

December 5, 2011

## PROPOSED RULE FOR HOSPITAL & CAH CONDITIONS OF PARTICIPATION

### AT A GLANCE

#### **The Issue:**

On October 18, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule to revise the existing Medicare and Medicaid Conditions of Participation (CoPs) for hospitals and critical access hospitals (CAHs). Key provisions of the proposed rule include changes to the following requirements:

- **Governance and Medical Staff:** CMS proposes to recognize a single governing body over multiple-hospital systems, which is a change from its previous position that each hospital within a multi-hospital system had to have its own board. In addition, CMS stated that the current CoPs do not require a single and separate medical staff for each hospital in a multi-hospital system.
- **CAH Services:** CMS proposes to allow CAHs to provide certain services, such as diagnostic, therapeutic, laboratory, radiology and emergency services, under service arrangements. Current regulations require CAHs to provide these services directly.
- **Advanced Practice Practitioners:** CMS proposes several changes that would allow advanced practice practitioners (physician assistants, nurse practitioners) to serve in an expanded role. For example, the proposed changes would allow advanced practice practitioners to order medications for patients and to document and sign those orders.
- **Elimination of Paperwork:** CMS proposes to eliminate the current criteria around infection control logs and allow hospitals flexibility in their approach to the tracking and surveillance of infections.
- **Outpatient Services:** CMS intends to remove the requirement for a sole director over all outpatient services.

The [proposed rule](#) was published in the October 24 *Federal Register*, and comments are due to CMS by December 23.

#### **Our Take:**

The AHA is pleased that CMS proposes to revise some antiquated CoP policies and remove several regulatory barriers and burdens. These changes, many recommended by the AHA, will allow hospitals and CAHs to deliver more efficient, higher-quality care. While we will likely seek further refinements of the proposed rule, the AHA is supportive of CMS's overall direction to modernize the CoPs and ease outdated regulations.

#### **What You Can Do:**

- ✓ Share this advisory with your chief financial officer, chief quality officer, compliance managers, risk managers, and physician and nursing leaders.
- ✓ Submit comments directly to CMS on this proposed rule by December 23, describing how each proposed regulatory change listed above will impact your hospital's ability to provide high-quality care to patients.
- ✓ Share this advisory and your comments with your state survey agencies.

#### **Further Questions:**

Please contact Evelyn Knolle, AHA senior associate director of policy, at (202) 626-2963 or [eknolle@aha.org](mailto:eknolle@aha.org).

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### BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) requires hospitals to meet specified Conditions of Participation (CoPs) in order to participate in the Medicare and Medicaid programs. The CoPs set forth basic requirements related to a hospital's structure, operations and delivery of care. CMS believes the standards required by the CoPs are essential to protect the health and safety of patients and improve the quality of care delivered. CMS published a [proposed regulation](#) to revise the existing CoPs for hospitals and CAHs in the October 24 *Federal Register*. Comments are due to CMS by December 23.

In anticipation of a revision of the CoPs, the AHA and The Joint Commission met with CMS officials in April 2010. We also sent a detailed list of issues for CMS to consider as the agency sought to comply with the President's Executive Order to reduce regulatory burden. CMS adopted many of the AHA's suggestions. While not perfect, the proposed rule provides much-needed regulatory relief for hospitals.

Specific proposed changes are highlighted below. These changes represent a subset of the CoP's in need of revision. The AHA will continue to advocate for modifications to the CoPs that will better enable hospitals to continue to provide high-quality care.

### AT ISSUE

#### ***Changes to CoP Regulations***

The following table compares the current CoPs for hospitals and CAHs to the proposed changes. Current regulations are listed in the left-hand column; proposed modifications are outlined in the right-hand column. There are critical changes in the CoPs for governance, patient's rights, medical staff, critical access hospital (CAH) services, advanced practice practitioners and more.

