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Proposed Changes to Medicare's Conditions of Participation for Hospitals

INSIDE THIS ISSUE

Carla DewBerry, J.D., editor (cdewberry@gsblaw.com)

Hospitals and critical access hospitals (CAHs) must meet certain requirements in order to participate in the Medicare and Medicaid programs. These requirements are referred to as the Conditions of Participation ("CoPs").

On October 24, 2011, CMS published proposed revisions to the CoPs. (Please see http://www.gpo.gov/fdsys/pkg/FR-2011-10-24/html/2011-27175.htm.)

Starting on page two of this newsletter we have summarized the proposed changes.

CMS believes these changes will reduce certain processes that are an unnecessary burden to hospitals. CMS has asked for comments on the proposed changes. Comments are due by December 23, 2011.

CMS considered a number other changes, and elected not to make changes in some areas but is also requesting comments on the changes not made.

The proposed changes are summarized, beginning on page 2.

Please see *Chart starting* on page 2

Summary of Proposed Changes to CoPs	
Governing body (§482.12)	The governing body CoP (§482.12) states that a hospital must have an effective governing body that is legally responsible for the conduct of the hospital as an institution. CMS has interpreted the governing body CoP as requiring that each hospital facility have its own separate governing body. (*See* http://www.cms.gov/manuals/downloads/som107ap_a_hospitals.pdf.) CMS has reviewed this rule in the context of multi-hospital systems. A "multi-hospital system" means organizations having more than one CMS Certification Number (CCN). CMS has concluded that multi-hospital systems can be effectively governed by a single governing body. Therefore CMS proposes to revise and clarify the governing body requirements to allow multi-hospital systems that have integrated their governing body functions to qualify under the CoP. Regulation 43 C.F.R §482.12 would be revised to read as follows: "There must be an effective governing body that is legally responsible for the conduct of the hospital." CMS will retain the current provisions in the CoPs that require the persons legally responsible for the conduct of the hospital to carry out the functions specified in Part 482 of the regulations that pertain to the governing body, if the hospital does not have an organized governing body.
Patient's rights (§482.13)	The current CoPs require hospitals to report no later than the close of business on the next business day following knowledge of a patient's death: (1) each death that occurs while the patient is in restraint or seclusion; (2) each death that occurs within 24 hours after the patient has been removed from restraint or seclusion; and (3) each death known to the hospital that occurs within one week after restraint or seclusion where it is reasonable to assume that the restraint or seclusion contributed directly or indirectly to the patient's death. CMS is proposing to modify the reporting requirements for hospitals when the circumstance of a patient's death involves only the use of soft two-point wrist restraints and no use of seclusion. CMS proposes to amend 42 C.F.R. §482.13(g)(4) so that hospitals would be required to notify CMS of the deaths where soft two-point wrist restraints were used but there was no use of seclusion, within seven days after the date of death and that reporting would be accomplished through developing a log or other recording system. CMS proposes that the log/record would include, at a minimum, the patient's name, date of birth, date of death, attending physician, primary diagnosis(es), and medical record number. CMS proposes that hospitals make the log or other system accessible to CMS upon request at all times.

