

CMS REDUCES REGULATORY BURDENS ON HOSPITALS AND CAHS - FINAL RULE MODIFIES COPS

OVERVIEW

CMS has released a final rule ("Final Rule") revising the hospital and critical access hospital ("CAH") Medicare conditions of participation ("CoPs"). This Final Rule implements President Obama's Executive Order 13563 calling for removal or modification of obsolete or unnecessary regulations on hospitals and CAHs. Indeed, the Final Rule reduces burdens, provides flexibility and saves a great deal of money estimated to be almost \$5,000,000,000 for hospitals and CAHs over the next five years. The Final Rule finalizes a proposed rule published on October 24, 2011 and summarized in a previous edition of Hall Render's [Health Law News](#). This Health Law News article will discuss the hospital CoP revisions. A companion article found [here](#) summarizes the CAH CoP revisions. The Final Rule will be effective on or about July 16, 2012 and is scheduled to be published in the Federal Register on May 16, 2012.

THE FINAL RULE - HOSPITALS

The following summarizes the final revisions to the Hospital CoPs found in Part 482 of the Medicare regulations.

Governing Body Requirements (42 C.F.R. §482.12)

Proposed Revision. CMS proposed to permit a single governing body for hospitals in a multi-hospital system.

Final Rule. CMS approved this revision and also added an additional requirement for at least one member of a hospital's medical staff to serve as a member of the multi-hospital system governing body in order to ensure appropriate communication and coordination between the system governing body and the medical staffs of the individual hospitals comprising the system. CMS clarified that it is *not* requiring a medical staff member from *each* of the system hospitals to serve. CMS also notes that a system governing body is free to place as many medical staff members on the governing body as it desires and also that it would expect the governing body to consider each individual hospital's patient population when it determines the number and composition of medical staff members to serve on a system board.

Patient's Rights Requirements (42 C.F.R. §482.13)

Proposed Revision. Under the proposed rule, if the circumstances of a patient's death only involved the use of soft two-point wrist restraints without seclusion, the hospital would be obligated to report the death within seven days after the date of death via a log or other system and make the log or other system immediately accessible to CMS upon request. The log would include, at a minimum, patient name, dates of birth and death, attending physician's name, primary diagnosis and medical record number. The reporting requirements for all other deaths involving restraints (e.g., hard restraints) and/or seclusion would remain the same as under the current CoP, meaning, next business day notification following knowledge of a patient's death. CMS also proposed to permit, in addition to telephone notification, reporting of seclusion and/or other restraint-related deaths by fax or electronic reporting.

Final Rule. CMS has finalized the proposed rule as set forth above but clarified that hospitals need only record in an "internal" log or "other system," soft wrist restraint-related deaths and need not submit the information in the log or other system to CMS (unless specifically requested) or publicly release the information in any way. Further, CMS clarified that the name of the attending physician "or other licensed independent practitioner" responsible for the care of the patient would be included in the log entry. CMS added "other licensed independent practitioner" to reflect the fact that non-Medicare patients may be under the care of a licensed independent practitioner if permitted under state law and hospital policy.

Medical Staff Requirements (42 C.F.R. §482.22)

Proposed Revision. CMS proposed to clarify that a hospital may privilege physicians as well as non-physician practitioners within their state-designated scope of practice even if they do not seek medical staff membership. In other words, formal appointment to the medical staff would not be required to apply for and obtain practice privileges. Further, all those granted practice privileges, even in the absence of medical staff appointment, would be subject to generally the same medical staff requirements and approval process as that set forth in 42

C.F.R. §482.22. Finally, CMS proposed to permit doctors of podiatric medicine ("DPM"), as permitted by state law, to assume managerial positions such as president of the medical staff.

Final Rule. CMS modified the proposed rule and current requirements under the CoP as follows: First, in response to multiple commenter concerns regarding the unintended consequences of bifurcating medical staff "membership" from "privileging" (e.g., loss of participation in and protection of the medical staff), CMS removed the proposed concept of physicians and other practitioners being privileged to practice without appointment to the medical staff. Under the Final Rule, the medical staff may include other categories of non-physician practitioners, determined as eligible, for appointment to the medical staff by the governing body. The medical staff must examine the credentials of all eligible candidates for the medical staff and make recommendations on appointment in accordance with state scope of practice laws and medical staff bylaws, rules and regulations. Any candidate recommended by the medical staff and appointed by the governing body would be subject to all medical staff bylaws, rules and regulations. Finally, as proposed, responsibility for organization and conduct of the medical staff now may be assigned to DPMs if permitted by state law.

Nursing Services Requirements (42 C.F.R. §482.23)

Proposed Revision. CMS proposed to revise the CoPs to permit the hospital to integrate the nursing care plan into the overall hospital interdisciplinary care plan, thus avoiding the requirement of two care plans for nursing services. Further, under the proposed revised CoPs, the nursing staff would be permitted to prepare and administer drugs and biologicals ordered by midlevel practitioners, such as APRNs, PAs and Doctors of Pharmacy, subject to state scope of practice laws and appropriately granted hospital privileges or pursuant to pre-printed and electronic standing orders, order sets and protocols. Additionally, nursing staff no longer would require special training for administration of blood transfusions and IV Meds, and patients or their caregivers would be permitted to self-administer certain home or hospital-issued drugs and biologicals, if the hospital develops policies and procedures covering this practice.

