Deep Sedation by Non-Anesthesiologist Practitioners: What Has Changed and What Are the Implications?

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On December 11, 2009, the Centers for Medicare and Medicaid Services (CMS) issued revised Interpretive Guidelines (IGs) pertaining to the hospital Conditions of Participation. These revised IGs were subsequently updated and modified by CMS in May 2010, and more recently in January 2011. The most current version of the IGs may be found on the American Society of Anesthesiologists (ASA) Web site at http://www.asahq.org/For-Members/Advocacy/Federal-Legislative-and-Regulatory-Activities/Interpretive-Guidelines.aspx.

In the IGs, CMS reaffirmed its long-standing definition of “anesthesia,” to mean general anesthesia, regional anesthesia, deep sedation/analgesia or monitored anesthesia care. In contrast, the CMS definition of “analgesia/sedation” includes local/topical anesthesia, minimal sedation, and moderate sedation/analgesia (“conscious sedation”). Only qualified personnel are permitted to administer “anesthesia” as defined above. CMS defines those individuals as qualified anesthesiologists, non-anesthesiologist MD/DOs, nurse anesthetists (CRNAs), anesthesiologist assistants (AAs), and dentists, oral surgeons, and podiatrists who are qualified to administer anesthesia under state law.

Moreover, CMS has affirmed that:

The anesthesia services must be under the direction of one individual who is a qualified doctor of medicine (MD) or doctor of osteopathy (DO).

Although CMS does not directly state that the director of anesthesia services must be an anesthesiologist, clearly anesthesiologists are uniquely qualified.
to perform this function. It behooves anesthesiologists and anesthesia departments to be proactive in this regard in view of the following statements from the 2011 revision of the IGs:

Consequently, each hospital that provides anesthesia services must establish policies and procedures, based on nationally recognized guidelines, that address whether specific clinical situations involve anesthesia versus analgesia…

Furthermore:

We encourage hospitals to address whether the sedation typically provided in the emergency department or procedure rooms involves anesthesia or analgesia. In establishing such policies, the hospital is expected to take into account the characteristics of the patients served, the skill set of the clinical staff in providing the services, as well as the characteristics of the sedation medications used in the various clinical settings.

In addition, Frequently Asked Questions that accompany the IG regulations include reference to ASA’s sedation guidelines in addition to those of other specialty societies (such as emergency and gastroenterology physicians), and to the range of qualifications of emergency physicians. The ASA is planning to address these concerning issues with CMS. However, in the regulations it is the hospitals and the physician directors of anesthesia services who determine the anesthesia policies and procedures. Decisions on privileging will be made locally.

The practical implication of these updated CMS regulations is that the responsibility for the oversight of the administration of deep sedation falls under the purview of the director of anesthesia services at a hospital or ambulatory surgery center (ASC), whether or not an anesthesiologist administers the deep sedation. This means that while qualified anesthesia personnel, as defined above, may administer deep sedation, the parameters both for privileging of individual practitioners and for the quality assurance of deep sedation care nonetheless are the responsibility of the director of anesthesia services. Because deep sedation and anesthesia in areas of the hospital outside of the surgical suites, such as the emergency department, fall under the purview of the director of anesthesia services, it would seem reasonable that an anesthesiologist, who is uniquely qualified to understand the quality-of-care issues involved, should assume the role of director of anesthesia services.

By creating this oversight responsibility, CMS is forcing anesthesia departments to redefine how they interact with other hospital departments and individual providers who provide deep sedation services. In California for a number of years the reality has been that non-anesthesiologists such as critical care specialists, gastroenterologists, and emergency room physicians have been administering sedation (and frequently deep sedation) for procedures, possibly with minimal input from the anesthesia department regarding privileging or
quality assurance. The new IGs essentially mandate that hospitals and anesthesia departments review their policies on deep sedation.

The issue of privileging non-anesthesiologists for deep sedation is certainly not new. In 2005 the CSA presented a resolution to the Annual Meeting of the American Society of Anesthesiologists (ASA) House of Delegates (HOD) asking for assistance in clarifying whether non-anesthesiologists should be privileged to administer deep sedation, and if the answer were affirmative, then how they could be so privileged.