CURRENT REGULATIONS	PROPOSED CHANGES
<b>Governing Body: § 482.12</b>	
<p>Currently each hospital must have its own governing body or must identify persons who are legally responsible for the conduct of the hospital. Thus, each hospital in a multi-hospital system must have a separate governing body. <b>The AHA pointed out to CMS that multi-hospital systems have integrated their governing body and medical staff functions to oversee care in a more efficient and effective manner and will have to go through a duplicative process to comply with CoPs.</b></p>	<p>CMS proposes to change the Governing Body requirement to reflect the current organizational framework of multi-hospital systems. CMS’s proposal would allow hospital systems with more than one CMS certification number to have one governing body.</p>
<b>Patient’s Rights: § 482.13</b>	
<p>Under current regulations, hospitals must report several kinds of deaths associated with restraint and seclusion, including:</p> <ul style="list-style-type: none"> <li>• the deaths of patients in restraints or seclusion;</li> <li>• the deaths of patients who have died within 24 hours after being removed from restraints or seclusion; and</li> <li>• the deaths of patients who have died within one week of being removed from restraint or seclusion when the restraint or seclusion contributed to the patient’s death.</li> </ul> <p>Hospital administrators must report each death to CMS via telephone by close of business on the next business day after they learn of the death.</p>	<p>CMS is modifying the reporting requirements of hospitals when a patient’s death involves the use of soft two-point wrist restraints and no seclusion. Under proposed regulations, deaths in these circumstances would have to be reported in seven days through a log or other system available to CMS.</p> <p>CMS will retain the reporting requirements for deaths involving other types of restraints and seclusion, but CMS proposes to provide additional reporting options, such as fax and electronic (not just email) reporting.</p>

<b>Medical Staff: § 482.22</b>	
<p>Current regulations require hospitals to have a medical staff that is responsible for the quality of the medical care provided. Interpretive guidance states that, “A hospital may have only one medical staff for the entire hospital (including all campuses, provider-based locations, satellites, remote locations, etc.).”</p>	<p>CMS believes the current Medical Staff requirements can be interpreted to allow multi-hospital systems to have one medical staff. Therefore, CMS is not proposing to change the language of the Medical Staff Conditions of Participation. CMS is seeking comment on this issue.</p> <p>As noted above, <b>the AHA pointed out to CMS that multi-hospital systems have integrated their governing body and medical staff functions to oversee care in a more efficient and effective manner.</b></p>
<p>The medical staff must conduct reviews of their members, appraise the credentials of candidates for appointment to their medical staffs, and make recommendations to the governing body. The medical staff must be composed (at a minimum) of doctors of medicine or osteopathy. When state law permits, the medical staff also may be composed of other practitioners appointed by the governing body. <b>The AHA pointed out to CMS that sometimes advanced practice registered nurses (APRNs) are not allowed to perform functions that are within their state scope of practice.</b></p>	<p>CMS proposes to clarify in the final CoP rule that a hospital may grant privileges to both physicians and non-physicians to practice within their state scopes of practice. In other words, practitioners may be granted privileges even if they are not members of the medical staff. This change would align the rule with existing interpretive guidance on this issue. All practitioners with privileges would continue to follow the rules set out in § 482.22 for Medical Staff.</p>
<p>Current regulations dictate that the responsibility for the organization and conduct of the medical staff may only be given to a doctor of medicine or osteopathy. If state law permits, this responsibility also may be given to a doctor of dental surgery or dental medicine.</p>	<p>CMS would expand the list of practitioners who may be given the responsibility for the organization and conduct of the medical staff to doctors of podiatric medicine. Therefore, DPMs also could serve as the president of a hospital’s medical staff.</p>

**Nursing Services: § 482.23**

A hospital must develop a nursing care plan for each patient. **However, as the AHA pointed out to CMS, many hospitals use an integrated plan of care that includes a variety of different health care disciplines, including respiratory care, pharmacy and other services.**

CMS proposes to let hospitals integrate a nursing care plan into a more comprehensive interdisciplinary plan of care. Hospitals would no longer need to have a separate nursing plan of care, as long as the nursing services were integrated into the overall interdisciplinary plan of care.

Generally, orders for drugs and biologicals must be prepared and administered in accordance with:

- federal and state laws;
- accepted standards of practice; and
- the orders of a practitioner who is 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 or a clinical psychologist.

Revisions to the CoPs would allow for drugs and biologicals to be *prepared and administered* on the orders of practitioners other than 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, or a clinical psychologist. This change brings the rule into closer alignment with interpretive guidance, which states that under certain circumstances, nurse practitioners and physician assistants may order drugs and biologicals.

Orders for drugs and biologicals, with the exception of certain vaccines, must be documented and signed by a practitioner who is:

- authorized by hospital policy and State law to write orders; and
- 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 or a clinical psychologist.

Orders for drugs and biologicals also could be *documented and signed* by practitioners other than 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 or a clinical psychologist.

