ASC Regulatory Update and Survey Trends
ASC/ASOA Symposium and Congress
San Diego, CA
April 2015
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Objectives
• Describe recent changes to the CMS interpretive guidelines.
• Identify Top Cited Deficiencies on accreditation and deemed status surveys.

Disclosure
• Regina Boore is the principal of Progressive Surgical Solutions, LLC, an ASC consulting firm.
Recent CMS Changes:  
August 29, 2014

- Change in Terminology and Update of Survey and Certification (S&C) Memorandum 09-55 Regarding Immediate Use Steam Sterilization (IUSS) in Surgical Settings
- Reverses Flash Sterilization Clarification position published Sept 4, 2009:
  - Sterilization of unwrapped/uncontained loads should not be a routine practice.
  - Utilization of short sterilization cycle of a wrapped/contained load is OK long as ASC follows ALL IFUs for devices involved.

Current CMS Position

- Abandons term “flash” sterilization and replaces it with “IUSS”.
- Surgical disinfection and sterilization must be consistent with accepted standards of practice.
- ASCs must adhere to professionally acceptable standards of practice as defined by nationally recognized organizations with expertise in infection prevention.
- IUSS is for instruments needed immediately, not intended for storage/later use, and allows minimal or no dry time.

Current CMS Position (continued)

- IUSS is not equivalent to short cycle sterilization (SCS)
- SCS involves a wrapped/contained load, adherence to all IFUs.
- SCS is equivalent to terminal sterilization IF it includes a dry time and is packaged in a wrap or rigid container intended to be stored for later use.
Concerns with Routine Use of IUSS

- Increased risk of complications due to potential barriers to thorough completion of all necessary steps
- Potential for contamination and instrument damage during transfer to the field
- Risks related to wet instruments and potential for burns

“Therefore use of IUSS, even when all the steps are performed properly, should be limited to situations in which there is an urgent need and insufficient time to process an instrument by using terminal sterilization.”

Recent CMS Changes: September 26, 2014

- Categorical Waiver on the Use of Power Strips in Patient Care Areas

Recent CMS Changes: November 21, 2014

- Directions on the Off-Label/Modified Use of Waived Blood Glucose Monitoring Systems (BGMS)
- It is important to note that device labeling does not limit use of the device in non-critically ill patients, and thus those uses are not “off-label.”
Recent CMS Changes: July 11, 2014

- Appendix L Revisions – Surveyor Guidance
- 416.41(b) Standard: Hospitalization
  - Written policies must address the following:
    - Circumstances which warrant transfer, decision maker
    - Documentation sent w/patient
    - Procedure for safe efficient transfer, including communicating w/the receiving hospital
  - Clarification of “local” hospital is based on
    - Capacity to accommodate the patient population
    - Capacity to treat predominant medical emergencies associated with ASC scope of care

416.44(a) Standard: Physical Environment

- ORs (operating rooms) must be designed in accordance with industry standards for sterile and unsterile procedures
- Humidity must be appropriate for surgical and anesthesia equipment and supplies that require a different humidity should be stored outside the OR until needed

416.49(b) Standard: Radiologic Services

- Only allowed when integral to the procedure
- Scope of Radiologic Services must be defined and approved by the GB
- Provision of Radiologic Services must meet Hospital Radiology Services requirements regardless if it is directly or under arrangements
### 416.50(a) Standard: Notice of Rights
- Correction to web address for Medicare Ombudsman

### 416.50(e) Standard: Exercise of rights and respect for property and person
- Allows patient's representative to sign verification of informed consent form

### 416.52(c) Standard: Discharge
- Allows surgeon to write a discharge order for “patient may be discharged when stable”. Pt is expected to leave w/in 15-30 minutes after the surgeon signs the order
**Top Cited Deficiencies AAAHC**

- Contract management and approval
- Credentialing and privileging
- QAPI activities measure current performance against performance goal
- QAPI activities measure current performance against previous performance goal
- Allergies prominently identified in record and updated on each visit
- Compliance with Life Safety Code

**Top Cited Deficiencies AAAHC**

- Emergency drills quarterly
- Staff education on MH
- Comprehensive, current health history and physical, current medication list
- Safe medication management (Look alike-sound alike)
- Review of test results

**Top Cited Deficiencies AAAASF**

- Medical records (incomplete)
- Safe medication management (labeling, expired, refrigerator log, key management)
- Emergency management (Pt transfer agreement, emergency supplies/drugs)
- Preventive Maintenance program for all essential mechanical, electric and patient care equipment
Top Cited Deficiencies AAAASF

- Environmental standards (trip hazards, sharps management, cord chaos, hazardous materials storage)
- Storage, handling and administration of drugs and biological (labeling, disposal, expired)
- Lab services (quality control logs)
- Policies and procedures (development, timely review, governance approval)

Top Cited Deficiencies TJC

- Credentialing and Privileging
- Infection control associated with medical equipment, devices and supplies
- Safe medication storage
- Safe management of high alert and hazardous medications
- Influenza vaccination of LIPs and staff

Top Cited Deficiencies TJC

- Staff and LIPs performing waived tests are competent
- Infection control risk assessment
- Inspection, testing and maintenance of equipment
- Hazardous materials and waste management
- Safe medication management of look-alike/sound-alike medications
Top Cited Deficiencies PSS

- Credentialing and privileging
- Infection Control program includes comprehensive approach to identify and manage risks and to prevent, control and investigate infections
- Staff education and training
- Hazardous materials and waste management
- Safe medication management

Top Cited Deficiencies PSS

- Current, comprehensive H&P within 30 days
- Hand hygiene compliance
- Contract management
- Governance - Annual reviews and approval: P&Ps, Contracts, QAPI program, Infection Control program, Disaster preparedness program, delegations of authority
- Unlicensed Assistive Personnel scope of practice

Thank you

- Questions?
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