of all patients' medical information.

In interpreting the more general CoP regulatory text, CMS has frequently created standards that directly conflict with guidance issued by the HHS Office for Civil Rights (OCR) regarding compliance obligations under the HIPAA rules. For example, HIPAA permits a covered entity hospital or other provider to share without patient authorization information about a patient with another provider for treatment, payment or certain health care operations – even if that provider is not itself a HIPAA-covered entity. The sharing of information is permitted as long as both providers have a current or past relationship with the patient and the shared information relates to that relationship. In contrast, CMS interprets the more general CoP regulations to require specific patient authorization for the sharing of the patient's medical information between a covered entity and a separate provider. Such conflicting interpretations create confusion for providers and interfere with effective confidentiality and security protections for patient medical information.

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The comprehensive HIPAA standards, not the general COP provisions, provide the appropriate basis for protecting the privacy and security of patient medical information without inhibiting the coordination of patient care. We recommend that CMS eliminate the COP obligations for medical records confidentiality for providers. Instead, CMS should rely on and defer to OCR's interpretation, oversight and enforcement of the compliance obligations under the HIPAA privacy and security standards.

Thank you again for the opportunity to comment. If you have any questions, please contact me or Nancy Foster, vice president for quality and patient safety policy, at (202) 626-2337 or nfoster@aha.org.

Sincerely,

Rick Pollack
Executive Vice President