

Certification and Environmental Issues

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Disclosures

None



Objectives

- Describe regulations for certification as related to the environment of care in an ambulatory surgery center (ASC)
- Review possible deficiencies cited for the environment of care in ASCs
- Apply knowledge of certification requirements and potential deficiencies to maintain certification of an ASC

Background

- o ASCs accredited by national accreditation bodies under CMS-approved programs are deemed to meet Medicare CfCs (conditions for coverage). These suppliers are referred to as deemed status suppliers. ASCs accredited by the Accreditation Association for Ambulatory Health Care (AAAHHC) and JCAHO (TJC) as of December 19, 1996, are deemed to meet the CfCs and are Medicare participating ASCs...

Background

- o ...The ASCs accredited by the American Association for Accreditation for Ambulatory Surgery Facilities, Inc (AAAASF) as of December 2, 1998, and AOA (American Osteopathic Association – HFAP – Healthcare Facilities Accreditation Program) as of January 30, 2003, are deemed to meet the CfCs and are Medicare participating ASCs.

416.2 – Definitions*

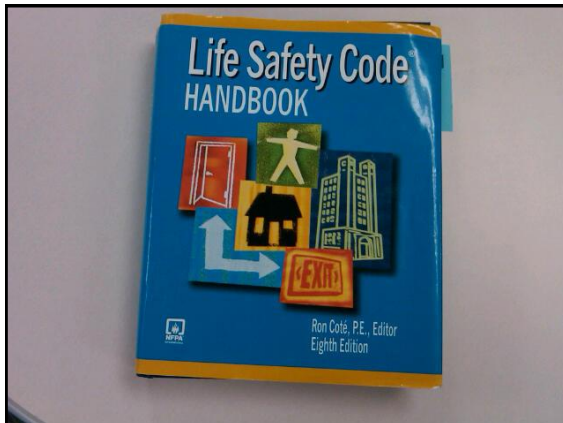
- o According to the definition of an Ambulatory Surgical Center, or ASC, its key characteristics are that it:
- o Is a distinct entity;
- o Operates exclusively for the provision of surgical services to patients not requiring hospitalization, with the ASC's services expected not to exceed 24 hours in duration following an admission;
- o Has an agreement with Medicare to participate as an ASC; and
- o Complies with the Conditions for Coverage (CfCs) in Subparts B and C, i.e., 42 CFR 416.25-52.

*CMS State Operations Manual, Appendix L, Guidance for Surveyors: Ambulatory Care. p34.

416.25 Basic Requirements*

- o Participation as an ASC is limited to facilities that:
- o (a) Meet the definition in 416.2; and
- o (b) Have in effect an agreement obtained in accordance with this Subparts B and C, i.e., 42 CFR 416.25-52

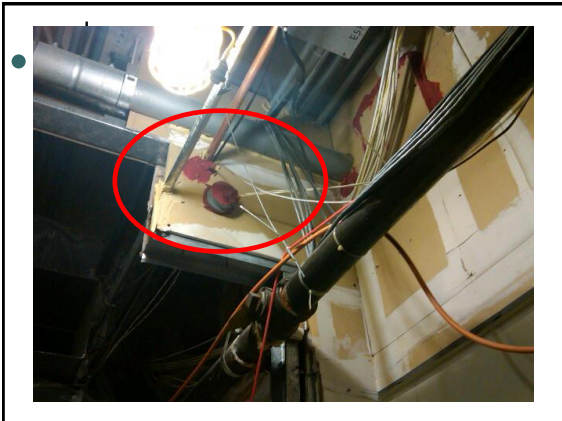
* CMS State Operations Manual, Appendix L, Guidance for Surveyors: Ambulatory Care, p33.



