

# AAAHHC/Medicare Deemed Status Survey – new Conditions for Coverage

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# CMS Conditions for Coverage (CfC)

**Electronic Code of Federal Regulations, Title 42,  
Public Health, Part 416 ASCs, Subpart C – Specific  
Conditions for Coverage of the Code of Federal  
Regulations**

**<http://ecfr.gpoaccess.gov/cgi/t/text/text-dx?c=ecfr&tpl=%2Findex.tpl>**

**CMS Published the State Operations Manual (SOM)  
Appendix L, Ambulatory Surgical Centers (ASC) –  
May 15, 2009**

**[http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09\\_37.pdf](http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09_37.pdf)**

# 416.2 ASC Definition (1 of 2):

## REVISED

***Ambulatory surgical center or ASC means:***

- **distinct entity**
- **physical separation by at least a 1-hour separation from any other entity**
- **exclusively for providing surgical\* services not requiring hospitalization**
- **has an agreement with CMS as an ASC**
- **meets conditions in subparts B (*General Conditions and Requirements*) and C (*Specific CfC*) of 42 CFR 416**

**{\*Definition of surgery adopted from American College of Surgeons ([www.facs.org/fellow\\_info/statement/st-11.html](http://www.facs.org/fellow_info/statement/st-11.html))}**

# 416.2 ASC Definition (2 of 2)

**Surgical procedures **not expected to exceed 24 hrs****

- **time documented in clinical record:**
  - **admission - when pt moves from waiting/reception area**
  - **discharge order signed by MD *and* patient exits recovery room**
- **exceptional cases that require longer than 24 hours - documented clearly**

# 416.40 Condition: Compliance with State licensure law

- **ASC must submit current ASC license with its *AAAHC Application for Survey***
- **AAAHC Surveyors will review personnel and credential files for currency of licenses**

# 416.41 Condition: Governing body and management

- **AAAHC Surveyors will review GB minutes: frequency of meetings and agenda items**
  - **Evidence of monitoring, oversight and accountability**
    - **Review of delegated responsibilities**
    - **Compliance with policies, including written disaster preparedness**
    - **QAPI**

# 416.41 Standards:

## (a) Contract services

Contracts for currency, periodic review by GB, ensure services are provided appropriately within ASC P/Ps and CfC

## (b) Hospitalization

Policies and procedures that include:

- Provision of emergency care
- Initial stabilization
- Arrangement of immediate transport

Agreement/contract with receiving hospital(s) – Medicare / non-Medicare (482.2) OR Physician with admitting privileges

## (c) **Disaster Preparedness Plan**

Written plan: hazard identification, mitigation, preparedness, response, recovery

Coordination with local and state authorities

Evidence of testing, evaluation and update of plan

# 416.42 Condition: Surgical Services

- **Review credentials files of Physicians: MD, DO, DDS, DMD, DPM, OD, DC**
  - **Licensed**
  - **Criteria for privileging / specific list of privileges granted**
- **Determine provision of surgical services in a safe manner:**
  - **Compliance with state and federal laws**
  - **Compliance with acceptable standards of practice**
    - **AMA / ACOS / AORN / APIC**
  - **Compliance with other CfC: 416.43-45, 416.51-2**

# 416.42 Standards:

## (a) Anesthetic risk and evaluation

### Policies and procedures and medical record review:

- Assessment for anesthesia risk prior to procedure
- Evaluation of patient for proper anesthesia recovery

## (b) Administration of Anesthesia

- Anesthesiologist
- CRNA (physician supervision unless in opt-out state)
- Anesthesiology assistant (supervised by physician)

## (c) State exemption – opt-out states

Iowa

New Hampshire

Washington

Nebraska

New Mexico

Alaska

Idaho

Kansas

Oregon

Minnesota

North Dakota

South Dakota

Wisconsin

Montana

# 416.43 Condition: Evaluation of Quality

## Review for evidence that **QAPI program**:

- Is proactive and ongoing
- Is comprehensive and data driven – process and frequency of data collection and analysis
- Evaluates systems, policies, practices, processes or events to identify problems that have occurred or may occur
- Requires the determination of the root cause of problems
- Results in effective actions to correct problems
- Requires follow up to ensure performance improvement