**For both of these revisions, practitioners still must comply with state laws and scopes of practice, and they must have privileges at the hospital.**

<p>The nursing section of the CoPs does not directly address the use of standing orders. Recently-updated interpretive guidance states that it is permissible for hospitals to use standing orders in “well-defined clinical scenarios involving medication administration.” The guidance outlines CMS’s expectations with regard to the development of standing order policies and implementation.</p>	<p>CMS proposes to include language in the regulations 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. However, these orders must meet Medical Record Services requirements at § 482.24(c)(3). For example, a hospital must:</p> <ul style="list-style-type: none"> <li>• establish that these orders/protocols have been reviewed/approved by the medical staff;</li> <li>• demonstrate that its standing orders and protocols are consistent with nationally recognized and evidence-based guidelines;</li> <li>• ensure that the medical staff periodically reviews the orders/protocols; and</li> <li>• ensure that such orders are dated, timed and authenticated promptly in the patient’s medical record by the ordering practitioner or another practitioner who has responsibility for the patient and who has authorization to write orders.</li> </ul>
<p>Existing regulations require non-physicians who administer blood transfusions and intravenous medications to have special training. <b>The AHA suggested elimination of this requirement because these duties have been nursing care functions for more than 20 years.</b></p>	<p>CMS proposes to eliminate this requirement. CMS will continue to require that those who administer blood transfusions and intravenous medications must abide by state law and medical staff policies.</p>

<p>Currently, CMS requires that all drugs and biologicals be administered by, or under supervision of, nursing or other personnel in accordance with federal and state laws and regulations.</p>	<p><b>At the urging of the AHA</b>, CMS proposes to add a section 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). Hospitals would need to establish policies and procedures for such a program using a collaborative effort that includes the medical staff, the nursing department and the pharmacy department.</p> <p>A hospital must ensure that:</p> <ul style="list-style-type: none"> <li>• a practitioner has issued an order allowing self-administration;</li> <li>• the capacity of the patient or their caregiver has been assessed;</li> <li>• the patient or the caregiver has been given adequate instructions;</li> <li>• the medication is secure; and</li> <li>• there is documentation of the administration of each medication.</li> </ul>
<p><b>Medical Record Services: § 482.24</b></p>	
<p><i>Verbal Orders:</i>          CMS currently requires all orders, including verbal orders, to be dated, timed and authenticated promptly by the <u>ordering</u> practitioner. There is a five-year exception to this rule (until Jan. 26, 2012) that allows another practitioner to authenticate orders as long as that practitioner is one who is responsible for the patient’s care. All verbal orders must be authenticated in 48 hours, absent a state law requiring another timeframe.</p>	<p>CMS would remove the sunset provision, thus permanently adopting the five-year exception. <b>In addition, in response to suggestions by the AHA that a 48-hour window is too rigid for community hospitals that do not have the benefit of medical residents</b>, CMS proposes to remove the 48-hour timeframe requirement for authentication of verbal orders. CMS would instead defer to hospital policies and state law for timeframes. For example, if no state law establishes a timeframe, hospitals could develop their own.</p>

<p><i>Standing Orders:</i> Recently-updated interpretive guidance states that it is permissible for hospitals to use standing orders in “well-defined clinical scenarios involving medication administration.” The guidance outlines CMS’s expectations with regard to the development of standing order policies and implementation</p>	<p>CMS proposes to include language in the regulations 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. However, these orders must meet Medical Record Services requirements at § 482.24(c)(3). For example, a hospital must:</p> <ul style="list-style-type: none"> <li>• establish that these orders/protocols have been reviewed/approved by the medical staff;</li> <li>• demonstrate that its standing orders and protocols are consistent with nationally recognized and evidence-based guidelines;</li> <li>• ensure that the medical staff periodically reviews the orders/protocols; and</li> <li>• ensure that such orders are dated, timed and authenticated promptly in the patient’s medical record by the ordering practitioner or another practitioner who has responsibility for the patient and who has authorization to write orders.</li> </ul>
<b>Infection Control: § 482.42</b>	
<p>Hospitals must keep a log identifying problems with regard to infections and communicable diseases. <b>The AHA suggested that CMS offer more flexibility in how hospitals collect infection control information.</b></p>	<p>Hospitals would no longer need to have a separate infection control log. CMS believes the same activities are already required by another part of this section.</p>

