

**PARSONAGE VANDENACK WILLIAMS LLC**  
*"Focused Experience in Action"*

5332 South 138<sup>th</sup> Street, Suite 100  
Omaha, NE 68137  
402-504-1300  
www.pvwlaw.com

**A SUMMARY OF THE CURRENT RULES AND REGULATIONS GOVERNING ASCS**

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**I. Changes in CMS Regulations**

The Centers for Medicare and Medicaid Services ("CMS") recently updated the Conditions for Coverage ("CFC") applicable to ambulatory surgery centers ("ASCs"). The CFC are the minimum standards that an ASC must meet in order to participate in Medicare. CFC are mainly enforced at the state level, through surveys conducted by state departments of health and human services.

The most recent CFC updates represent the first non-payment related changes to the ASC CFC since they were first published in 1982. The effective date of the updated CFC is May 18, 2009.

ASCs should review their current policies and procedures to make sure they are in full compliance with the updated standards. The below text sets forth all changes to the CMS regulations that were effective May 18, 2009. The language in each provision that has been changed is italicized.

**§ 416.2 Definitions.**

Ambulatory surgical center or ASC means 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 an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC, and must meet the conditions set forth in subparts B and C of this part.*

**§ 416.41 Conditions for Coverage – Governing Body and Management**

The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. *The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health in a safe environment, and develops and maintains a disaster preparedness plan.*

- (a) Standard: Contract services. When services are provided through a contract with an outside resource, the ACS must assure that these services are provided in a safe and effective manner.
- (b) Standard: Hospitalization.
- (c) (1) The ASC must have an effective procedure for the immediate transfer to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC. (2) This hospital must be a local, Medicare-participating hospital or a local,

nonparticipating hospital that meets the requirements for payment for emergency services under § 482.2 of this chapter. (3) The ASC must – (i) have a written transfer agreement with a hospital that *meets the requirements of paragraph (b)(2) of this section*; or (ii) *ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital that meets the requirement of paragraph (b)(2) of this section.*

- (d) Standard: Disaster preparedness plan. (1) *The ASC must maintain a written disaster preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event of 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.* (2) *The ASC coordinates the plan with State and local authorities, as appropriate.* (3) *The ASC conducts drills, at least annually, to test the plan's effectiveness. The ASC must complete a written evaluation of each drill and promptly implement any corrections to the plan.*

#### **§ 416.42 Conditions for Coverage – Surgical Services**

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

- (a) Standard: Anesthetic risk and evaluation. (1) A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. (2) Before discharge from the ASC, each patient must be evaluated by a physician or by an anesthesiologist as defined at § 410.69(b) of this chapter, in accordance with applicable State health and safety laws, standards of practice, and ASC policy, for proper anesthesia recovery.
- (b) Standard: Admission of anesthesia. Anesthesia must be administered by only – (1) a qualified anesthesiologist; or (2) a physician qualified to administer anesthesia, a certified registered nurse anesthetist (“CRNA”) or an anesthesiologist’s assistant as defined at § 410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (c) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist’s assistant, under the supervision of an anesthesiologist.
- (c) Standard: State exemption. (1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State’s Board of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with the State Board of Medicine and Nursing about issues related to access and to the quality of anesthesia services in the State and has concluded that it is in the best interests of the State’s citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law. (2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

#### **§ 416.43 Conditions for Coverage – Quality Assessment and Performance Improvement**

The ASC must develop, implement and maintain an ongoing, data-driven quality assessment and performance improvement (“QAPI”) program.

- (a) Standard: Program scope. (1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors. (2) The ASC must measure, analyze, and track quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.
- (b) Standard: Program data. (1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC. (2) The ASC must use the data collected to – (i) monitor the effectiveness and safety of its services, and quality of its care; and (ii) identify opportunities that could lead to improvements and changes in its patient care.
- (c) Standard: Program activities. (1) The ASC must set priorities for its performance improvement activities that – (i) focus on high risk, high volume, and problem-prone areas; (ii) consider incidence, prevalence, and severity of problems in those areas; and (iii) affect health outcomes, patient safety, and quality of care. (2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time. (3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.
- (d) Standard: Performance improvement projects. (1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC’s services and operations. (2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project’s results.
- (e) Standard: Governing body responsibilities. The governing body must ensure that the QAPI program – (1) is defined, implemented, and maintained by the ASC; (2) addresses the ASC’s priorities and that all improvements are evaluated for effectiveness; (3) specifies data collection methods, frequency, and details; (4) clearly establishes its expectations for safety; and (5) adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.

#### **§ 416.49 Conditions for Coverage – Laboratory and Radiologic Services**

- (a) Standard: Laboratory services. If the ASC performs laboratory services, it must meet the requirements of part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of part 493 of this chapter.
- (b) Standard: Radiologic services. (1) The ASC must have procedures for obtaining radiological services from a Medicare approved facility to meet the needs of patients.

(2) Radiologic services must meet the hospital conditions of participation for radiologic services specified in § 482.26 of this chapter.

#### **§ 416.50 Conditions for Coverage – Patient Rights**

The ASC must inform the patient or the patient's representative of the patient's rights, and must protect and promote the exercise of such rights.

(a) Standard: Notice of rights. (1) The ASC must provide the patient or the patient's representative with verbal and written notice of the patient's rights in advance of the date of the procedure, in a language and manner that the patient or the patient's representative understands. In addition, the ASC must -

(i) post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients (or their representative, if applicable) waiting for treatment. The ASC's notice of rights must include the name, address, and telephone number of a representative in the State agency to whom patients can report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman;

(ii) the ASC must also disclose, where applicable, physician financial interests or ownership in the ASC facility in accordance with the intent of part 420 of this subchapter. Disclosure of information must be in writing and furnished to the patient in advance of the date of the procedure.

