CfC Compliance Update

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Ambulatory surgery centers (ASC) got a wake-up call in May 2009 with the release of the revised and expanded CMS Conditions for Coverage (CfC), which was accompanied by increased surveillance and enforcement activity. The interpretive guidelines in the new rule are more comprehensive and prescriptive than the previous rule; however, the survey experience remains surveyor-dependent to some degree. We have worked with scores of facilities over the past 2 years assisting with plans of correction. This article summarizes some of what we have learned.

Standard of care

Many ASCs operate under the misunderstanding that the standard of care for laser procedures is different than surgical procedures. It is important to note the CMS CfCs apply to every patient encounter in a Medicare-certified ASC, regardless of type of procedure, payer, or anesthesia. All procedures must be performed in a procedure room or operating room. The physician performing the laser procedure must be appropriately credentialed and

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appointed to the ASC medical staff per the dictates of the medical staff bylaws. Required physician medical record documentation includes

- a current (within 30 days) comprehensive history and physical,
- a pre-surgical assessment by a physician documenting an examination for any changes in the patient's condition since the H&P,
- operative report, and
- physician orders, including a signed, dated, and timed discharge order post-op.

Meeting the new physician documentation requirements has been particularly challenging for high-volume ophthalmic ASCs. Some high-volume surgeons do not leave the operating room and often "flip flop" between two ORs. It is just not possible to comply with the new CfCs in this operating model. Physician activity and documentation requirements are dictated throughout the perioperative patient process.

Only licensed personnel may administer medications (including eye drops). RN pre- and post-op assessments are required for all patient encounters. Therefore, you cannot perform laser procedures without an RN. Laser lenses must be cleaned per manufacturer's recommendations, which typically is a bleach solution or glutaraldehyde.

H&P requirements/ patient assessment

Many centers struggle with the pre-op H&P requirement, and this continues to be a frequent citation on surveys. The comprehensive H&P must be performed within 30 days of surgery. It should include, at a minimum, chief complaint, history of present illness, ocular exam, diagnosis and plan, current medications, allergies, baseline vital signs, and review of systems. (In December 2010 CMS issued a clarification that allows the H&P to be done on the same day as the procedure.)

The surgeon must assess the patient pre-op, prior to transfer to the operating room, to mark the surgical site and document the pre-surgical update. The pre-surgical update is a patient assessment to confirm there are no significant changes in the patient clinical condition since the H&P that would preclude proceeding with the surgery. The medical record entry should be signed, dated, and timed. After surgery, the surgeon must assess the patient to determine appropriateness for discharge and document a discharge order that must be signed, dated, and timed. The CfCs state the patient is generally expected to be discharged within 15 to 30 minutes of that signed order.

Medication management

Medication management is a survey focus. Two previous articles (in **AE eZine Summer 2011** and **AE eZine Winter 2012**) addressed the regulations associated with compounding and medication safety best practices.

Labeling. Proper medication labeling requires open multi-dose medication to be "relabeled" with the open date, initials of who opened it, and the revised expiration date (28 days after opening, unless otherwise dictated by the manufacturer). All medication must be appropriately labeled, including medications on the sterile field.

Administration. As noted earlier, medication (including eye drops) may only be administered by licensed personnel. Ophthalmic techs may not administer medications in an ASC. Physician orders must be documented for all pre-op, intra-op, and post-op medications administered.

Compounding. No high-risk compounding can be performed in the ASC. Any low-risk drug compounding (i.e., blocks) must be done by licensed personnel and comply with USP 797.

Sterilization

Routine flash sterilization is unacceptable. Routine short-cycle steam sterilization requires a closed container system and instruments to be covered during transport. The standard process for decontamination and sterilization includes the following:

1. Instruments are wiped on the sterile field after use.
2. All single-use devices are properly disposed of after use.
3. Instruments are transported, covered, to soiled utility when the case is over.
4. Mechanical decontamination occurs, with some combination of ultrasonic, brushing, and rinsing, as well as flushing of lumens (per manufacturer directions for use).
5. Instruments are sterilized in a closed container system.
6. Instruments are transported to the sterile field in the closed container system after sterilization.

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Surgical site identification

The universal protocol for surgical site identification must be consistently implemented. The process starts with scheduling and culminates in the "Time Out" intraoperatively. The surgeon must mark the surgical site pre-op. The RN circulator typically initiates the Time Out process, but all members of the surgical team should actively participate.

Infection control

Infection control is still one of the most frequently cited deficiencies. Appropriate hand hygiene by all facility staff, including physicians, is scrutinized during the survey process. Regular compliance monitoring should be documented, and staff should be in-serviced on your infection control program, including proper cleaning of the glucometer. Turnover in the OR must be standardized. The ASC should approve one germicidal wipe for use throughout the facility. It must be used according to manufacturer directions. Housekeeping staff should be in-serviced on terminal cleaning standards and adherence should be regularly monitored.

Recommendations

There are a number of reasons why ASCs get into survey trouble. Success on a prior survey may result in a false sense of security. Surprisingly, there are still centers caught unaware of the regulatory changes and increased surveillance. Still others find some of the requirements unreasonable and refuse to make the necessary changes.

After two-and-a-half years under the new rule, we are beyond resistance. It is essential for the facility leadership to be "on board" and supportive of compliance efforts. Instill a sense of ownership in your medical and facility staff. Educate and involve them in compliance activities and make sure they understand their role in ensuring a successful survey. Stay up-to-date with regulatory changes and best practices. Numerous electronic and print publications provide regular updates on changes and resources for your compliance efforts. Conduct an annual review of your facility policies and procedures for adherence to the CMS CfCs as well as annual changes to accreditation standards.

In our experience, leadership and education are the keys to success. Commitment to compliance starts at the top and must be a cultural value. ASCs that embrace this concept generally find it reduces stress, improves their performance, and makes them a better organization all around. AE

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