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CMS Touts Increased Flexibility and Reduced Regulatory Burden in Issuing Final Rules

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On May 10, 2012, the Centers for Medicare and Medicaid Services ("CMS") released two final rules revising the Medicare Conditions of Participation and updating Medicare regulations to eliminate outdated and burdensome requirements. These rules are a response to President Obama's executive order requiring federal agencies to reduce unnecessary burdens on business and to achieve a more effective and streamlined regulatory framework.[1] Most of the rule changes are designed to provide hospitals with flexibility to implement applicable alternatives as they see fit.

The final rules were published in the Federal Register on May 16, 2012, and closely resemble the proposed rules that we described in our December 2011 alert titled Easing the Burden of Medicare Regulations: Round-Up of New Final and Proposed Rules. Among other changes and clarifications, the rules require a member of the medical staff to serve on the hospital's governing body and allow the flexibility for a hospital to add non-physician practitioners to its medical staff and to be governed by a single governing body over a multi-hospital system. The final rules did not, however, finalize the CMS proposal that physicians and non-physicians be able to be granted privileges without becoming members of the medical staff, based on public comments that, among other things, raised concerns related to quality improvement initiatives, peer review protections, and due process procedures afforded by medical staff membership.

Below is a summary of highlights in the final rules.

Hospital and Critical Access Hospital ("CAH") Conditions of Participation[2]

Hospital Final Rules

- Multi-hospital health systems can choose to be governed by a single governing body. In commentary, CMS stated that it was clarifying this issue in recognition of the fact that many health systems had already adopted this type of structure. CMS stated further that it was not endorsing one model of hospital governance over another; rather, it was simply clarifying that a separate governing body was not required at each institution for Conditions of Participation purposes. CMS noted, however, that health systems must still comply with state and local law (including corporate law) that could limit the entity's ability to use this organizational model. Finally, CMS confirmed that each separately-certified hospital, regardless of whether it is a part of a multi-hospital system, must have its own medical staff.

[1] E.O. 13563, Jan. 18, 2011.

[2] 77 Fed. Reg. 29034 (May 16, 2012) (amending 42 CFR Parts 482, 485).

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- A hospital's governing body must include at least one member of a hospital's medical staff. CMS stated that, while some hospitals may already require this, it did not understand it to be the norm, and CMS was requiring it in order to ensure a link between the medical staff and the governing body. In the case of a multi-hospital system, CMS further stated that it was not requiring that a member of each separately-certified hospital's medical staff serve on the board, but only that the governing body must include a member of the medical staff of one system hospital.
- A hospital may appoint non-physician practitioners to its medical staff. This clarification was prompted in part by a report from the Institute of Medicine recommending that Medicare allow greater flexibility for hospitals to use advanced practice registered nurses.[3] CMS stated that its intent was to encourage hospitals to be inclusive in the medical staff membership, and as a result of this change, a hospital could choose to include nurse practitioners and physician assistants, for example, on its active medical staff. CMS did not accept commenters' suggestions that it adopt more specific requirements for the credentialing process itself (e.g., a specific timeframe or formal decision). CMS instead emphasized that the medical staff should continue to examine the credentials of all eligible candidates and make recommendations for medical staff membership, and for categories of practitioners to be included, in accordance with state law, including scope-of-practice laws, and the medical staff bylaws, rules and regulations.
- The final rule also clarifies that all members of the medical staff must be subject to all medical staff bylaws, rules, and regulations and that state licensing requirements will still apply. CMS did not finalize its proposal to explicitly allow hospitals to grant privileges to practitioners who are not members of the hospital's medical staff, apparently due to commenters' concerns that this practice might undermine the functioning of, and protections afforded to, the medical staff.[4]
- CMS emphasized that, despite physicians' concerns that CMS was attempting to replace them with non-physician practitioners, the purpose of the rule is only to provide increased flexibility to hospitals to address their staffing needs. The revisions also allow podiatrists to serve in leadership roles on the medical staff in any hospital where they are members of the medical staff, when permitted by state law.
- Drugs and biologicals can be prepared and administered on the orders of non-physician practitioners, subject to state law and medical staff privileges. CMS clarified that the rule does not expand the types of practitioners who are able to prescribe or order medications. In particular, nurses still may not initiate drug orders, other than those currently allowed for influenza and pneumococcal vaccination.
- Standing orders are allowed in certain circumstances, provided that hospitals follow the procedures outlined in the rule and state law. In particular, standing orders must be (i) approved by the medical staff and the hospital's nursing and pharmacy leadership; (ii) based on nationally recognized, evidence-based guidelines; (iii) regularly reviewed; and (iv) authenticated promptly upon use.
- Verbal orders do not have to be authenticated within 48 hours, leaving the required timeframe for authentication to be determined by hospital policy in accordance with state law. However, the final rule still requires that all orders must be authenticated "promptly." CMS will also continue to allow other practitioners who are responsible for the care of the patient to authenticate such orders.

[3] Institute of Medicine of the National Academies, *The Future of Nursing: Leading Change, Advancing Health* (Oct. 2010).

[4] *But see* CMS, S&C-12-17-Hospitals (Feb. 17, 2012) (transmittal to state survey agencies allowing licensed community physicians to order outpatient services at hospitals under certain conditions).

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Although this provision technically "sunsetted" on January 25, 2012, this final rule makes the provision permanent.