# 416.43 Standards: (1 of 2)

## **(a) Program scope**

The QAPI program :

- **Uses quality indicators or performance measures associated with improved health outcomes**
- **Must include identification and reduction of medical errors/adverse events**

## **(b) Program data**

- **Data regarding services provided**
- **Use data to evaluate effectiveness/safety/quality of care**
- **Identify opportunities for improvements**

# 416.43 Standards: (2 of 2)

## **(c) Program activities**

- **Track adverse events – determine causes / requires sustained improvement**
- **Implement preventive strategies**
  - **Staff training**

## **(d) Performance improvement projects**

- **Projects reflect the scope and complexity of services**
- **Documented evidence of projects conducted, including reason and outcome**

## **(e) Governing body responsibilities**

- **Compliance with 416.41**

## 416.44 Condition: Environment

- **Evaluation of compliance with standards to ensure provision of surgical services in a safe and sanitary environment that is properly constructed, equipped and maintained.**
- **Evaluation of Life Safety Code compliance**

# 416.44 Standards: (1 of 2)

## (a) Physical environment

- **Review of operating rooms**
  - **Equipment - logs document testing and maintenance**
  - **Surgical instruments – adequate supply, sterilization processes / logs**
  - **OR temperature / humidity is monitored**
- **Separate recovery room and waiting area**
- **Infection control policies**

## (b) Safety from fire

- **Compliance with 2000 NFPA 101 ® Life Safety Code**
- **Waivers, effective until next survey**
- **Emergency lighting requirements**
- **Alcohol-based hand rub dispensers**

# 416.44 Standards: (2 of 2)

## (c) Emergency equipment

- **Ensure compliance with required emergency equipment**
  - **Use of cricoidotomy set in place of tracheostomy set**
  - **AED may be used if ASC determines appropriateness for types of patients served**

## (d ) Emergency personnel

- **Review personnel files**
  - **Training and competence to use emergency equipment and supplies**
  - **CPR training**
  - **Staffing to ensure such personnel are present when there is a patient in the ASC**

# 416.45 Condition: Medical Staff

**Medical staff responsibilities are outlined and they are held accountable to the governing body**

- **Is the process for physician privileging written and detailed?**
- **Are there periodic reappraisals?**
- **Are reappraisal timelines met?**
- **Is the provider's ASC-specific record part of the reappraisal process?**
- **Is the appropriate evidence of credentials present in each provider file?**

# 416.45 Standards:

## (a) Membership and clinical privileges

### Policies and procedures and credentials and personnel record review:

- State licensure, certifications
- Relevant training and experience
- Recommendations by qualified medical personnel
- Specific list of privileges granted

## (b) Reappraisals

- Reappointment, including peer review

## (c) Other practitioners

- Specific types of clinical activities that each class of practitioner will be eligible to perform (must not be outside of licensed scope of practice)
- Process by which oversight is provided
- Process and criteria for reviewing qualifications before practitioner is permitted to provide care

# 416.46 Condition: Nursing Service

## 416.46(a) Standard: Organization and Staffing

**Nursing services must be under direction of an RN.**

- **Is an RN designated to direct nursing services?**
  - **Determine if the person serving in that capacity is an RN – view credentials**
  - **Review staffing patterns – are there sufficient staff to address patient needs?**
  - **Do nursing staff members have the appropriate qualifications for assigned tasks?**

### **(a) Organization and staffing**

- **Clear, written responsibilities (job description)**
- **Nursing services consistent with “recognized standards of practice” (State laws and nationally recognized standards/guidelines, e.g., ANA, AORN)**
- **Verify RN with (ACLS) is on premises and sufficiently free from duties to respond rapidly to emergency situations**

# 416.47 Condition: Medical Records

Ensure ASC maintains complete, comprehensive, and accurate medical records; review policies and procedures and medical records:

**(a) Organization**

- Interview with designated person responsible for clinical records
- Description of system
- Collected and stored in a consistent manner
- Timely access

**(b) Form and Content of Record**

- (1) Patient identification
- (2) Significant medical history and results of physical examination
- (3) Pre-op diagnostic studies (entered before surgery), if performed
- (4) Findings / techniques of operation including path report on all tissues removed during surgery, except those exempted by GB
- (5) Any allergies and abnormal drug reactions
- (6) Entries related to anesthesia administration
- (7) Documentation of properly executed informed patient consent
- (8) Discharge diagnosis

# 416.48 Condition: Pharmaceutical Services

## 416.48 Standards: Administration of Drugs

- **Interview with licensed healthcare professional designated responsible – evidence of active direction and oversight**
- (a) Administration of drugs**
  - **P/P regarding medication dispensing and administration and use of biologicals in accordance with state and federal laws and nationally recognized standards, e.g., State Pharmacy Board, Institute of Safe Medication Practices**
  - **Staff responsibilities regarding prescription pad security, security of controlled and non-controlled substances, and drug recalls**
  - **Safe practices for the use of single use syringes and needles and multi-dose vials**
  - **Pharmaceutical logs/inventory/wastage, including samples**
  - **Pharmacy consultant contract (if applicable)**

# 416.48 Standards: Administration of Drugs

- (1) Process for reporting adverse reactions to the physician responsible and evidence of documentation in clinical records**
- (2) If ASC administers blood or blood products, policies and procedures require administration only by physicians or RNs**
- (3) Determine process for verbal orders including evidence of read-back and verification and signed written order by the MD**

416.49 Condition: Laboratory and radiologic services

416.49 Standard: (a) Laboratory services

**If ASC performs laboratory services:**

- **Must have current CLIA Certificate or CLIA Waiver**

**If ASC *does not* provide laboratory services:**

- **Must have procedures and well-defined contract for obtaining routine and emergency laboratory services from certified laboratory**

# 416.49 Standard: (b) Radiologic services

**If ASC does not provide radiologic services and is integral to procedures performed:**

- **Must have procedures for obtaining radiological services from a Medicare approved facility**

**If ASC provides radiologic services:**

- **Meets hospital CoPs for radiologic services specified in §482.26 (*Radiologic services*)**

**If not integral to services, requirement not applicable**

# The following are three new CfC

**416.50 Patient rights**

**416.51 Infection Control**

**416.52 Patient assessment and discharge**

# 416.50 Condition: Patient Rights

## 416.50(a) Standard: Notice of Rights

- **Review of patients rights statement and location of postings**

### **(1)(2) Review ASC's patient rights notification process**

- in advance of the date of the procedure,
- provisions for exceptions (i.e., same day surgery).
- provisions for communicating in language/manner of patients
- **View areas where notice posted**
- **Verify inclusion of physician financial interest/ownership**
- **Information provided about advance directives and process for documentation in clinical records**

# 416.50(a)(3): Submission and investigation of grievances

- **Review ASC policy regarding the patient grievance process**
  - **Specified timeframes**
  - **How grievance addressed**
  - **Outcome**
  - **Name of ASC staff person responsible**
  - **Steps taken**
  - **When resolved**
  - **Reporting of and documentation of grievances**
  - **Process for reporting substantiated grievances to state authorities**

# 416.50(b): Exercise of rights and respect for property and person

The patient rights documents outlines the patient may:

- (i) Exercise rights without being subjected to discrimination or reprisal.**
- (ii) Voice grievances regarding treatment or care that is (or fails to be) furnished.**
- (iii) Be fully informed about treatment/procedure and the expected outcome before it is performed.**
- (iv) If patient determined to be incompetent, rights exercised by designated appointed representative**
- (v) If patient determined to be competent, they may designate a representative to exercise their rights.**

