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INTERPRETIVE GUIDELINES FOR HOSPITAL ANESTHESIA SERVICES – REVISION REDUX!

EXECUTIVE SUMMARY

After making significant revisions to the Hospital Conditions of Participation Interpretive Guidelines for Anesthesia Services ("Interpretive Guidelines") only thirteen months ago, CMS has once again revisited and revised the Interpretive Guidelines. An advance copy of the newly revised Interpretive Guidelines was published January 14, 2011 and was effective immediately. The Interpretive Guidelines include new requirements for anesthesia/analgesia policies, as well as certain clarifications concerning the timing of specific aspects of pre- and post-anesthesia evaluations. You may access the Guidelines, including a short list of FAQs.

POLICIES AND PROCEDURES EMPHASIZED

Acknowledging that there is often no bright line or clear boundary between anesthesia and analgesia, particularly with respect to moderate versus deep sedation and labor epidurals, CMS is now requiring hospitals to establish and implement policies and procedures based on "*nationally recognized guidelines*" addressing whether specific clinical situations involve anesthesia versus analgesia. Based on these policies, hospitals may permit certain non-anesthesiologists to provide analgesia and sedation. The new revisions do not alter CMS's position that only the persons delineated at 42 CFR §482.52(a) may provide anesthesia (i.e., general anesthesia, regional anesthesia, and monitored anesthesia care/deep sedation).

In particular, CMS is encouraging individual hospitals to develop policies addressing whether sedation customarily provided in the emergency department or procedure rooms is anesthesia or analgesia. Each hospital is expected to consider the characteristics of the patients served, the skill set of the clinical staff providing the services, and the characteristics of the sedation medications used in various clinical settings when formulating its policies. Hospitals also must specify qualifications and any supervision requirements for practitioners administering anesthesia and analgesia.

The new requirements contain several noteworthy provisions. First, CMS is requiring hospital policies to be based on "nationally recognized guidelines," even though this is not mandated by the relevant regulations. In attempting to define the term "nationally recognized guidelines," CMS states the guidelines should be issued by a "national organization that has appropriate expertise and which has used [a] consensus-setting process of professionals with appropriate expertise in developing its guidelines." CMS acknowledges that professional society guidelines may not always be entirely consistent with one another and, in fact, a hospital may cite the guidelines of different organizations for different applications (e.g., the American College of Emergency Physicians ("ACEP") for policies covering sedation in the emergency department and the American Society of Anesthesiologists ("ASA") for policies covering anesthesia/sedation in surgical services). CMS identifies the ASA, the ACEP, the American Dental Association, and the American Society for Gastrointestinal Endoscopy as examples of organizations whose practice guidelines and statements may form the basis of hospital policies governing procedural sedation and analgesia.

Second, while the new Interpretive Guidelines provide an alternate path for CRNAs to administer analgesic labor epidurals and spinals without supervision vis-a-vis policymaking, CMS has struck the explicit language first set forth in the 2009 Interpretive Guidelines which very clearly provides for this practice based on a CMS finding that analgesia simply is not anesthesia subject to the supervision requirements of 42 CFR §482.52(a).

Third, CMS has made the requirements for anesthesia services less prescriptive by removing examples previously used to illustrate levels of anesthesia care. The new Interpretive Guidelines now appear to permit drugs such as propofol to be administered by nurses who are not CRNAs in certain settings so long as the hospital approves policies citing nationally-recognized guidelines permitting this practice. Until this latest set of revisions, some hospitals believed that CMS had adopted in subregulatory guidance the propofol manufacturer's usage recommendations stating that only anesthesiologists and CRNAs may administer the drug. CMS is now requiring that anesthesia services policies and procedures address "the minimum qualifications and supervision requirements for each category of practitioner who is permitted to provide analgesia services, particularly moderate sedation." Further, CMS expects each hospital to periodically reassess its

anesthesia services policies and procedures, taking into account any adverse events, medication errors and other quality and safety issues that may arise with respect to administration of anesthesia and analgesia.

Last, CMS has again emphasized the need for hospitals to develop policies and procedures that ensure patient safety by maintaining rescue capacity in all areas where anesthesia services are furnished. According to CMS, rescue capacity is not only required as an essential component of anesthesia services, but is also required under the Patients Rights standard at 42 CFR §482.13(c)(2).

FURTHER CLARIFICATIONS ADDRESSING PRE- AND POST-ANESTHESIA EVALUATIONS

Pre-Anesthesia Evaluation. Pre-anesthesia evaluations must be completed and documented within 48 hours immediately prior to any inpatient or outpatient surgery or procedure requiring anesthesia services. CMS has clarified that certain elements of the evaluation (e.g., notation of anesthetic risk, identification of potential anesthetic problems) may be performed prior to the 48-hour timeframe but no more than 30 days prior to the surgery/procedure so long as these elements are reviewed and updated within the 48-hour timeframe. See the Interpretive Guidelines at the link above for further details.

Post-Anesthesia Evaluation. Post-anesthesia evaluations must be completed and documented no later than 48 hours after the surgery or procedure under all circumstances. CMS has clarified that while the evaluation should begin in the designated recovery area, it may be completed after the patient is moved to another inpatient location or is discharged (subject to State law/hospital policy). The evaluation must be completed within the 48-hour timeframe even if the patient is unable to participate in the evaluation. If the patient is unable to participate, the clinician should so document. The post anesthesia evaluation should also document expectations for recovery time; for patients undergoing long-acting regional anesthesia, the clinician should document that full recovery from anesthesia has not yet occurred and is not expected within the 48-hour period.

FINAL THOUGHTS AND RECOMMENDED ACTION STEPS

CMS's action in again updating these Interpretive Guidelines likely reflects the ongoing tension between ensuring the safety of patients and ensuring broad access to anesthesia care. Hospitals should review their anesthesia policies to ensure they are compliant with this latest set of surveyor instructions. In particular, policies should address: the qualifications of practitioners administering anesthesia and analgesia; clinical applications involving analgesia based on identifiable, documented national guidelines; and the hospital's defined system for tracking and addressing anesthesia services adverse events.

If you have any questions, or need assistance preparing or revising policies, please do not hesitate to contact:

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