ASCs Under the Looking Glass: A Regulatory Update

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ASCs operate in a heavily regulated environment with increasing scrutiny and decreasing reimbursements. Keeping abreast of all the regulations that affect the operations of an ASC is a never-ending challenge.

Since the sweeping revision to the ASC Conditions for Coverage in 2009, CMS has issued a number of clarifications, proposals and changes. In this article, I'll review the most recent revisions, which were published earlier this year. At that time, there were updates/revisions to the following:

- Emergency equipment
- Patient rights
- Physical environment
- Radiology
- Advance directives
- Infection control

Many of the changes are simply wording or reorganization and don't carry significant operational implications. For the purposes of this discussion, I'll limit my review to the substantive changes, which are italicized in the excerpts throughout this article.

Emergency Equipment Changes

A welcome change affords ASCs more latitude in selection of emergency supplies:

§416.44(c) Standard: Emergency Equipment
The ASC medical staff and governing body of the ASC coordinates, develops, and revises ASC policies and procedures to specify the types of emergency equipment required for use in the ASC's operating room. The equipment must meet the following requirements:
(1) Be immediately available for use during emergency situations
(2) Be appropriate for the facility's patient population
(3) Be maintained by appropriate personnel

Previous mandates were more specific and included a mechanical ventilator and tracheostomy set, among other things. The new standard allows flexibility for facilities to standardize their emergency supplies to suit their scope of care and patient population in conjunction with their medical staff and in accordance with acceptable standards of care in the ASC industry. Policies and procedures must specify the emergency supplies (including quantity), medications and equipment present in each OR and outside the ORs, including location, so all are readily available to the OR(s) in an emergency. They must also address how the emergency supplies and equipment will be maintained. Having malignant hyperthermia (MH) emergency supplies is a standard of care if general anesthesia is included in the scope of care and/or if the ASC includes any MH triggering agents, such as succinylcholine, in its formulary.

It's a requirement that ASC clinical staffing, specifically the number of RNs, be sufficient to handle an emergency that may arise without compromising patient safety. The revised interpretive guidelines are even more specific. Surveyors are directed to inquire as to how the ASC would handle concurrent emergencies happening simultaneously in different locations within the center.

Patient Rights Changes

The most significant changes are to the condition of Patient Rights.

§416.50 Condition for Coverage — Patient Rights
The ASC must inform the patient or the patient's representative *or surrogate* of the patient's rights and must protect and promote the exercise of *these* rights, *as set forth in this section. The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the*

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patient's representative or surrogate, if applicable.

A patient surrogate may be identified in writing through an advance directive, medical power of attorney or verbally. Some ASCs may need to consider posting more than one notice, depending on the size of the ASC and the physical layout. The critical point is ensuring that they're posted in a manner and location in which patients and surrogates are likely to see it. Failure to post the written notice of patient rights in a single place (or places) within the ASC that are likely to be noticed by the patient or surrogate will result in a standard level citation.

§416.50(a) Standard: Notice of Rights
An ASC* must, *prior to the start of the surgical procedure,* provide the patient, or the patient's representative, *or the patient's surrogate* with verbal and written notice of the patient's rights in a language and manner that *ensures* the patient, the representative, *or the surrogate* understand *all of the patient's rights as set forth in this section. The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.

It's recommended that ASCs provide all patients with a verbal and written notice of their rights as soon as possible after scheduling a procedure. Mail and email are acceptable methods of communication. It's required that the notice be provided preoperatively and prior to administration of any medication that suppresses consciousness. If the ASC has a large number of non-English speaking patients, patient rights must be available in a language that the entire patient population will understand. If written notice is not available, the ASC must make translators available to provide a verbal notice of rights.

Ownership of an ASC

The interpretive guidelines for disclosure of physician financial interest or ownership have been revised to require written notice and include a list of physicians who have a proprietary interest in the ASC in writing. A generic statement of ownership isn't acceptable.

Advance Directive Changes

A major revision is how ASCs handle patient advance directives as shown.

§416.50(c) Standard: Advance Directives

(1) **Provide the patient or, as appropriate, the patient's representative with *written* information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms.**

Interpretive Guidelines: §416.50*(c)* Information on Advance Directives
Each ASC patient has the right to formulate an advance directive consistent with applicable State law and to have ASC staff implement and comply with the advance directive, *subject to the ASC's limitations on the basis of conscience. To the degree permitted by State law, and to the maximum extent practicable, the ASC must respect the patient's wishes and follow that process.*

An advance directive may be in the form of a living will or a medical power of attorney. Since this requirement was implemented 4 years ago, most ASCs have adopted a policy of informing patients that the ASC doesn't honor advance directives, and in the event of a medical emergency, will implement resuscitative measures immediately while activating 911 for an emergency transfer. This policy is no longer acceptable. Under the current regulation, ASCs can refuse to implement specific provisions of an advance directive on the basis of conscience, to the extent permitted by state law. The ASC policy should include a statement of limitations, identify the state authority permitting a conscience objection, and describe the range of medical conditions affected by the conscience objection.