The ASA referred this issue to an ad hoc committee that produced two proposed Statements, one a Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners Who Are Not Anesthesia Professionals and another similar Statement for deep sedation. In 2005, the HOD approved the first document, which subsequently was revised in 2006. However, the latter document proved very controversial and did not pass. In fact, in 2006 the HOD substituted for the original extensive document titled Statement on Granting Privileges to Non-Anesthesiologist Practitioners for Personally Administering Deep Sedation or Supervising Deep Sedation by Individuals Who Are Not Anesthesia Professionals the simple declaration:

Because of the significant risk that patients who receive deep sedation may enter a state of general anesthesia, privileges to administer deep sedation should be granted only to practitioners who are qualified to administer general anesthesia or to appropriately supervised anesthesia professionals.

This attempt to settle the matter at the ASA did not solve the CSA’s practical problem: within California, members still needed guidance on how to respond to their hospitals and medical staffs when asked how non-anesthesiologists could become qualified and privileged to administer deep sedation. Within the CSA, the Legislative and Practice Affairs Division (LPAD) started with the defeated ASA statement on deep sedation and revised its language to reflect the recommendations of the CSA to its members on this topic. The result was the CSA Statement on Deep Sedation by Non-Anesthesiologists, a document that reviewed criteria and guidelines that could be used by a health care facility to privilege non-anesthesiologists to perform deep sedation so as to advance patient safety and high quality care. This document passed the CSA HOD in 2007 and was posted on the CSA Web site for use by members to help guide deep sedation privileging criteria at their hospitals.

With the advent of the 2009 CMS IGs, the CSA document became suddenly obsolete because there were serious inconsistencies between the CSA and CMS documents. Fortunately, ASA leadership recognized both the opportunity and the problem created by the IGs for the ASA. The opportunity was to make recommendations on deep sedation privileging that could fill a void and would be used by hospitals and medical staffs. The problem was that no (ASA)
HOD-approved statement existed that could be used for this purpose. To respond to the need for an updated statement, then ASA President Alex Hannenberg appointed a committee to develop guidelines for deep sedation privileging for non-anesthesiologists that members could use at their facilities. This ad hoc committee, led by Beverly Philip, M.D., used the CSA Statement on Deep Sedation by Non-Anesthesiologists as the starting point for its deliberations. Things now had come full circle, back to the original inquiry to the ASA from the CSA.

After a series of revisions, the ad hoc committee produced a document titled Statement on Granting Privileges for Deep Sedation to Non-Anesthesiologist Sedation Practitioners. The committee worked assiduously to ensure that the guidelines require the most rigorous level of education, training, experience, and quality assurance for non-anesthesiologists to be credentialed as qualified anesthesia professionals. In addition, the document is very specific in mandating specific levels of education and training, the need for ACLS certification, and a high level of proficiency in airway management and intubation should rescue be needed. The statement also provides guidance regarding how best to perform ongoing quality assurance and review of the performance of qualified anesthesia professionals administering deep sedation.

Owing to the changes that have occurred in the medical and political environment in 2010, and the consequent changes in attitudes within the anesthesia community, the statement passed at the ASA HOD with little controversy. This approval reflects the reality that in many practice settings throughout the nation, non-anesthesiologists were already delivering deep sedation. The ASA’s interest in this matter was to create the strongest possible statement to ensure patient safety and proper oversight of deep sedation privileging by anesthesia departments.

The CSA has retired its 2007 Statement on Deep Sedation by Non-Anesthesiologists and replaced it with the ASA 2010 Statement on Granting Privileges for Deep Sedation to Non-Anesthesiologist Sedation Practitioners. CSA leadership recommends that all members become familiar with the contents of the new document. It may be used in its entirety, in part, or adapted as needed for use by hospitals and medical staffs as a definitive guide in privileging non-anesthesiologists to perform deep sedation. Using it in the individual facilities where CSA members practice will help maintain the appropriate involvement of anesthesia department leadership in the oversight of deep sedation by non-anesthesiologists, thus ensuring the safest possible care for our patients. This statement may now be found on the ASA Web site at the link below or on the CSA Web site at the following link: http://www.csahq.org/professional_issues.php?c=13. In addition, all of the ASA documents referred to above are at http://asahq.org/For-Members/Clinical-Information/Standards-Guidelines-and-Statements.aspx.