Interpretation

- Determine through interview and observation and consultation with the LSC surveyor whether the ASC facility is physically separated by at least a 1 hour separation from any other healthcare facility or physician office
 - 1 hour rated firewalls
 - 1 hour rated glass windows







Citations

- Facility separated from adjacent occupancies by non fire rated materials, glass, walls, panels with gaps
- Penetrations not properly fire sealed

CMS Condition Level Requirements

- 416.2 – Definitions
- 416.25 – Basic Requirements
- 416.40 – 416.52
- 416.41 (c) Standard: Disaster Preparedness Plan

416.41 (c) 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

*CMS State Operations Manual, Appendix L, Guidance for Surveyors: Ambulatory Care, p51.

Interpretation

- Show the plan and briefly summarize
- Describe staff education on plan and staff responsibilities
- Show evidence of state or local emergency management coordination, minimally be able to identify
- Drill documentation, evaluation, revisions to plan, and implementation of revisions

CMS Condition Level Requirements

- 416.44 – Conditions for Coverage: Environment
 - 416.44(a) Standard: Physical Environment
 - 416.44(b) Standard: Safety from Fire
 - 416.44(c) Standard: Emergency Equipment
 - 416.44(d) Standard: Emergency Personnel

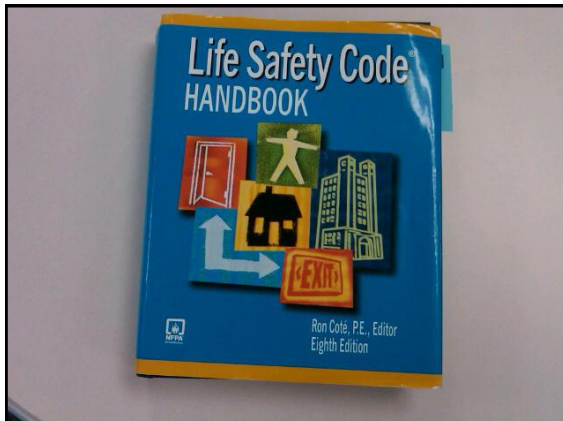
416.44 Conditions for Coverage: Environment

- “The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients” *

*CMS State Operations Manual, Appendix L, Guidance for Surveyors: Ambulatory Care. P81.

Interpretation

- Applicable Life Safety Codes (LSC)
- Construction and Maintenance
 - Does it look like it's falling apart?
 - Ceiling tiles stained?
 - Water quality testing?
- Physical Plant Sanitation
 - Does it look clean?
 - Does it smell?



416.44 (a) Standard: Physical Environment

- The ASC must provide a functional and sanitary environment for the provision of surgical services
 - (1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area*

*CMS State Operations Manual, Appendix L, Guidance for Surveyors: Ambulatory Care. P81.

Interpretation

- Does the ASC's OR meet applicable design standards?
- Is the right type of equipment in the room?
- Is there enough equipment, including instruments?
- Are there maintenance logs on the equipment?
- Who is responsible for testing and maintenance?
- Is the OR big enough to allow unobstructed movement of staff and patients?

416.44 (a) Standard: Physical Environment

(2) The ASC must have a separate recovery room and waiting area.*

*CMS State Operations Manual, Appendix L, Guidance for Surveyors: Ambulatory Care. P83.

Interpretation

- Is there a separate room for patient recovery?
- Is it equipped appropriately?
- Is there a separate area for visitors, or patients waiting to start pre-op preparation?

416.44 (a) Standard: Physical Environment

- (3) The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.*

*CMS State Operations Manual, Appendix L, Guidance for Surveyors: Ambulatory Care. P84.

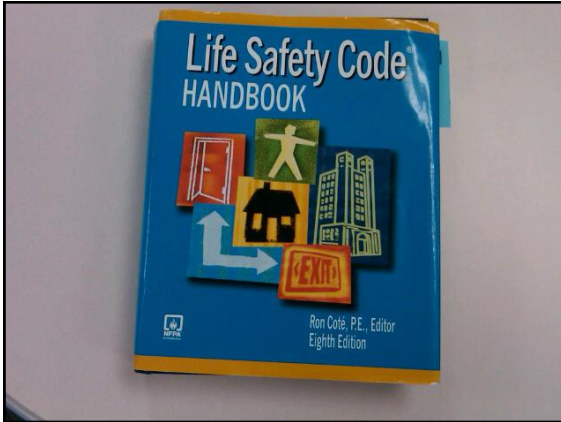
Interpretation

- How are infections tracked?
 - Patients
 - Staff
- List of reportable diseases
 - Ever reported a reportable to the state?
 - Documentation