Written notice of the advance directive policy **and** information on advance directives, including the state approved form, must be made available to the patient, prior to the start of the surgical procedure. The revision further specifies that whether or not the patient has an executed advance directive must be documented for **each visit**. Staff must be educated on facility policies and procedures regarding advance directives and the patient's right to make informed decisions regarding his health.

Other changes to the standards under the Patient Rights condition are largely aimed at inclusive language to extend the requirements to the patient's surrogate or representative. The interpretive guidelines for 416.50(e) Standard: Exercise of rights and respect for property

and person have been revised to mandate that the ASC must not engage in reprisals or discriminatory behavior in response to a patient exercising his rights. While this may be obvious and logical, the conditions for coverage require it to be codified in a policy and procedure.

Infection Control Changes

Significant changes to 416.51(b) Standard: Infection control program are to the interpretive guidelines. While the vast majority of ASCs have a formal program for tracking post-op infections, the revised guidelines specifically require a formal tracking investigation and reporting system. Of note to practice-owned ophthalmic ASCs is this: ***ASCs may delegate portions of this follow-up responsibility to the physicians on the ASC's staff who will see the patients in their office post-discharge only if the ASC's process includes a mechanism for ensuring that the results of the follow-up are reported back to the ASC and documented in the patient's medical record.***

ASCs are also obligated to comply with all applicable county, state and federal disease-reporting requirements. There are also changes to Exhibit 351, Infection Control Surveyor Worksheet.

Updated AAAHC Standards

In addition to CMS regulations, ASCs that obtained Medicare certification through a deemed status survey are accredited and must therefore comply with evolving accreditation standards. The national deemed status agencies include The Joint Commission, Health Facilities Accreditation Program, Accreditation Association for Ambulatory Health Care (AAAHC) and American Accreditation Association of Ambulatory Surgical Facilities. Since the majority of accredited ASCs are accredited by AAAHC, it's worth mentioning many AAAHC standards, which have been edited or revised for 2013.

In the core standard, Quality of Care Provided, standard 4.E.4 has been edited to state ***medication reconciliation is performed.*** There has been discussion around this for years within the industry and accrediting bodies. The risk associated with inadvertent mismanagement of medication regimens in the acute care setting is well documented. The opportunity for unintended inconsistencies in medication management may occur at any point during transitions in care. Medication reconciliation is the process of reconciling medication regimens upon admission, transfer and discharge. Some have asserted this process is equally important in the outpatient setting, as some patients receive prescriptions from multiple outpatient providers. Unfortunately, in the ophthalmic ASC setting, this is rarely the case. Nonetheless, AAAHC now requires that a process of medication reconciliation be in place in ASCs.

In the core standard, Clinical Records and Health Information, standard 6.B.4 requires ***a system for tracking access to medical records to block unauthorized access.*** While most ASCs manage this process well, it may be wise to formalize the process you have in place to meet the standard. More burdensome for ophthalmic ASCs is standard 6.E, which requires a diagnostic summary for patients who have three or more admissions to the ASC. The concept of diagnostic summaries is not new and is a standard in clinic settings. However, it has not been standard in ASCs and in ophthalmic and pain management ASCs in particular, where patients often meet the three-admission threshold.

Finally, in the adjunct standards of Surgical and Related Services, 10.I.F is a new standard that requires ***a written policy is in place for the risk assessment and avoidance practices related to deep vein thrombosis (DVT), when appropriate.*** According to the Association of Perioperative Registered Nurses, in a December 2010 publication, Byron Burlingame notes that the patient population in the ambulatory setting is typically at low risk for developing DVT using the procedure-based risk stratification of the American College of Physicians. However, risk can exist in surgical patients when comorbidities and type and length of surgical procedures are considered.

CMS Conditions for Coverage and AAAHC accreditation standards are only two of the reference points dictating the operation of ASCs. OSHA, HIPAA, CDC guidelines, state licensing regulations, and many other local, state and federal regulations and guidelines also impose requirements upon ASC operators. It behooves owners and administrators to be "plugged in" to appropriate resources to ensure awareness of evolving standards and take appropriate action to ensure ongoing compliance. ◇

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