Final Rule. CMS finalized the nursing care plan efficiency measures by permitting either a stand-alone nursing care plan or one integrated into an interdisciplinary care plan. CMS also will allow for drugs and biologicals to be prepared and administered on the orders of non-physician practitioners only if such practitioners are acting pursuant to state law, including scope of practice laws, hospital policies and medical staff bylaws, rules and regulations. The non-physician practitioners also may document and sign these orders, again, pursuant to state law and hospital policy. CMS finalized its proposal to permit non-physician personnel to administer blood transfusions and intravenous medications without "special training" but clarified that administration must be done in accordance with state law and medical staff policies and procedures. Finally, CMS will allow hospitals to institute an optional program for patient/caregiver administration of patient's own or hospital-issued medications. The hospital must institute policies and procedures that:

- Ensure that there is a practitioner-written order permitting self-administration;
- Assess the patient's or caregiver's capacity for self-administration;
- Instruct the patient or caregiver on safe and accurate administration;
- Address the security of the medications;
- Document the administration of each medication in the medical record as reported by the patient/caregiver;
- With respect to medications brought from home, provide for identification of the medications and visual evaluation of the medication integrity.

Medical Record Services Requirements (42 C.F.R. §482.24)

Current CoP. Currently, all orders, including verbal orders, must be dated, timed and authenticated promptly by the ordering practitioner. Until January 2012, the orders could also be authenticated by "another practitioner responsible for the patient's care and authorized by hospital policy to write orders," but that temporary provision expired ("Sunset Provision"). Also, verbal orders must be authenticated within the specific time frame specified by state law or, if the state law is silent, within 48 hours.

Proposed Revision. At the time the proposed rule was published, the Sunset Provision was still in force and CMS proposed to maintain the Sunset Provision permanently so that "another practitioner..." could continue to authenticate patient orders without any time limit on that authority. CMS also proposed to strike the 48-hour requirement for authentication of verbal orders, opting instead to defer to state law or

hospital policy for the required timing on authentication of verbal orders. Finally, CMS proposed to allow hospitals to use standing orders and protocols for patient orders subject to a number of requirements.

Final Rule. CMS has made permanent the previous Sunset Provision, which permitted another practitioner, also responsible for the patient's care, to authenticate any patient orders. CMS dropped the 48-hour requirement for authentication of verbal orders deferring instead to state law or hospital policy to establish authentication timeframe requirements. Finally, CMS is permitting hospitals to use pre-printed or electronic standing orders, order sets and protocols for patient orders subject to the following requirements:

- The orders and protocols must be reviewed and approved by the medical staff and nursing and pharmacy leadership;
- Orders and protocols must be based on nationally recognized and evidence-based guidelines and recommendations;
- The orders and protocols must be reviewed regularly to ensure continued usefulness and safety;
- The orders and protocols must be dated, timed and authenticated promptly in the patient's record.

Infectious Control Requirements (42 C.F.R. §482.42)

Proposed Revision. CMS proposed to rescind the requirement for maintenance of a log of incidents related to infections and communicable diseases.

Final Rule. CMS has eliminated the requirement that hospitals maintain an infection control log, noting that hospitals must monitor infections through other surveillance methods.

Outpatient Services Requirements (42 C.F.R. §482.54)

Proposed Revision. CMS proposed to eliminate the requirement that there be one individual responsible for all outpatient services.

Final Rule. CMS has finalized the proposed rule, noting that requiring a single "Director of Outpatient Services" to oversee all outpatient departments is unnecessarily duplicative, particularly when there exist separate directors for individual outpatient departments.

Transplant Center Process Requirements - Organ Recovery and Receipt (42 C.F.R. §482.92)

Proposed Revision. To reduce the amount of blood type verification paperwork and the associated costs, CMS proposed to amend the transplant center CoPs to eliminate the requirement that transplant teams verify blood type before organ recovery if the intended transplant recipient is known.

Final Rule. The proposed rule was finalized as proposed, with CMS noting that the provision to be removed is redundant with the organ procurement organizations conditions for coverage.

PRACTICAL CONSIDERATIONS

The Final Rule should facilitate significant savings in staff time and administrative costs and will create needed flexibility for staffing hospitals and caring for patients. Hospitals will need to do an extensive review and update of hospital bylaws; medical staff bylaws and rules and regulations; as well as hospital and department policies and procedures to implement changes required or permitted by the revised CoPs. For example, hospitals desiring to establish a medication self-administration program or to use standing orders and protocols will need to craft the required policies and ensure that staff are educated on these new policies. CMS intends to issue new interpretive guidelines providing guidance on the revised CoPs. Stay tuned for future updates.

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