416.44 (b) Standard: Safety From Fire*

- (1) ASC must meet the provisions applicable to Ambulatory Healthcare Centers of the 2000 edition of the Life Safety Code of the National Fire Protection Association, regardless of the number of patients served
- (4) An ASC must be in compliance with Chapter 21.2.9.1, Emergency Lighting, beginning on March 13, 2006

*CMS State Operations Manual, Appendix L, Guidance for Surveyors: Ambulatory Care. P85.



Interpretation

- LSC Surveyor will review to see NFPA standards are met:
 - Egress
 - Hazard protection
 - Alarms
 - Emergency requirements





Citations

- Various violations of NFPA standards
- Improper penetration sealing in smoke/fire rated walls
- Space heaters

Egress

- The number of means of egress shall be not less than two
- The clear width of any passageway required for exit access shall be not less than 44 inches
- Exit access shall be arranged so that there are no dead ends in corridors
- Egress illumination shall be continuous during times of occupancy
- Illumination of means of egress shall be from a source considered reliable





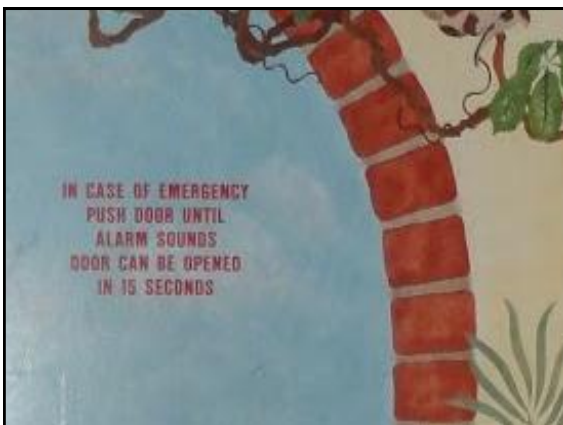


Citations

- Fire exit signage inappropriate
- Lighted exit signs missing
- Lighted exit signs without appropriate directional indicators
- Incorrect size and shape of exit signs
- Fire extinguishers out of date
- Staff unable to speak to using extinguisher







Hazard Protection

- Chemicals – cleaning, instrument processing
- Combustibles

Interpretation

- Chemical and combustible handling and storage
 - Appropriate ventilation
 - PPE
 - Fire rated storage area
 - Sprinklered
 - Maximum amount per rated area

Citations

- Improperly secured med gas cylinders
- Must be individually secured (in facilities built after 3/11/2003)
- Excessive combustibles in storage area (oxygen, ABHR, surgical scrub, skin prep)



Alarms

- Fire alarm system shall be installed, tested and maintained in accordance with NFPA 70
- Fire alarm installation wiring shall be monitored for integrity
- Fire alarm systems shall have a approved maintenance and testing program
- Records of maintenance and testing and a copy of the certificate of compliance should be maintained and producible

Alarms

- Manual pulls fire alarm at each exit from ASC
- No further than 5 feet from exit

Citations

- Manual pull stations missing from egress doors (must be within 5 feet)
- Pull stations only in common areas
- Staff unable to locate pull stations

Emergency Requirements*

- Emergency Power (built or renovated after January 10, 2003) needs a type 1 essential electrical system (EES) such as a generator
- ASCs that use general anesthesia for life support equipment will be required to upgrade EES to a type 1
- ASCs are expected to have a reliable source of back-up power

*CMS State Operations Manual, Appendix L, Guidance for Surveyors: Ambulatory Care. P87.