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	With respect to deaths that will continue to be covered by the existing rule, CMS has proposed that reporting could be via facsimile or other electronic means.
Medical staff (§482.22)	CMS has stated that, although technically, the current regulations allow hospitals to appoint non-physician practitioners as members of their medical staffs, if this is consistent with State law, there appears to be doubt in the hospital community about whether this practice is consistent with CMS' rules. CMS is proposing to modify the regulations to clarify that a hospital may grant privileges to both physicians and non-physicians to practice within their State licensed scope of practice, regardless of whether those individuals are also appointed to the hospital's medical staff. A second change in this area is a proposal to revise the regulations to clarify that being a member of a hospital's medical staff is not a prerequisite to being granted privileges in the hospital, regardless of whether a practitioner is a physician or a non-physician. This proposed modification to the regulations would require those physicians and non-physicians who have been granted practice privileges but who are not on the medical staff to be subject to the hospital's requirements, medical staff bylaws, and medical staff oversight. Alternatively, a hospital could establish categories within its medical staff to create distinctions between practitioners who have full membership and a new category for those who could be classified as having an "associate," "special," or "limited" membership. The third proposed change concerns the organization and accountability of the hospital's medical staff. These requirements are set forth at §482.22(b)(3). Presently, a hospital may assign these management tasks to either an individual doctor of medicine or osteopathy or, when permitted by State law, to a doctor of dental surgery or dental medicine. CMS proposes to expand the list to include doctors of podiatric medicine (DPMs).
Nursing Services - Care Plans (§482.23)	CMS' current rules require a hospital to ensure that the hospital's nursing staff develops, and keeps current, a nursing care plan for each patient. CMS proposes that for those hospitals which use an interdisciplinary plan of care, the care plan for nursing services can be developed and kept current as part of the hospital's overall interdisciplinary care plan; thus, eliminating the need for a separate nursing care plan.
Nursing Services CoP - Drug administration (§482.23)	CMS proposes to adopt new regulations which will allow hospitals to prepare and administer drugs and biologicals on the orders of practitioners other than those specified under §482.12(c), if the practitioner can do so

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	under State law and if the hospital has granted the practitioner privileges to do this. In addition, the rules would be revised to expand the types of practitioners who can sign orders for drugs and biologicals to include practitioners acting within the limits of State law if the hospital has granted the practitioner privileges to exercise this authority.
Nursing CoPs - Drug Administration (§482.23(c))	The proposed rules would allow hospitals to use standing orders for the preparation and administration of drugs and biologicals. These standing orders could be contained in pre-printed or electronic standing orders, order sets, or protocols for patient orders, but only if such orders meet the requirements of §482.24(c)(3), discussed below. The proposed rules would also eliminate the requirement, currently at §482.23(c)(3), that non-physicians must have special training in administering blood transfusions and intravenous medications. CMS proposes that individuals who administer blood transfusions and intravenous medications do so in accordance with State law and approved medical staff policies and procedures.
Nursing CoPs - Patient Administered Medications (§482.23(c))	Regulation §482.23(c)(6) would be revised to allow hospitals the flexibility to develop and implement policies and procedures to allow a patient (and his or her caregivers/support persons) to administer non-controlled drugs and biologicals. CMS states that this proposal is consistent with the current practice of giving patients access at the bedside to urgently needed medications, such as nitroglycerine tablets and inhalers, and selected non-prescription medications, such as lotions and rewetting eye drops. These proposed changes would apply to the self-administration of both hospital-issued medications and the patient's own medications brought into the hospital. A hospital would need to: (1) assure that a practitioner had issued an order, consistent with hospital policy, permitting self-administration of medications; (2) assess patient and caregiver/support person capacity to self-administer specific medications; (3) provide instructions to the patient and caregiver/support person regarding the safe and accurate administration of the specified drugs and biologicals (for specific hospital-issued medications and, if determined to be needed, for a patient's own medications brought in from home); (4) ensure the security of medications for each patient; (5) identify a patient's own medications and visually evaluate those medications for integrity; and (6) document the administration of each medication in the patient's medical record.