(b) Standard: Advance directives. The ASC must comply with the following requirements –

(i) provide the patient or, as appropriate, the patient's representative in advance of the date of the procedure, with information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms;

(ii) inform the patient or, as appropriate, the patient's representative of the patient's right to make informed decisions regarding the patient's care;

(iii) document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive.

(c) Standard: Submission and investigation of grievances.

(i) The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC.

(ii) All alleged violations/grievances relating, but not limited to, mistreatment, neglect, verbal, mental, sexual, or physical abuse, must be fully documented.

(iii) All allegations must be immediately reported to a person in authority in the ASC.

(iv) Only substantial allegations must be reported to the State authority or the local authority, or both.

(v) *The grievance process must specify timeframes for review of the grievance and the provisions of a response.*

(vi) *The ASC, in responding to the grievance, must investigate all grievances made by a patient or the patient's representative regarding treatment or care that is (or fails to be) furnished.*

(vii) *The ASC must document how the grievance was addressed, as well as provide the patient with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed.*

(d) Standard: Exercise of rights and respect for property and person. (1) *The patient has the right to –*

(i) *Exercise his or her rights without being subject to discrimination or reprisal.*

(ii) *Voice grievances regarding treatment or care that is (or fails to be) furnished.*

(iii) *Be fully informed about a treatment or procedure and the expected outcome before it is performed.*

(2) *If a patient is adjudged incompetent under applicable State health and safety laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf. (3) If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law.*

(e) Standard: Privacy and safety. *The patient has the right to – (1) personal privacy; (2) receive care in a safe setting; and (3) be free from all forms of abuse or harassment.*

(f) Standard: Confidentiality if clinical records. *The ASC must comply with the Department's rules for the privacy and security of individually identifiable health information, as specified at 45 CFR parts 160 and 164.*

#### **§ 416.51 Conditions for Coverage – Infection Control**

*The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.*

(a) Standard: Sanitary environment. *The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.*

(b) Standard: Infection control program. *The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. The program is – (1) under the direction of a designated and qualified professional who has training in infection control; (2) an integral part of the ASC's quality assessment and performance improvement program; and (3)*

*responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.*

## **§ 416.52 Conditions for Coverage – Patient Admission, Assessment and Discharge**

*The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed.*

- (a) Standard: Admission and pre-surgical assessment. (1) Not more than 30 days before the date of scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy. (2) Upon admission, each patient must have a pre-surgical assessment completed by a physician or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy that includes, at a minimum, an updated medical record entry documenting an examination for any changes in the patient's condition since completion of the most recently documented medical history and physical assessment, including documentation of any allergies to drugs and biologicals. (3) The patient's medical history and physical assessment must be placed in the patient's medical record prior to the surgical procedure.
- (b) Standard: Post-surgical assessment. (1) The patient's post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable State health and safety laws, standards of practice, and ASC policy. (2) Post-surgical needs must be addressed and included in the discharge notes.
- (c) Standard: Discharge. The ASC must (1) Provide each patient with written discharge instructions and overnight supplies. When appropriate, make a follow-up appointment with the physician, and 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. (2) Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy. (3) Ensure all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician.

## **II. Important Changes for ASCs**

ASCs should be sure that they have updated their policies, procedures and practices to comply with the following primary changes to the CFC:

- Governing body and management need to have **disaster preparedness plan** in effect
  - Written plan – provides for emergency care of patients, staff and others in facility in the event of disaster
  - Coordinate with Nebraska and local authorities

- Conduct annual drills to test plan's effectiveness
- Develop, implement and maintain an ongoing, data-driven quality assessment and performance improvement ("QAPI") program
- Inform the patient or the patient's representative of the patient's rights, and must protect and promote the exercise of such rights
  - Post notice of rights
  - Advance directives
  - Grievance procedure
  - Privacy and safety
- Maintain an infection control program that seeks to minimize infections and communicable diseases
- Ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed
- An anesthetist is permitted to perform the pre-discharge anesthesia recovery evaluation.
  - Previously, only a physician could do this
- Radiologic services must meet the hospital conditions of participation for radiologic services specified in § 482.26

**C. Other CFC Guidelines**

The following Medicare CFC have not changed. However, ASCs need to maintain current compliance with such standards.

- Basis and scope (§ 416.1)
- Definitions – except the definition of ASC as noted above (§ 416.2)
- Basic requirements (§ 416.25)
- Qualifying for an agreement (§ 416.26)
- Terms of agreement with CMS (§ 416.30)
- Termination of agreement (§ 416.35)
- Compliance with State licensure law (§ 416.40)
- Environment (§ 416.44)
- Medical staff (§ 416.45)
- Nursing services (§ 416.46)

- Medical records (§ 416.47)
- Pharmaceutical services (§ 416.48)

Note that many of the detailed requirements will already be covered in the policies and procedures being followed by the ASC for one or more other purposes, such as accreditation and state licensure, maintaining insurance coverage, OSHA compliance, and other regulatory or business drivers. Therefore, the most effective way to ensure compliance with the updated CFC will be to check the specific requirements of each of the new and revised conditions against existing facility policies and procedures so that gaps can be identified and amendments or new policies and procedures or can be crafted and implemented where necessary.

