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June 5, 2009

New Medicare Conditions of Coverage and Interpretive Guidelines for Ambulatory Surgery Centers

In order to receive Medicare reimbursement, the Centers for Medicare and Medicaid Services ("CMS") requires that all ambulatory surgery centers ("ASCs") comply with the Medicare ASC Conditions for Coverage ("CfCs"). The Hospital Outpatient Prospective Payment System final rule (73 FR 68502), which was published by CMS November 18, 2008 and took effect May 18, 2009, included significant revisions to the ASC CfCs (42 CFR 416.2-416.52). These revisions represent the most significant change in the ASC CfCs since they were originally published August 5, 1982.

In May, CMS also published extensive updates to the Interpretive Guidelines (SOM, Appendix L). The Interpretive Guidelines now reflect the new and revised CfCs, as well as provide more detailed guidance on the existing CfCs that were not altered. CMS expects that further refinements will need to be made and has requested feedback on the Interpretive Guidelines for this purpose.

Key changes in the ASC CfCs include:

- Revision of the definition of an ASC;
- Revision of the Governing Body and Management CfCs;

- Revision of the Surgical Services CfCs regarding anesthetic risk and evaluation;
- Renaming of the Evaluation of Quality CfCs to "Quality Assessment and Performance Improvement" and the addition of regulatory standards;
- Reorganization of the Laboratory and Radiologic Services CfCs and the addition of requirements for Radiologic Services;
- Addition of a Patient Rights CfC;
- Addition of an Infection Control CfC; and
- Addition of a Patient Admission, Assessment and Discharge CfC.

Below is an overview of the specific changes CMS made to each of the revised or newly implemented ASC CfCs:

42 CFR 416.2 – Definitions

Revised – The definition of an ASC was modified to mean any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which *the expected duration of services would not exceed 24 hours following admission.*



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42 CFR 416.41 – Governing Body and Management

Revised – The governing body responsibilities were added to explicitly include 1) oversight and accountability for the quality and performance improvement program (QAPI) and 2) development and maintenance of a disaster preparedness plan. The disaster preparedness plan must provide for the emergency care of patients, staff and others in the facility in the event of a fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the ASC. Drills must be conducted, at least annually, to test the plan's effectiveness and the need for corrections.

42 CFR 416.42 – Surgical Services

Revised Standards – The standard concerning anesthetic risk and evaluation was modified to more clearly outline the requirements for evaluation before discharge. According to the revised standard, each patient must be evaluated by a physician or by an anesthesiologist before discharge from the ASC to determine whether the patient is properly recovering from anesthesia.

42 CFR 416.43 – Evaluation of Quality

Revised – This condition was completely revised and outlines the requirement that the ASC must develop, implement and maintain an ongoing, data-driven quality assessment and performance improvement (QAPI) program.

The QAPI program must incorporate quality indicator data regarding services furnished in the ASC and must use the data collected to monitor the effectiveness and safety of its services as well as to identify opportunities that could lead to improvements in patient care. Adverse patient events must be tracked and the ASC must examine their causes, implement preventative strategies, properly train staff on the preventative strategies implemented and ensure that improvements in patient care

are sustained over time. Specific quality improvement projects must be conducted at least once each year and must reflect the scope and complexity of the ASC's services and operations. Documentation should include the reason for implementing the project and a description of the project's results.

In addition, the governing body is responsible for ensuring that the QAPI program 1) is defined, implemented and maintained by the ASC; 2) employs quality and patient safety indicators that reflect appropriate prioritization; 3) evaluates changes designed to improve the ASC's performance; 4) specifies data collection methods, frequency, and details; 4) clearly establishes the governing body's expectations for safety; and 5) adequately allocates sufficient staff, time, information systems and training to support the program.

42 CFR 416.49 – Laboratory and Radiologic Services

Reorganized and Revised – This condition was reorganized and a standard for Radiologic Services was added requiring ASCs to meet the Hospital Conditions of Participation for radiologic services, 42 CFR 483.32. According to the Hospital Conditions of Participation, radiologic services must be available based on the needs of the patients served. Radiologic services, particularly ionizing radiology procedures, must be free from hazards and proper safety precautions and periodic inspections of the radiologic equipment must be conducted. In addition, employees who are regularly exposed to radiation must be periodically evaluated for exposure.