- Hospitals may develop and implement policies and procedures for a patient and his or her caregivers to self-administer specific medications, both hospital-issued medications and medications brought with the patient into the hospital. The final rule includes a requirement that hospitals have policies and procedures in place to (i) ensure that a practitioner responsible for the care of the patient issued an order for the medication; (ii) instruct the patient in the safe and accurate administration of the medication; (iii) address the security of the medication for each patient; and (iv) document the administration of each medication (as reported by the patient or the patient's caretaker) in the patient's medical record. If the hospital allows self-administering of a patient's own medications brought into the hospital, additional policies must be in place for hospital staff to identify the specified medication and visually evaluate the medication for integrity.
- Hospitals do not have to follow existing reporting procedures for patient deaths involving only the use of soft, two-point wrist restraints and no use of seclusion. The final rule does not change the definition of restraint, only the reporting requirements associated with the use of soft, two-point wrist restraints that are typically utilized in critical care settings to prevent patients from removing medical equipment. Rather than reporting deaths under this type of restraint to CMS, hospitals will instead record such deaths in a log or other internal system no later than seven days after the patient's death. These logs must include certain specified information and must be made available to CMS immediately upon request. For deaths involving all other types of restraints and all forms of seclusion, the existing rule applies: hospitals must report to CMS by telephone no later than the close of business on the next business day following knowledge of the patient's death.
- For hospitals that use an interdisciplinary plan of care, the nursing care plan no longer needs to be a separate document but can be incorporated into the interdisciplinary plan.
- Non-physicians are no longer required to have special training in administering blood transfusions and intravenous medications. These procedures must still be done in accordance with state law and approved medical staff policies and procedures.
- Hospitals are no longer required to maintain a separate infection control log, though infection control officers must develop a system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.
- Hospitals can now assign more than one person to oversee outpatient services. CMS removed the requirement for hospitals to have a single director of outpatient services. Management can now use more than one individual in this type of role and can base such personnel decisions on the "scope and complexity" of outpatient services offered.
- Redundancies were eliminated in rules that required transplant teams to verify blood type before organ recovery.

Certain proposed rules and requests for comments did not result in any changes to the rules. For example, CMS decided not to make any changes to the requirement to update a patient history and physical examination that was completed prior to admission, and changes to regulations referencing the Life Safety Code will be considered through a separate notice-and-comment rulemaking, targeted for publication in the near future.

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CAH Final Rules

- CAHs are no longer required to provide certain required services directly, but instead may do so through contractors. This change applies to diagnostic and therapeutic services commonly furnished in a physician's office, basic laboratory services, radiology services and emergency procedures. In keeping with this change, CMS has also removed references to "direct services" throughout the Conditions of Participation.
- The rules clarify that surgical services are not a required service of CAHs.
- Definitions and terms. The term "quality assurance program" is replaced with the more current term "quality assessment and performance improvement program" to clarify the expectation that drug errors, adverse reactions and incompatibilities are to be addressed in such a program. The definition and qualifications of a "clinical nurse specialist" have been updated.

Provisions to Promote Program Efficiency, Transparency and Burden Reduction[5]

CMS also finalized the majority of the provisions detailed in the proposed rule targeting regulatory efficiency, as described in our prior alert. Notably, however, CMS did not finalize its proposal related to CMS's authority to deactivate Medicare billing privileges when an enrollee has not submitted a claim for twelve consecutive months. In regard to its decision not to revise this rule, CMS emphasized that its authority to deactivate billing privileges in such a situation is, and will remain, discretionary. Finalized provisions include:

- End-stage renal disease facilities are no longer subject to certain provisions of the Life Safety Code, unless they are situated in high hazardous locations.
- Ambulatory surgical center operating rooms are no longer mandated to have all the emergency equipment from a predetermined list. The governing body and medical staff are now free to determine what types of emergency equipment are necessary at a particular facility. Redundant requirements related to infection control in ambulatory surgery centers have also been deleted.
- Enrollment. The Medicare re-enrollment waiting period has been eliminated for providers and suppliers, when revocation of billing privileges is based on the failure to respond in a timely fashion to revalidation or other requests for information. Furthermore, CMS is allowed to deactivate, rather than revoke, Medicare billing privileges for a provider or supplier who fails to respond within 90 calendar days to a request from CMS to submit requested enrollment documentation.
- Definitions and terms. The rule also finalizes broad nomenclature changes in the regulations. The term "individuals with intellectual disabilities" replaces "mentally retarded persons," and Medicaid "beneficiaries" replaces the term "recipients." Definitions related to organ procurement have also been updated, and duplicate regulations governing organ procurement organizations have been removed.
- Intermediate care facilities for individuals who are intellectually disabled now have open-ended agreements that will remain in effect until the Secretary or a state determines that the facility no longer meets Conditions of Participation. There is also increased flexibility in the survey schedule.
- Newer versions of e-prescribing transaction standards have been adopted.
- Certain outdated Medicare appeals procedures were deleted.

[5] 77 Fed. Reg. 29002 (May 16, 2012) (amending 42 CFR Parts 482, 485).

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Conclusion

Hospitals should review the revised Conditions of Participation to assess whether any changes to their operations may be required, including in particular ensuring that a medical staff member is serving on the governing board. Hospitals should also evaluate whether any of their existing processes can be simplified in light of the new flexibility incorporated into certain provisions of the Conditions of Participation. In addition, hospitals should watch for updates from The Joint Commission and other accrediting bodies with possible changes in accrediting standards to reflect these revised regulations.

These final rules become effective on July 16, 2012.

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