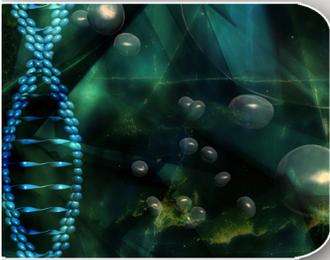




August 2012



## CMS Revised Hospital Conditions of Participation Now in Effect

A Polsinelli Shughart Update

### CMS Revised Hospital Conditions of Participation Now in Effect

**O**n July 16, 2012, in response to the President's Executive Order directing federal agencies to achieve a more streamlined and efficient regulatory framework for hospitals, a final rule revising hospital and critical access hospital (CAH) Conditions of Participation (CoPs) became effective. The CoPs revisions are expected to reduce the total regulatory burden for hospitals and CAHs by nearly \$940 million initially and \$5 billion over the next 5 years.

### Hospital Governing Body & Medical Staff Requirements

The final rule included two significant substantive changes to the hospital governing body requirements that had not been previously addressed in proposed rulemakings. First, the Centers for Medicare & Medicaid Services (CMS) now permits one governing body to oversee multiple hospitals in a multi-system hospital system; and second, CMS added a requirement that at least one member of a hospital's medical staff be included on the governing board to

ensure effective communication and coordination between a single governing body and the medical staffs of individual hospitals in the system.

These changes drew immediate criticism from the American Hospital Association (AHA), which offered a letter decrying the final rule as a violation of the Administrative Procedures Act (APA) because hospitals and other stakeholders had no notice that CMS was considering these revisions and could not adequately comment on them. CMS responded, noting the numerous questions and concerns raised by various stakeholders regarding the revised regulation requiring inclusion of one or more members of the medical staff on a hospital's governing body. Given the "complexity of the issues that have been raised" and the "interaction of this requirement with other Federal, State, or local laws," CMS stated its intention to carefully review comments and reconsider the requirement in future rulemaking. Additionally, Medicare-approved hospital accreditation programs are not expected to revise their accreditation standards related to this rule until it has been addressed completely by CMS.

## Definition of Medical Staff & Medical Staff Leadership

CMS also expanded the role of non-physician practitioners, redefining the "medical staff," to give hospitals flexibility to include other practitioners as eligible candidates for medical staff membership. Under the final rule, non-physician practitioners such as advanced practice nurses, physician assistants, and pharmacists are eligible for appointment to a hospital's medical staff and would be subject to the same approval process and medical staff requirements as physician practitioners, albeit within the scope of their practice permitted by state laws. Although hospitals may consider using this broadened definition of the medical staff, the final rule does not *require* that non-physician practitioners be eligible for medical staff appointment. Hospitals that elect to adopt the expanded definition must amend their medical staff bylaws and

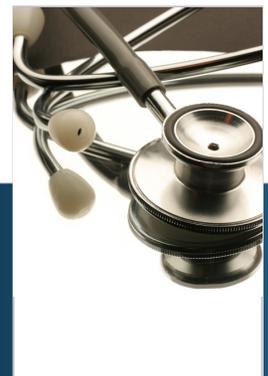
regulations—as well as other corporate documents—to reflect such changes.

In addition to expanding the role of non-physician practitioners, the final rule allows podiatrists to assume responsibility in the organization and conduct of the medical staff. This change permits podiatrists to assume new leadership roles within medical staffs where not otherwise prohibited by state law. Hospitals may expand the roles of podiatrists within their medical staff leadership structure but are not required to do so.

## Critical Access Hospitals Provision of Services

Prior to the final rule, the CoPs required CAHs to furnish certain types of services directly rather than through contracts or other arrangements. Specifically, the CoPs at § 485.602 defined "direct services" as those provided by CAH staff, not through arrangements or agreements. The CoPs at 485.635(b) required CAHs to furnish certain types of services directly, including (1) diagnostic and therapeutic services that are commonly furnished in a physician's office or another entry point into the health care system; (2) laboratory services; (3) radiology services; and (4) emergency procedures.

