

From the CEO

Mis-Interpretive CMS Guidelines

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In December 2009 the Centers for Medicare and Medicaid Services released revisions of the anesthesia services sections of the Interpretive Guidelines for Hospitals and for Ambulatory Surgery Centers. Without any fanfare or foreknowledge of the ASA, several changes in requirements for anesthesia services in both types of facilities went into effect. How important are interpretive guidelines? CMS's description is informative.

“Survey protocols and Interpretive Guidelines are established to provide guidance to personnel conducting surveys. They serve to clarify and/or explain the intent of the regulations and all surveyors are required to use them in assessing compliance with Federal requirements. The purpose of the protocols and guidelines is to direct the surveyor's attention to certain avenues for investigation in preparation for the survey, in conducting the survey, and in evaluation of the survey findings.”¹

In essence, Interpretive Guidelines instruct surveyors what to look for to determine whether a hospital or ASC complies with the applicable Medicare Conditions of Participation. Interpretive guidelines are developed at the staff level within CMS and are not subject to public notice and hearing requirements; hence, the perception that the new guidelines came out of the blue.

The new guidelines are based on existing Medicare conditions of participation. Using existing regulatory language, several additions to both the hospital and ASC guidelines established significant changes for anesthesia practice and facility procedures.

Interpretive Guidelines for Hospitals²

Some of the modifications to the hospital guidelines are positive for anesthesiologists and patients, and a few are highly objectionable. On the positive side, other than Critical Access Hospitals, hospitals are now required to organize all anesthesia services throughout the hospital and in off-site locations under one anesthesia service under the direction of a qualified Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.).

From the CEO (cont'd)

Hospitals are required to establish policies and procedures defining provision of these services that are consistent with State scope of practice law.

The anesthesia service (department) must develop policies and procedures on provision of ALL anesthesia services (including analgesia) and minimum qualifications for each practitioner permitted to provide ALL anesthesia services.

The interpretive guidelines draw a distinction between anesthesia (medication to produce a loss of pain, movement, function and memory and/or consciousness) and analgesia (relief of pain by blocking pain receptors).

Two guidelines go beyond current interpretations, seemingly expanding the scope of practice for CRNAs and narrowly defining the term “immediately available,” creating an onerous requirement. In addition, time requirements for pre- and post-evaluation of patients are specified.

- CRNAs are specifically permitted to administer labor epidurals for the purpose of analgesia without physician supervision. However, if anesthesia effect is necessary for delivery, supervision is required.
- “Immediately available” is specifically defined. Guidelines now define immediately available to mean that the anesthesiologist must be physically located within the same area as the CRNA or AA—for example, in the same operative suite, same labor and delivery unit, or same procedure room, and not otherwise occupied in a way that prevents the anesthesiologist from immediately conducting hands-on intervention, if needed.
- Pre-anesthesia evaluations must be performed within 48 hours prior to any surgery (administration of first dose of anesthesia marks end of 48 hours) with general, regional, or monitored anesthesia.
- Post-anesthesia evaluations must be completed and documented within 48 hours of any surgery involving general, regional, or monitored anesthesia in both inpatient and outpatient settings. Time begins when the patient is moved into the designated recovery area.

Evaluation cannot begin immediately upon arrival to the designated recovery area and cannot occur until after patient has sufficiently recovered from the effects of anesthesia so as to participate in the evaluation (e.g., answer questions and perform tasks).

For outpatients—must be completed prior to discharge even if 48 hours is later.

Interpretive Guidelines for Ambulatory Surgery Centers

In May 2009, CMS issued a modification of the Conditions of Participation for ASCs.³ Following that release, significantly revised interpretive guidelines became effective December 30, 2009.⁴

Section 416.52(b) details requirements for post-surgical assessment and discharge. A physician or anesthetist (depending on scope of practice) must assess the patient's recovery from anesthesia following surgery. Overall assessments, also required, may be performed by a physician or other qualified provider, including a registered nurse with experience with post-operative care.

A new guideline at 416.52(c) specifies that the operating physician must sign the discharge order and that the patient is expected to leave the facility within 15–30 minutes after the order. This rule varies from standard practice in many ASCs, where the anesthesiologist writes the discharge order with the operating physician off-site.

ASA Response

ASA President Dr. Alex Hannenberg sent a letter to CMS Acting Director Charlene Frizzera⁵ protesting the lack of transparency in developing the guidelines, which lacked an opportunity for input by interested parties. In addition, he addressed the benefits and shortcomings of the rules, noting the positive effects of consolidating all anesthesia services under one department, establishing policies and procedures and minimum requirements for all personnel providing all anesthesia services. The change in requirements for CRNAs administering labor epidurals without physician supervision was challenged with questions about patient safety, particularly when complications occur or a cesarean section is needed. He also addressed the logistical complications created by the narrow time requirements for pre- and post-anesthesia evaluation.

New information will be posted on the ASA Web Site and distributed to CSA members. Members who are experiencing the practical effects of the changes are urged to inform the CSA at csa@csahq.org.

¹ http://www.cms.hhs.gov/GuidanceforLawsAndRegulations/08_Hospitals.asp

² <http://www.asahq.org/Washington/12-11-09%20RevisedANHospitalInterpretiveGuidelines.pdf>

³ <http://www.asahq.org/Washington/narules.pdf>

⁴ <http://www.cms.hhs.gov/transmittals/downloads/R56SOMA.pdf>

⁵ <http://www.asahq.org/news/asanews011810.htm>