# 416.50(c): Privacy and safety and (d): Confidentiality of clinical records

**The patient notice includes patient right to:**

- (1) Personal privacy**
- (2) Received care in a safe setting**
- (3) Be free from all forms of abuse or harassment**

**The ASC must have policies that comply with the Department's rules for the privacy and security of individually identifiable health information, as specified at 45 CFR parts 160 (General Administrative Requirements) and 164 (Security and Privacy).**

**Update: July 27, 2009 HHS Secretary delegated to Office of Civil Rights.**

# 416.51 Condition: Infection Control

## 416.51(a) Standard: Sanitary Environment

### Review the ASC's:

- Infection control program consistent with professionally acceptable standards of practice (e.g., CDC, APIC, Society for Healthcare Epidemiology of America [SHEA], and AORN)
- Maintenance and cleanliness of facility
- Ventilation and water quality control issues, including during construction/renovation
- Maintaining safe air handling systems in areas of special ventilation, such as operating rooms
- Cleaning and disinfection of environmental surfaces
- Sanitation for employee food storage and eating area
- Disposal of regulated and non-regulated waste
- Pest control

# 416.51 Standard: (b) Infection control program

**An active surveillance component that covers patients and personnel**

- **Surveillance activities address:**
  - **Mitigation of risks associated with HAI**
  - **Identifying infections**
  - **Monitoring compliance**
  - **Program evaluation**

# 416.51 Standard: (b)(1) and (2) Infection control program

- **Must designate, in writing, a qualified licensed health care professional who will lead the infection control program**
- **Individual must have training in infection control, and maintain qualifications through ongoing education/training**
- **Certification in infection control, “while highly desirable,” is NOT required**
- **Infection control data and program activities are an ongoing component of the QAPI program**
- **Actions are taken in response to data analyses to improve the ASC’s infection control performance.**

# 416.51 Standard: (b)(3) Infection control program

## The plan of action:

- **Must include mechanisms that result in immediate action to take preventive or corrective measures that improve the ASC's infection control outcomes**
- **Should be specific to each particular area of the ASC – waiting room, OR, recovery, etc**
- **Addresses the activities discussed in the Interpretive Guidelines for 416.51(b), i.e., surveillance activities**

## During survey, an ASC would be asked about:

- **Actual examples of how infection control issues were identified**
- **How corrective or preventive actions were taken**
- **Documentation of how actions were evaluated to assure they resulted in improvement**
- **How the plan addresses all the basic elements of infection control**

## 416.52 Condition: Patient admission, assessment & discharge

### 416.52 Standard: (a) Admission & pre-surgical assessment

**Review medical record policies and procedures and medical records:**

- (1) For evidence that not more than 30 days before the date of the scheduled surgery, each patient has a comprehensive medical H&P assessment completed by a physician or other qualified practitioner**
  
- (2) For evidence that an update of the H&P done pre-procedure and any changes documented by a physician**
  
- (3) For verification H&P in patient's medical record pre-procedure**

# 416.52 Standard: (b)(1) and (2) 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**
  - **An RN with, at a minimum, post-operative care experience**
  - **Assessment of patient's recovery from anesthesia only by physician or anesthesiologist**
- (2) Post-surgical needs must be addressed and included in the discharge notes.**

# 416.52 Standard: (c) Discharge (1 - 3)

Observe discharge and documentation provided upon discharge:

(1) Verify each patient received written discharge instructions and overnight supplies.

- Prescriptions
- Written post-operative instructions
- Physician contact information for follow-up care

(2) Verify that discharge orders are signed by the physician who performed the surgery or procedure.

(3) Review policy regarding discharge

- Document the responsible adult for each patient
- Develop policies that provide criteria for exemption

# AAAHHC/Medicare Deemed Status Surveys

- Unannounced Survey – 90-day survey window
- Policy changes effective December 1, 2008
  - Initial surveys – condition level deficiencies, ASC not recommended for deemed status
  - Previously deemed – condition level deficiencies, ASC must have follow-up survey

# Regional Corps Service Model for Texas

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# Contact AAAHC

## AAAHC

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