Citations

- No emergency lighting for back-up power sources
- EES batteries not being inspected every 7 days
- Non-sealed batteries not having electrolyte levels tested

416.44 (b) Standard: Safety From Fire Alcohol Placement*

- (5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, an ASC may place alcohol-based hand rub (ABHR) dispensers in its facility if:
 - (i) Use of alcohol-based hand rub dispensers does not conflict with any state or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in healthcare facilities;
 - (ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;
 - (iii) The dispensers are installed in a manner that adequately protects against inappropriate access; and

Alcohol Placement Continued

- (iv) The dispensers are installed in accordance with the following provisions:
 - (A) Where dispensers are installed in a corridor, the corridor shall have a minimum width of 6 feet (1.8 meters);
 - (B) The maximum individual dispenser fluid capacity shall be:
 - (1) 0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors
 - (2) 0.5 gallons (2.0 liters) for dispensers in suites of rooms
 - (C) The dispensers shall have a minimum horizontal spacing of 4 feet (1.2 meters) from each other;
 - (D) Not more than an aggregate of 10 gallons (37.8 liters) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet;

Alcohol Placement Continued

- (E) Storage of quantities greater than 5 gallons (18.9 liters) in a single smoke compartment shall meet the requirements of NFPA 30, Flammable and Combustible Liquids Code;
- (F) The dispensers shall not be installed over or directly adjacent to an ignition source;
- (G) In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments; and
- (v) The dispensers are maintained in accordance with dispenser manufacturer guidelines

*CMS State Operations Manual, Appendix L, Guidance for Surveyors: Ambulatory Care, P86.

Citations

- ABHR placement not in accordance with local fire marshal
- ABHR placement impedes width of egress corridors
- ABHR placement too close to ignition sources (i.e., electrical outlets, light switches)
- AHBR in carpeted areas that are non-sprinklered

416.44 (b) Standard: Safety From Fire*

- Alcohol-based skin preparation use at an ASC is not considered safe unless appropriate fire risk reduction measures are taken

*CMS State Operations Manual, Appendix L, Guidance for Surveyors: Ambulatory Care. P88.

ETOH Skin Prep Safety

- Single-use packaging with clear and explicit instructions
- Not allowing ETOH skin prep to soak into patient's hair or linens. Sterile towels should be placed to absorb drips and removed prior to draping patient
- Allowing skin prep to dry completely prior to draping
- Verifying all this has been done prior to time out

416.44 (c) Standard: Emergency Equipment

Emergency equipment available to the operating rooms must include at least the following:

- (1) Emergency call system
- (2) Oxygen
- (3) Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator
- (4) Cardiac defibrillator
- (5) Cardiac monitoring equipment
- (6) Tracheostomy set
- (7) Laryngoscope and endotracheal tubes
- (8) Suction equipment
- (9) Emergency medical equipment and supplies specified by the medical staff

*CMS State Operations Manual, Appendix L, Guidance for Surveyors: Ambulatory Care. P89.

Interpretation

- Above listed equipment readily available to each OR
- Sufficient equipment to handle multiple simultaneous emergencies
- ASCs are permitted to have a cricoidotomy set instead of a tracheostomy set

Interpretation

- Must have written policy describing use of emergency equipment and supplies
- Which equipment/supplies/medications should be in each OR
- For supplies not in each OR, how much/many and location readily available for each OR

Interpretation

- Produce emergency equipment policy
- Staff able to speak to location/use of emergency equipment
- Documentation of maintenance of mechanical or electrical equipment
- Are supplies current

Citations

- No code blue in call system
- Expired emergency medications
- No documentation of equipment inspection or maintenance
- Staff on site without proper documentation of emergency equipment competency

416.44 (d) Standard: Emergency Personnel

Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC*

*CMS State Operations Manual, Appendix L, Guidance for Surveyors: Ambulatory Care. P91.

Interpretation

- Provide documentation that staff has been trained and is competent to use all required emergency supplies and equipment as well as CPR certification
- Show evidence that staff trained with emergency equipment is always in house when patients are present
- Staff able to speak to their role in emergencies
- Staff able to speak to back up system should primary emergency responder be busy with another emergency

Citations

- Staff on site without proper documentation of competency
- Staff unable to speak to emergency equipment use and staff roles in emergency

Questions?????

Thank You!!!

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