CMS Update for ASCs

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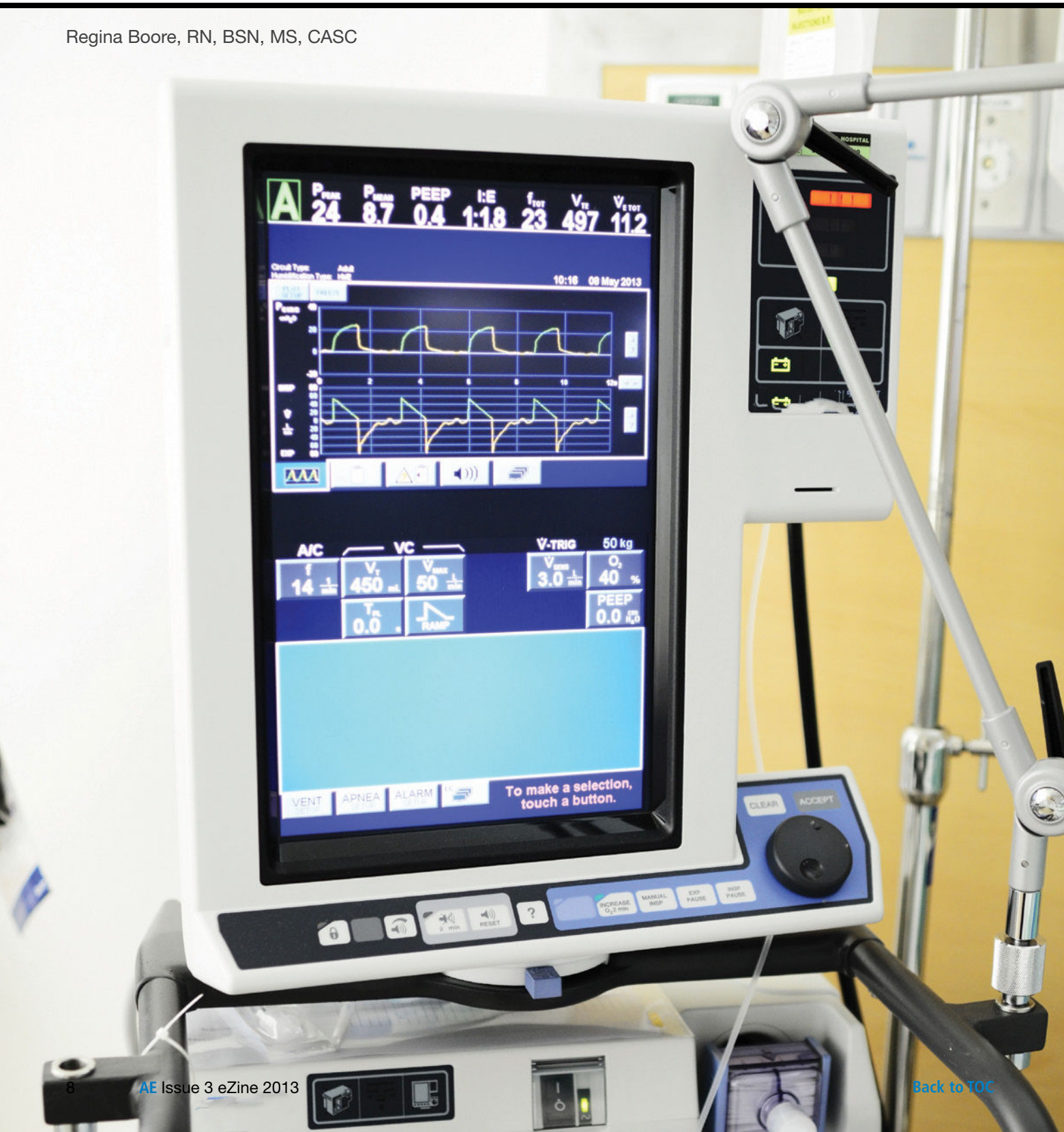

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Since the sweeping revision to the ASC Conditions for Coverage (CfC) in 2009, CMS has issued a number of clarifications, proposals, and changes. The most recent CfC update was published on March 15, 2013. Many of the changes involve wordsmithing or reorganization without significant operational implications. However, some warrant the attention of ASC operators.

Emergencies and emergency supplies

A welcome change to 416.44(c) *Emergency Equipment* affords ASCs more latitude in selection of emergency supplies. Previously, this standard specified equipment, including a mechanical ventilator and tracheostomy set. The revised standard allows flexibility for facilities to standardize their emergency supplies appropriate to 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 that they are readily available to the OR(s) in an emergency. They must also address how the emergency supplies and equipment will be maintained. "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.

CMS has required that ASC clinical staffing 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 how the ASC will handle concurrent emergencies simultaneously in different locations within the center.

Patient rights

Significant changes have been made to 416.50 *Patient Rights.* Throughout this section CMS has clarified that the regulations extend beyond the patient to the patient's representative or surrogate. A patient surrogate may be identified in writing through an advance directive or medical power of attorney, or verbally. Additionally, *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 patient's representative or surrogate, if applicable.* Some ASCs might need to post more than one notice, depending on the size of the ASC and the physical layout. The critical factor is whether they are posted in a manner that all patients and surrogates are likely to see. Failure to post the written notice of patient rights in a place or places within the ASC likely to be noticed by the patient or surrogate will result in a standard level citation.

Verbal and written "Notice of Rights" must occur prior to the start of the surgical procedure. It must include state agency contact information for filing a complaint and the website for the Medicare Beneficiary Ombudsman. Ideally, ASCs provide patients notice of their rights as soon as possible after procedure scheduling. Mail and email are acceptable methods of communication. These rights must 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 that language. If that written notice is not available, the ASC must make translators available to provide verbal notice of rights.

Physician financial interest or ownership

The interpretive guidelines for *Disclosure of physician financial interest or ownership* have been revised to require written notice, including putting a list of physicians who have a proprietary interest in the ASC in writing. A generic statement of ownership is not acceptable.

Advance directives

Another major revision is to 416.50(c) *Advance Directives:*

The ASC must comply with the following requirements:

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.

Further, the interpretive guidelines state, *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 medical power of attorney. Since this requirement was implemented four years ago, most ASCs had adopted a policy of informing patients that the ASC does not honor advance directives and in the event of a medical emergency would 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 an objection of conscience, and describe the range of medical conditions affected by that 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/her health.

Rights of property and person

The interpretive guidelines for 416.50(e) *Exercise of rights and respect for property and person* mandate that the ASC must not engage in reprisals or discriminatory behavior in response to a patient exercise of rights. While this might be obvious and logical, the CfCs require it is codified in a policy and procedure.

Infection control programs

Practice-owned ASCs may find changes to the interpretive guidelines of 416.51(b) *Infection control program* noteworthy. 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. They also state *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.* There are also changes to Exhibit 351, Infection Control Surveyor Worksheet.

Ongoing compliance

CMS Conditions for Coverage and local/state/federal disease-reporting requirements are but 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 "plug in" to appropriate resources to ensure awareness of evolving standards and take appropriate action to assure ongoing compliance. AE

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