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Verbal Orders (§482.24(c))	CMS' current rules specify that all orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner. An exception allows, for the five-year period beginning January 26, 2007, authentication by the ordering practitioner or another practitioner who is responsible for the care of the patient as specified under §482.12(c) and who is authorized to write orders by hospital policy and in accordance with State law. If State law does not provide a timeframe for the authentication of verbal orders, current CMS rules provide a 48-hour timeframe. CMS would eliminate the five-year sunset provision referenced above. In addition, CMS would eliminate the existing 48-hour timeframe requirement for authentication of orders and instead defer to hospital policy and State law for the establishment of a timeframe. If there is no State law establishing such a timeframe, then a hospital would be allowed to establish its own timeframe for authentication of orders, including verbal orders.
Nursing CoPs – Standing Orders (§482.24(c))	CMS proposes new provisions to be added to §482.24(c)(3) which would allow a hospital to use pre-printed and electronic standing orders, order sets, and protocols for patient orders, but only if the hospital: (1) establishes that such orders and protocols have been reviewed and approved by the medical staff in consultation with the hospital's nursing and pharmacy leadership; (2) demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines; (3) ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff, in consultation with the hospital's nursing and pharmacy leadership, to determine the continuing usefulness and safety of the orders and protocols; and (4) ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner responsible for the care of the patient and who is authorized to write orders by hospital policy in accordance with State law. In discussing this proposal, CMS referenced a memorandum (CMS S&C-09-10) issued on October 24, 2008 (http://www.cms.gov/SurveyCertificationGenInfo/downloads/SCLetter09-10.pdf), which CMS characterized as stating its strong support of the use of evidence-based protocols, developed by the medical staff and based on recognized standards of practice, that advance the quality of care provided to patients.
Infection control (§482.42)	Currently, a hospital's infection control officer is required to develop a system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel. Further, a hospital is required to maintain a log to identify infection problems.

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	CMS has determined that the requirement for a separate infection control log is unnecessarily redundant and burdensome and should be deleted.
Director of Outpatient Services (§482.54(b))	Currently, §482.54(b)(1) requires a hospital to assign an individual to be responsible for outpatient services. CMS recognizes that this rule means that hospitals which are currently using multiple executive leaders in the oversight of specific areas of out-patient hospital operations, must often hire another director to oversee this team of executives. The current proposal is to revise §482.54(b)(1) to allow hospitals to assign one or more individuals to be responsible for outpatient services. CMS would also revise §482.54(b)(2), which currently requires a hospital to have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, by adding a measure of flexibility such that hospitals would make staffing decisions based on the scope and complexity of outpatient services offered.
Transplant Services (§482.92)	CMS proposes to amend its existing regulations governing transplant centers by removing provisions which require the transplant team to verify blood type before organ recovery.
CAH (§485.635)	Current CoPs require critical access hospitals ("CAHs") to provide certain services directly, rather than under arrangements (such as diagnostic and therapeutic services that are commonly provided in a physician's office or other point of entry into the health care system, laboratory services, radiology services and emergency procedures). CMS has determined that these requirements do not provide sufficient flexibility to CAHs. Thus, the proposed regulations would eliminate the requirement that CAHs provide these services directly. The CAH's governing body (or person principally responsible for the operation of the CAH) would continue to be responsible for all services furnished by the CAH, whether furnished directly, under arrangements or under other agreements.
Pharmaceutical services (§482.25) Infection Control (§482.42)	Currently, drug administration errors, adverse drug reactions and incompatibilities must be reported to a hospital's quality assurance program. The proposed change is to replace the term "quality assurance program" with the phrase "quality assessment and performance improvement program", to clarify that CMS expects drug errors, adverse reactions, and incompatibilities to be addressed in a hospital's QAPI program.
CAH Definitions (§485.604(a))	Many of the former EACH/RPHC CoPs were adopted for the new CAH program. In order to harmonize the definition of "*clinical nurse specialist*" in Regulation §485.604(a) with the definition in 1861(aa)(5)(B), the regulation would be amended to define a clinical nurse specialist as a

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	registered nurse licensed to practice nursing in the State in which the clinical nurse specialty services are performed, who holds an advance degree in a defined clinical area of nursing from an accredited educational institution.
Surgical services in a CAH (§485.639)	A CAH is not required to provide surgical services. (*See* Social Security Act Section 1820(c).) CMS is proposing to make changes to the CoPs to clarify that surgical services are an optional service for CAHs.