Attachment 2

FAQs for Revisions to Anesthesia Services Interpretive Guidelines

The revised interpretive guidelines (IG) require each individual hospital to develop its own internal policies and procedures as to what medications, under what circumstances, constitute anesthesia and therefore require administration by an anesthesia professional as delineated at 42 CFR 482.52(a). The IG also requires that hospitals base their policies on nationally recognized guidelines.

The following questions and answers are provided to facilitate understanding of the revised guidance:

Q1: How can the same drug be used at the same facility for general anesthesia in the operating room and for a sedative in the emergency department or a procedure room?

A1: The physiological result in terms of level of sedation for a particular medication may vary based on dosage, route and timing of administration, the metabolism and interaction with other medications, the clinical status and body habitus of the patient, etc. However, there is neither a bright line nor predictability about when a patient will inadvertently convert from moderate to deep sedation, or how much medication will bring about the desired sedation state. In addition, for some medications there is no antidote that can quickly reverse its effects; rescue of an overly-sedated patient requires very specific skills in airway management and ventilation. For this reason the IG continues to require that hospitals ensure that procedures are in place to rescue patients whose level of sedation becomes deeper than originally intended.

Q2: What nationally recognized guidelines are available for hospitals to use to develop their policies concerning what is anesthesia and what is analgesia and which procedures need which? What does "nationally recognized guidelines" mean?

A2: CMS' expectation is that such guidelines are issued by a national organization that has appropriate expertise and which has used consensus-setting process of professionals with appropriate expertise in developing its guidelines. We recognize that such organizations may not always fully agree with each other. Examples of organizations with guidelines related to anesthesia administration include, but not limited to, the following:

- The American Society of Anesthesiologists (ASA)
    - Practice Guidelines on Sedation and Analgesia by Non-anesthesiologists and the ASA House of Delegates statement on the use of propofol are available at http://www.asahq.org/For-Healthcare-Professionals/Standards-Guidelines-and-Statements.aspx

- The American College of Emergency Physicians (ACEP)
    - Clinical Policies Subcommittee, which included members of ACEP and the Emergency Nurses Association (ENA) published their "Clinical policy on

Procedural Sedation and Analgesia in the Emergency Department" in *Ann Emerg Med.* 2005;45:177-196.

- The following statement on procedural sedation and analgesia is located at: http://www.acep.org/content.aspx?id=30060

  "The Emergency Nurses Association (ENA) and the American College of Emergency Physicians (ACEP) support the delivery of medications used for procedural sedation and analgesia by credentialed emergency nurses working under the direct supervision of an emergency physician. These agents include but are not limited to etomidate, propofol, ketamine, fentanyl, and midazolam."

- The American Dental Association (ADA) policy is at: http://www.ada.org/sections/professionalResources/pdfs/anxiety_guidelines.pdf

- The American Society for Gastrointestinal Endoscopy (ASGE)
  - Guidelines for Conscious Sedation and Monitoring during Gastrointestinal Endoscopy is located at http://www.asge.org/uploadedFiles/Publications_and_Products/Practice_Guidelines/Sedation%20and%20Anesthesia%20in%20GI%20Endoscopy%202008.pdf
  - A joint collaboration amongst the American Society for Gastrointestinal Endoscopy (ASGE), the American Gastroenterology Association (AGA), the Society for Gastroenterology Nurses and Associates (SGNA), and the American College of Gastroenterologist(ACG) policy on Non-anesthesiologist Administered Propofol or Gastroenterologist-Directed Propofol which can be accessed at this website: www.SedationFacts.org.

CMS expects surveyors to verify that the hospital can identify appropriate guidelines that support its policies. A hospital could use multiple guidelines, for example, ACEP for sedation in the emergency department and ASA for anesthesia/sedation in surgical services, etc.

Q3: What is the appropriate training for a "sedation" nurse?

A3: Currently there is no Medicare definition of a "sedation nurse," nor does there appear to be any uniformly accepted training for a sedation nurse. Some states specifically address RN-administered sedation in their professional licensure laws and regulations. It is possible that national organizations producing anesthesia guidelines may develop guidelines/recommendations in this area in the future.

Q4: Why is there a particular mention in the IG on the emergency department's (ED's) sedation policies?

A4: The ED is a unique environment where patients present on an unscheduled basis with often very complex problems that may require several emergent or urgent interventions to proceed simultaneously to prevent further morbidity or mortality. In addition, emergency medicine-trained physicians have very specific skill sets to manage airways and ventilation that is

necessary to provide patient rescue. Therefore, these practitioners are uniquely qualified to provide all levels of analgesia/sedation and anesthesia (moderate to deep to general).

Q5: The regulations and IG state that hospital anesthesia services be under the direction of one individual. How can hospitals ensure that the policies and procedures that define the various uses of analgesia and anesthesia are not too narrow (or broad) or based on the opinions of one individual?

A5: In the IG, hospitals are encouraged to develop the anesthesia services policies in collaboration with other hospital disciplines, such as surgery, pharmacy, nursing, safety experts, etc. A hospital may choose to require medical staff review and approval of the anesthesia policies. These collaborative approaches are not, however, a regulatory requirement. A hospital may therefore allow the director to develop the policies alone. However, as in all cases, the hospital's governing body is ultimately responsible to assure that the policies adopted meet the regulatory requirements.

Q6: Is it acceptable if a hospital adopts a policy stating that all anesthetic agents in lower doses can be used for sedation and therefore no medications qualify as anesthesia, and thus there is no need for them to be administered by anesthesia professionals? Is this acceptable?

A6: We are not aware of any such nationally recognized guidelines at this time, nor do we think it likely that an organization would adopt a broad guideline stating that there are no medications that ever qualify as anesthesia.