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CMS ISSUES REVISED INTERPRETIVE GUIDELINES FOR AMBULATORY SURGICAL CENTER (ASC) REGULATIONS

On November 18, 2008, the Centers for Medicare & Medicaid Services (CMS) issued the Hospital Outpatient Prospective Payment System final rule (Final Rule). Included within the Final Rule are substantial revisions applicable to ASCs that became effective on May 18, 2009. Some of the more notable revisions are: (1) new ASC Conditions for Coverage (CfCs); (2) additions to and clarification of Appendix L which include: (a) Part 1, Survey Protocol; and (b) extensive changes to the Interpretive Guidelines with an emphasis on new and revised CfCs with more-detailed guidance for existing CfCs; and, (3) revised and renumbered ASPEN Tags for ASC surveys.

A brief summary of significant regulatory changes follows:

- Revision of the ASC definition establishing a maximum stay not to exceed 24 hours;
- Revisions to and reorganization of the Governing Body and Management CfC with a focus on explicit responsibilities for the quality assurance/performance improvement program as well as a disaster preparedness plan;
- Revisions to the Surgical Services CfC regarding anesthetic risk and evaluation;
- Renaming the Evaluation of Quality CfC to Quality Assessment and Performance Improvement with significantly expanded and detailed regulatory standards;
- A new CfC regarding Patient Rights requiring ASCs to inform patients of their rights. This CfC includes the requirements to obtain informed consent prior to a procedure and notify each patient of the grievance process;
- Reorganization of the Laboratory and Radiologic Services CfC and a requirements that Radiologic services provided in the ASC comply with the Hospital CoP at 42 C.F.R. 482.26; and,
- Additional CfCs for (i) Patient Rights; (ii) Infection Control; and (iii) Patient Admission, Assessment, and Discharge.

Of particular importance is the inclusion of a detailed survey protocol. In most cases, a two-person survey team will conduct the three (3) to four (4) day health portion of an ASC survey. Specifically, the survey protocol expands the 2008 ASC survey process by incorporating the use of two (2) new standards: (1) a detailed infection control survey instrument; and (2) a tracer component (case observation). Please note the infection control and tracer component standards are not effective until late 2009 for some volunteer states and for all states in 2010. Information addressing these two (2) standards has not been published.

Through implementation of the Final Rule, it is CMS's goal to increase the accountability of ASCs with regard to improved patient safety, services and outcomes with an emphasis on the utilization of a quality assessment and performance improvement (QAPI) program and execution of the new regulations for Patient Rights, Infection Control and Patient Admission, Assessment, and Discharge.

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