<b>Outpatient Services: § 482.54</b>	
<p>Currently, hospitals must assign one person to be responsible for outpatient services. <b>The AHA urged CMS to consider that, as more care is delivered in an outpatient setting, some hospitals appoint more than one person to direct various services.</b> This framework ensures that individuals with the best expertise direct each type of care provided. Because of these regulations, many hospitals have hired another person to oversee multiple directors.</p>	<p>CMS proposes to allow hospitals to assign one or more individuals to oversee the responsibility of outpatient services.</p> <p>CMS also proposes to change a requirement that a hospital have appropriate professional and non-professional employees at each location. CMS would now base this requirement on the scope and complexity of the outpatient services.</p>
<b>Transplant Center Process Requirements: § 482.92</b>	
<p>A provision at § 482.92(a) requires a transplant team to verify blood type before organ recovery. CMS believes this regulation overlaps with the regulations for Organ Procurement Organizations.</p>	<p>CMS would remove the blood type verification requirements for transplant centers at § 482.92(a).</p>
<b>Definitions and Provision of Services: § 485.602 and § 485.635(b)</b>	
<p>Current regulations require CAHs to furnish certain services directly, including general diagnostic/therapeutic services (such as those offered in a physician's office), radiology services, laboratory services and emergency procedures.</p>	<p>CMS proposes to change this requirement to allow CAHs more flexibility to use arranged services. CMS would remove language requiring direct services in the areas of general diagnostic/therapeutic services, radiology services, laboratory services and emergency procedures.</p> <p>A hospital's governing body would still be responsible for all services provided by the CAH, regardless of whether they are provided directly or under agreements.</p>

Clarifying Changes:	
<i>Pharmaceutical Services and Infection Control:</i>	CMS would replace the term “quality assurance program” with the more current term, “Quality assessment and performance improvement program” in § 482.25(b)(6) and § 482.42(b)(1). This will clarify that CMS expects drug errors, adverse reactions and incompatibilities to be addressed in the hospital’s Quality Assessment and Performance Improvement program.
<i>Personnel Qualifications:</i>	CMS would change the definition of clinical nurse specialist at § 485.604(a) to state that a clinical nurse specialist is a registered nurse licensed to practice nursing in the state in which the clinical nurse specialist services are performed <u>and</u> who holds an advanced degree in a defined clinical area of nursing from an accredited educational institution.
<i>Surgical Services:</i>	CMS would change the language in § 485.639 to clarify that surgical services are optional services for CAHs.

### Other Options Considered by CMS

**CMS is seeking comments on the following four issues:**

<b><i>Medical Staff.</i> The AHA pointed out that multi-hospital systems often have integrated medical staffs.</b>	CMS does not believe that the current Medical Staff language requires a single and separate medical staff for each hospital in a multi-hospital system. CMS seeks comment on whether they should propose language to clarify this position.
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<p><i>Medical Staff:</i> <b>The AHA urged CMS to allow flexibility in organizational structure and requirements.</b></p>	<p>CMS considered revising the overall organizational structure of the CoPs to condense regulations for departmental leadership into a single non-specific regulation. However, CMS thinks the department-specific organization and requirements of the CoPs are appropriate. CMS seeks comment on this issue.</p>
<p><i>Medical Record Services:</i> <b>The AHA noted that current regulations regarding History and Physical (H&amp;P) requirements can be interpreted too rigidly.</b></p>	<p>CMS does not believe the current regulation, which requires a hospital to update a H&amp;P in the last 30 days prior to admission, needs revision. The agency notes that some hospitals may think that a full H&amp;P is required when only an updated H&amp;P for changes in the patient’s condition is required. CMS does not specify the extent of the examination. CMS seeks comment on whether this regulation should be amended.</p>
<p><i>Physical Environment: <u>Life-Safety Code.</u></i> <b>The AHA pointed out that CMS is using an outdated version of the Life Safety Code.</b> Currently, hospitals are required to meet the standards of the 2000 edition of the Life-Safety Code, which is not the most recent edition. The 2012 edition was released earlier this fall.</p>	<p>CMS will decide if another edition of the Life-Safety Code should be incorporated in to the regulations. CMS is seeking comments on this issue.</p>

### **NEXT STEPS**

The AHA will submit comments to CMS and encourages members also to send comments outlining how the agency’s proposal will affect their facilities and patients. Comments are due by December 23 and may be submitted electronically at <http://www.regulations.gov>. Follow the instructions for “Comment or Submission.” You may use Microsoft Word, WordPerfect or Excel; however, CMS prefers Microsoft Word.