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Health Law ALERT

CMS Issues Two Final Rules Modifying Hospital Conditions of Participation and Updating Other Provisions

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After conducting a retrospective review of existing federal regulations, the Centers for Medicare & Medicaid Services (CMS) has issued two final rules aimed at eliminating regulations on hospitals and other health care providers that have become unnecessary, obsolete or overly burdensome. These rules were issued in response to Executive Order 13563, in which President Obama called upon various federal agencies to "modify, streamline, or repeal" regulations that have become outmoded or impose unnecessary burdens. The first rule updates the Medicare Conditions of Participation (CoPs) for hospitals and critical-access hospitals (CAHs). The second, known as the Medicare Regulatory Reform rule, impacts both hospitals and other providers/suppliers of health care, including ambulatory surgical centers. Both rules will become effective 60 days from the date of their publication in the Federal Register.

Revisions to the Conditions of Participation

The following are among the changes made by the final rule revising the CoPs:

1. One governing body may oversee multiple hospitals in a multihospital system.

2. Hospitals no longer need to report deaths that occur while a patient is in soft, two-point wrist restraints, but hospitals must maintain an internal log of such events.

3. Hospitals may include practitioners other than doctors (e.g., registered nurses, advanced-practice registered nurses) as eligible candidates for their medical staffs with hospital privileges, subject to state law.

4. Podiatrists may assume a leadership role with responsibility for the organization and conduct of the medical staff of a hospital.

5. Hospitals may adopt a single interdisciplinary care plan that addresses nursing and other disciplines in lieu of a stand-alone nursing care plan.

6. Hospitals may implement optional programs for patients/support persons on self-administration of appropriate medications.

7. Those who administer blood transfusions and intravenous medications are no longer required to have special training in these functions so long as they act in accordance with state law and approved medical staff policies and procedures.

8. Drugs and biologicals may be prepared and administered on the orders of practitioners other than doctors, and orders for such drugs and biologicals may be documented and signed by such practitioners, in accordance with hospital policy and state law.

9. Hospitals may use standing orders, including electronic standing orders, if approved by the medical staff, nursing and pharmacy, and based on nationally recognized evidence-based guidelines and recommendations.

10. State law will govern the timeframe for authentication of verbal orders, rather than the previous requirement for authentication within 48 hours. Additionally, the previously "temporary" requirement has been made permanent that verbal orders must be dated, timed, and authenticated by either the ordering practitioner or another practitioner who is responsible for the care of the patient and who is authorized to write orders under hospital policy and state law.

11. Hospitals are no longer required to maintain an infection-control log, in light of modern infection surveillance methods.

12. Hospitals no longer are required to have a single director of outpatient services, and may rely on separate directors for individual outpatient departments.

13. Because verification is accomplished two other times in the transplant process, an organ recovery team working for a transplant center is no longer required to conduct a "blood type and other vital data verification" before organ recovery when the recipient is known.

14. CAHs may furnish diagnostic and therapeutic services, laboratory services, radiology services, and emergency procedures under arrangement, rather than directly by CAH staff.

Other revisions and updates were also made to the language and definitions in the CoPs, some of which had become outdated or internally inconsistent.

Medicare Regulatory Reform Rule

The Medicare Regulatory Reform Rule includes the following changes:

1. Ambulatory surgical centers (ASCs) will now be required, in collaboration with their governing bodies and medical staff, to develop "policies and procedures specifying the types of emergency equipment that are appropriate for the facility's patient population, and make the items immediately available at the ASC to handle inter- or post-operative emergencies." Such equipment must meet current industry standards of practice. Previously, a specific list of emergency equipment was mandated at 42 CFR § 416.44(c)(1)–(9), but it has been eliminated due to outdated terminology and the recognition that not all equipment listed was the most current or appropriate for every ASC.

2. Because ASC infection-control programs are subject to the existing conditions of coverage specific to that subject, CMS eliminated redundant and obsolete language regarding infection control from the condition for coverage regarding "physical environment."

3. Former e-prescribing technical requirements for Medicare Part D have been "retired," and newer versions adopted to achieve greater consistency with current Health Insurance Portability and Accountability Act (HIPAA)-transaction standards.

4. The requirement to comply with the full National Fire Protection Agency Life Safety Code has been eliminated for many end-stage renal-disease facilities, except those with higher risk factors.

5. The rule updates the definition of "donor document" as it relates to organ donation.

6. Intermediate-care facilities for individuals who are intellectually disabled will be allowed open-ended agreements that would remain in effect until the Secretary of Health and Human Services or a state determines that the facility no longer meets conditions of participation. Additionally, the rule provides for such facilities to be surveyed for compliance with conditions of participation at intervals of between 12 and 15 months, rather than on a relatively fixed schedule every 12 months. This is intended to give agency resources more flexibility in the timing and frequency of surveys.

7. In the future, providers and suppliers who are subject to revocation of Medicare billing privileges based solely on a failure to respond in a timely manner to a CMS revalidation request or other request for information are no longer subject to any bar on re-enrollment, as this was determined to be unnecessarily punitive. However, this rule will not be applied retrospectively, and revocations for other reasons will continue to be subject to a re-enrollment bar of one to three years.

The Medicare Regulatory Reform Rule also made other changes to outdated terminology and eliminated publishing errors and redundancies in existing regulations. For example, the rule adopts a nomenclature change from the term "recipient" to "beneficiary" throughout the regulations, and removed outdated Medicaid personnel qualifications language for physical and occupational therapists in favor of updated descriptions under existing Medicare regulations.

For further information on these changes, please contact Angela M. Rust or your regular Hinshaw attorney.

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