Supervision of the radiology services may only be performed by a radiologist who is a member of the medical staff and the medical staff must develop policies identifying what types of radiologic procedures require interpretation by a radiologist. Radiologic services require an order from a physician with appropriate clinical privileges, and only qualified personnel may use the radiologic equipment and administer



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radiologic procedures. Radiologic reports must be signed by the administering radiologist and records of the radiologic procedures performed must be maintained for at least five years.

42 CFR 416.50 – Patient Rights

New – This new condition requires that ASCs inform patients of the patient's rights and protect and promote the patient's exercise of these rights. According to this standard, patients have the right to –

- make informed decisions regarding their care;
- exercise their rights without being subjected to discrimination;
- voice grievances regarding treatment or care that is furnished in the ASC;
- be fully informed about a treatment or procedure and expected outcome before it is performed;
- personal privacy; receive care in a safe setting; and be free from all forms of abuse or harassment.

This standard also requires that ASCs develop policies and procedures specifically addressing advance directives and grievance procedures. Lastly, this standard requires that ASCs disclose to the patient any physician financial interest or ownership in the ASC prior to the date of the patient's procedure.

42 CFR 416.51 – Infection Control

New – This new condition requires that ASCs maintain an infection control program that seeks to minimize infections and communicable diseases. ASCs are required to provide and maintain a functional and sanitary environment for surgical services. The ongoing infection control program must be designed to prevent, control, and investigate infections and communicable disease and be based on nationally recognized infection control guidelines. Finally, the program must be under the direction of a designated and qualified

professional who has training in infection control and who is responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventative measures that result in improvement.

42 CFR 416.52 – Patient Admission, Assessment and Discharge

New – This new condition requires that ASCs ensure that each patient has the appropriate pre-surgical and post-surgical assessments and that all elements of the discharge are completed. Each patient must have a comprehensive medical history and physical assessment completed by a physician no more than 30 days prior to the scheduled date of surgery. Upon admission, each patient must receive a pre-surgical assessment which includes an updated medical record entry documenting any changes in the patient's condition since completion of the medical history and physical assessment, including documentation of any drug allergies. Any assessment performed must be placed in the patient's medical record prior to the surgical procedure.

Following surgery, the patient's post-surgical condition must be assessed and documented in the patient's medical record. Post surgical needs must be addressed and included in the discharge notes. The ASC must provide each patient with discharge instructions and when appropriate schedule a follow-up appointment with the physician to ensure that all patients are informed either in advance of their surgical procedure or prior to leaving the ASC of their prescriptions, post-operative instructions and physician contact information for follow-up care.

Upon discharge, each patient must receive a discharge order signed by the physician who performed the surgery. Unless the physician who is responsible for the patient's care has



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exempted the patient, the ASC may not discharge any patient who is not accompanied by a responsible adult.

As of May 18, 2009, compliance with these new ASC CfCs was mandatory. ASCs should ensure that they have completed an extensive review of the regulatory changes and have updated their policies and procedures for compliance. While this Client Advisory provides a summary of the new regulatory requirements for ASC CfCs, it does not constitute legal advice and should not be relied on in lieu of a detailed and comprehensive review of the regulations and Interpretive Guidelines.

If you have any questions about the changes made by this CMS final rule, or if your organization would like assistance in complying with the final rule, please contact Mary C. Malone or Michelle E. Calloway by telephone at (804) 967-9604 or by email at mmalone@hdjn.com or mcalloway@hdjn.com. Additional information about Hancock, Daniel, Johnson & Nagle, P.C. is available on the firm's website at www.hdjn.com.

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Richmond 4701 Cox Road Suite 400 Glen Allen, VA 23060 PO Box 72050 Richmond, VA 23255-2050 ○ (804) 967-9604	Fairfax 3975 Fair Ridge Road Suite 475 South Fairfax, VA 22033 ○ (703) 591-3440
Harrisonburg 3210 Peoples Drive Harrisonburg, VA 22801 ○ (866) 967-9604	Virginia Beach One Columbus Center 283 Constitution Drive Suite 301 Virginia Beach, VA 23462 ○ (757) 321-6555