McDermott Will & Emery

CMS Issues One Final and Two Proposed Rules in Effort to Reduce Health Care Delivery Costs by Streamlining Regulations

October 24, 2011

CMS issued the rules on October 18, 2011, in response to President Obama's Executive Order 13563, "Improving Regulation and Regulatory Review," and consistent with the U.S. Department of Health and Human Services' Plan for Retrospective Review of Existing Rules. Overall, the final rule and two proposed rules appear to make significant progress in eliminating duplicative and unnecessary requirements, while providing hospitals and other providers with greater control over how to best achieve patient health care objectives.

On October 18, 2011, the U.S. Centers for Medicare & Medicaid Services (CMS) issued one final and two proposed rules in response to President Obama's Executive Order (EO) 13563, "Improving Regulation and Regulatory Review," and consistent with the U.S. Department of Health and Human Services' Plan for Retrospective Review of Existing Rules. Among the goals of EO 13563 is to reduce health care delivery costs by streamlining Medicare and Medicaid regulations for hospitals and other providers.

Final Rule, "Medicare Program; Changes to the Ambulatory Surgical Centers Patient Rights Conditions for Coverage"

The final rule "Medicare Program; Changes to the Ambulatory Surgical Centers Patient Rights Conditions for Coverage" provides flexibility in the timing of the provision of notice of patient's rights that enables Ambulatory Surgical Centers (ASCs) to perform surgeries on the same day that a patient is referred for or presents at the ASC for an ASC service. The revised ASC Conditions for Coverage (CfCs) effectively eliminate waiting periods for same-day surgeries and allows ASCs to provide the same types of same day surgeries that patients could alternatively receive at hospital outpatient departments.

Proposed Rule, "Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation"

The proposed rule "Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation" revises certain Medicare Conditions of Participation (CoPs) in a manner intended to allow flexibility, reduce regulatory burden and improve clarity in health care regulation. The proposed revisions address the following CoPs that hospitals and critical access hospitals must abide by in order to participate in Medicare and Medicaid:

1. Governing Body – Proposed changes to this CoP would allow multihospital systems to have one governing board to provide complete oversight across all hospitals, thus easing hospital operation requirements and allowing governing body oversight to function in a more efficient and effective manner. This proposed revision would provide welcome relief to health systems that have established a common governing board for all of their hospital entities.

2. Patient's Rights – Proposed changes to this CoP modify the reporting requirements related to a patient's death when not in seclusion but wearing two-point wrist restraints. CMS stated in the preamble text that there is no cause-and-effect relationship between the use of soft, two-point wrist restraints and patient death.

3. Medical Staff – Proposed changes to this CoP seek to modernize hospitals' medical staff policies by allowing a hospital to grant privileges to both physicians and non-physicians regardless of whether they are also appointed to the medical staff of the hospital. In other words, technical medical staff membership would not be required in order to grant practice privileges.

4. Nursing Services – Proposed changes to this CoP would expand access to care by allowing certain qualified practitioners to order the preparation and administration of drugs and biologics, among other changes that aim to streamline health care delivery to patients.

5. Medical Record Services – Proposed changes to this CoP would allow hospitals to defer to hospital policy and state law for designating specific timeframes for the authentication of verbal orders.

6. Infection Control – CMS proposes eliminating the Infection Control CoP to allow hospitals flexibility to track and survey infections.

7. Outpatient Services – Proposed changes to this CoP would enable hospitals to determine the management structure for outpatient services so that hospitals have the flexibility to assign one or more individuals to oversee this service area.

The remaining proposed revisions seek to clarify CoPs related to (1) Transplant Center Process Requirements—Organ recovery and receipt, (2) Definitions and Provision of services, (3) Pharmaceutical services and Infection control, (4) Personnel qualifications and (5) Surgical services.

Proposed Rule, "Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction"

The proposed rule "Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction" would make 14 specific reforms to existing Medicare regulations in order to improve efficiency, improve transparency and reduce regulatory burdens.

Proposed changes aimed at removing unnecessarily burdensome requirements include the following:

1. Revising CfCs for End-Stage Renal Disease to remove unnecessary and duplicative Life Safety Code (LSC) requirements. Specifically, costly federal LSC requirements would only apply to certain "high hazard" locations and facilities with treatment areas not at grade level.

2. Revising CfCs for ASCs by removing emergency response requirements and allowing ASCs flexibility in responding to emergencies.

3. Eliminating the one-year re-enrollment bar after revocation of Medicare enrollment in circumstances where the revocation related to failure to respond to requests for information or revalidations.

4. Eliminating deactivation of Medicare billing privileges for individual practitioners (*i.e.*, practitioners that enroll using a Form CMS-855I) that have not submitted a Medicare claim for 12 consecutive months. Note that the proposed rule would not apply to organizational providers, who would remain subject to deactivation for failure to submit a claim for 12 months.

5. Providing for the use of deactivation, rather than revocation, for failure to respond to requests for applications or certifications of accuracy of enrollment information.

6. Removing time limits on provider agreements and providing for more flexible survey requirements for Intermediate Care Facilities for the Intellectually Disabled.

Proposed changes aimed at removing obsolete or duplicative regulations or providing clarifying information related to regulations include (1) removing the mandate that CMS maintain a chart of OMB control numbers; (2) removing certain provisions related to initial determinations, appeals and re-openings; (3) removing certain provisions related to ASC infection control criteria; (4) revising the e-prescribing rules for consistency with HIPAA standards; (5) updating terminology related to certain types of therapists; (6) expanding the definition of "donor documents" for purposes of organ donation; (7) correcting clerical/typographical errors; and (8) redefining or replacing terms to make them consistent with current use/terminology.

Overall, the final rule and two proposed rules appear to make significant progress in eliminating duplicative and unnecessary requirements, while providing hospitals and other providers with greater control over how to best achieve patient health care objectives.

CMS is accepting comments regarding the two proposed rules. The comment period extends for 60 days following the publication in the *Federal Register*. Publication is currently scheduled for October 24, 2011. Comment may be submitted electronically at http://www.regulations.gov.

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