A New Era of Enforcement in ASCs

Regina Boore, RN, BSN, MS

On November 18, 2008, CMS approved major revisions to the ASC Conditions for Coverage (CfC) in 42 CFR 416.2-416.52. These changes became effective May 18, 2009. They are significant and include not only revisions to existing requirements but also the addition of 13 new conditions and 35 new standards. Whereas our past frustrations may have been the regulations' broad-brush language and lack of specificity, leaving room for subjective interpretation and application, that clearly will not be the main concern in the future.

The "rulebook" has expanded from 20 to 167 pages. The revisions are most significant in the areas of governance, patient rights, quality improvement, and infection control.

Many of the changes are long overdue and necessary to get the CfC in line with the current standard of care. However, the interpretive guidelines are very specific about the documentation required to demonstrate compliance and in some areas they are burdensome.

The document can be reviewed in its entirety at www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09_37.pdf. Here I will outline the four most significant revisions mentioned above, as well as some additional highlights of the new CfC.

Regulation and enforcement are more intense than I have ever experienced in my 27 years in ambulatory surgery. It is a certainty now: Your number will come up in the near future.

Governance

Policies, bylaws, meeting minutes, etc., must underscore the governance role of the governing body. Specifically, CMS wants to see active management by the governing board (GB) with respect to the quality improvement program, all quality-related issues, safety in the environment, and development and maintenance of a disaster preparedness plan. All GB delegations of authority, such as human resource administration, nursing services, pharmacy services, medical records, lab and pathology services, infection control, etc., must be documented. Policies and procedures must be reviewed and approved by the GB annually. Contracted services must be monitored on an ongoing basis and performance and quality data must be gathered and considered in the contract renewal process.

Coordinate with your local and state authority "as appropriate" in the development and implementation of your disaster preparedness plan. The extent of the coordination will vary based on your location and scope of care. Document your investigation and communication with the authorities and subsequent discussion and decision making by the governing body. You must activate your disaster preparedness plan at least annually and document an evaluation of the exercise. Further, you must evaluate your overall disaster preparedness plan annually and document review of this evaluation by the governing body.

Patient Rights

ASCs are required to notify patients of three items ***in advance of the procedure date***:

1. Patient rights, verbally and in writing, in a language and manner the patient or patient's representative understands. The CfC include specific information to be included in the patient rights.
2. Information on advance directives in writing, including your policy, relevant state laws, and an official state form if one exists.
3. Physician financial interest or ownership in writing, when applicable.

In response to an outcry from the industry that this requirement would limit patient access, CMS issued specific criteria to address allowable exceptions. The incidence of a patient receiving the required notices on the procedure date is expected to be a rare occurrence.

A detailed grievance policy is required and should be integrated into the QAPI plan. The new CfC is very specific in detailing a well-designed informed consent process. If you haven't visited your HIPAA program lately, dust it off and make sure it is being implemented as written and staff training is documented.

Quality Assessment and Performance Improvement

If your facility is accredited, you probably meet the new Quality Assessment and Performance Improvement condition. However, if you are not accredited, you will need to gear up to implement a robust and comprehensive quality management plan. CMS requires at least one QAPI project annually and ongoing monitoring and assessment of quality indicators.

Infection Control

This is a focal point for the surveyors. Make sure your program includes mandatory reporting of communicable disease, employee health, decontamination of gross spills, ventilation and water quality issues, food sanitation in employee eating areas, staff education and training, and ongoing monitoring of staff compliance. The infection control coordinator must have specific training in infection control. The CfC includes an infection control audit tool you can use to make sure your house is in order.

Other CfC Highlights

Surgical services. Clinical policies and procedures must be developed consistent with nationally recognized standards (i.e., AORN, APIC, ACS, ASA, CDC, NPSG, etc.), and such standards should be referenced in your policies. If you haven't reviewed all your policies and procedures recently, now is an excellent time to do it. In particular, be sure you have policies consistent with the current standard of care for pre-op patient verification, surgical site identification, time out, alcohol-based skin preparations, hand hygiene, germicidal disinfectants, pre-anesthetic risk assessment, admission criteria, and post-anesthesia care.

Environment. Polices must specifically address which emergency equipment (crash cart) will be available in each OR. For equipment not present in each OR, policies must designate such equipment (and its quantity) and state where it will be stored

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so that it is readily available when needed in the OR.

Membership and clinical privileges. Peer references are required in your credentialing process. Single-member (physician) medical staffs must solicit the opinion of an outside qualified medical professional on the competence of the applicant for privileges. The ASC's governing body is not bound by the reviewer's recommendation to grant, deny, or restrict privileges. However, if the governing body decision is contrary to the recommendation, it must document its rationale for the decision.

Nursing services. Patient assignments must be clearly documented on a daily assignment sheet. Assignments should provide evidence that at least one RN is readily available to provide emergency treatment. That means the RN can leave the current task to respond to an emergency without putting another patient at risk of harm.

Medical records. The old CfC required a "significant" history and physical (H&P). The new interpretive guidelines mandate a "comprehensive" H&P, no more than 30 days old. "Comprehensive" is not clearly defined. I recommend, at a minimum, including a review of systems with appropriate documentation of the clinical indications for the procedure, diagnostic tests, and informed consent.

Patient admission, assessment, and discharge. A pre-surgical assessment immediately prior to surgery must be documented by a physician to include at minimum:

- Patient examination to assess changes in patient condition since the H&P that might be significant for the planned surgery.
- Identification and documentation of allergies to drugs or biologicals.

A post-surgical assessment on patients recovering from anesthesia must be documented by a physician. (Note: The ASA does not define conscious sedation as anesthesia.)

Word to the Wise

These regulatory revisions arrive in the aftermath of at least one high-profile incident in an ASC last year in which more than 40,000 patients were potentially exposed to hepatitis C. The U.S. Government Accounting Office (GAO) issued a report in March calling on the Department of Health and Human Services (HHS) to collect better data about healthcare-associated infections (HAI) in ASCs. Their report suggests this recent incident may indicate a more widespread problem. They recommend HHS conduct periodic surveys of randomly selected ASCs (instead of facilities chosen based on perceived risk) for quality issues and the length of time since their last survey.

Over the last two years, budget cutbacks at the state level have resulted in an increase of "deemed-status" surveys, in which an ASC is surveyed by an accrediting agency using both accreditation standards and the CMS CfC for Medicare compliance. CMS has been conducting "validation" surveys. Such surveys occur unannounced on the heels of a deemed status survey to validate the compliance assessment of the deemed status agency.

CMS has made $10M available for expanded ASC surveillance through 2010. Regulation and enforcement are more intense than I have ever experienced in my 27 years in ambulatory surgery. It behooves you to do a thorough assessment of your operation and get your house in order. It is a certainty now: Your number *will* come up in the near future. AE

Regina Boore, RN, BSN, MS (rboore@progressivesurgicalsolutions.com), is president of Progressive Surgical Solutions, LLC, an ASC management and consulting firm based in San Diego, Calif.