In the final rule, CMS eliminated the burdensome requirement that these services be provided directly and permits CAHs to provide such services



“under arrangements”. This revision may offer hospitals opportunities to provide alternative and additional services while achieving significant cost savings. CAHs could consider potential joint ventures for providing basic, required services or expanded services otherwise unavailable to the hospital. The governing body, or the person wholly responsible for the operation of the CAH, will continue to be responsible for all services furnished by the CAH, whether they are furnished directly, under arrangements, or under agreements. Further, the CAH must continue to meet any other CoPs and should ensure that all services provided under arrangements comply with provider-based requirements and are permitted under state law.

### Additional Revised Hospital CoPs Include:

CMS replaced the requirement that hospitals report restraint-related deaths with a requirement that hospitals maintain an internal log of all such deaths. The log should reflect: the patient’s name, date of birth, date of death, attending physicians and staff, medical record number, and the primary diagnosis or diagnoses.

Hospitals are now permitted to have a stand-alone nursing care plan or a single interdisciplinary care plan that addresses nursing and other disciplines.

Hospitals may implement programs for patients to self-administer appropriate medications. Policies and procedures must be updated to reflect safe and accurate administration of medications, a process for training and medication security, and the method by which medications will be documented.

Non-physician personnel are no longer required to have special training in administering blood transfusions or intravenous medications. Additionally, drugs and biologicals are now permitted to be prepared and

administered on the order of a practitioner other than a physician in accordance with hospital policies and state law. Hospital policies and organizational documents should be updated to reflect these revisions.

CMS now allows standing orders and has added a requirement for medical staff, nursing, and pharmacy to approve written and electronic standing orders, order sets, and protocols. Further, the requirement that verbal orders are authenticated within 48-hours has been eliminated and all orders must be dated, timed, and authenticated by signature. Hospitals should defer to other applicable state laws to establish policies for orders.

The CoPs requirement that a hospital maintain an infection control log has been eliminated. Hospitals should ensure that their current infection control monitoring policies are effective and up to date.

Hospitals are no longer required to designate a single Director of Outpatient Services. Organizational and departmental structures can be established at the discretion of hospital directors or the governing board.

The revised CoPs eliminate a duplicative requirement for an organ recovery team to conduct a blood type and other vital data verification before organ recovery.



## What Hospitals Should Do Now

Hospitals should continue to monitor CMS guidance on this issue and postpone any significant changes to board composition until interpretive guidelines are released. However, hospitals should consider how to implement the revised CoPs if they are confirmed by CMS in the future. In addition to including at least one medical staff member on its governing board, hospitals' corporate bylaws and medical staff rules and regulations must be updated to reflect the new CMS requirements. Hospital culture, medical staff privileges and prerogatives, and roles of other hospital practitioners should be considered when amending corporate documents. Where a governing board oversees more than one hospital, it would not be required to have a representative from each hospital's medical staff on the board. Rather, a single medical staff member from one of the medical staffs must be included on the board.

Further, the CoPs revisions do not change the requirement that a hospital maintain separate medical staffs and executive committees for each individual National Provider Identifier (NPI).

## Conclusion

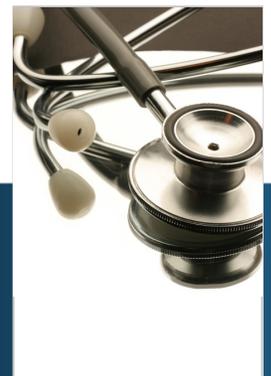
The final regulations should be reviewed by hospitals and other stakeholders to ensure ongoing compliance with the CoPs and to assess other opportunities for structural and organizational streamlining. Further, hospitals should be prepared for forthcoming Interpretive Guidelines or additional guidance as a result of controversial changes implemented by CMS to the structure of governing bodies. ■



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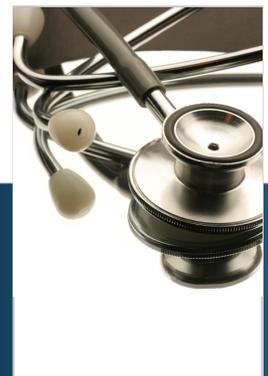
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