March 22, 2010

Thomas E. Hamilton
Director, Survey and Certification Group
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 21244

Re: Revised Hospital Anesthesia Services Interpretive Guidelines Ref. S&C 10-09 (revised 2/5/10) 42. CFR.482.52

Dear Mr. Hamilton:

With a combined membership of 70,000 emergency physicians and nurses, the American College of Emergency Physicians, the Emergency Nurses Association, and the American Academy of Emergency Medicine wish to express our concerns and ask for timely clarification of the above-referenced interpretive guidelines, given their deleterious effects on patient care in the nation's emergency departments (EDs).

We are particularly concerned with CMS's interpretation of what constitutes "anesthesia" and who may administer conscious sedation. There is an ample and growing body of clinical literature that documents improvements in clinical safety of drugs such as propofol over previously used drugs including midazolam plus a narcotic.

CMS surveyors are now interpreting the administration of Propofol as deep sedation and thereby requiring the criteria for anesthesia administration to be met. We disagree with this interpretation in the overwhelming majority of procedures in the ED. Propofol (INN, marketed as **Diprivan** by AstraZeneca) is defined as a short-acting, intravenously administered hypnotic agent. Its uses include the induction and maintenance of general anesthesia, sedation for mechanically ventilated adults, and **procedural sedation.**

While emergency physicians typically use moderate or procedural sedation in the ED, they are trained in all aspects of resuscitative measures – so should the administration of Propofol to a patient accidentally result in deep sedation they are capable of dealing with the situation and protecting the patient's airway as per the CMS definition of "rescue capacity". The administration of Propofol by appropriately trained and credentialed emergency nurses in the presence of an emergency physician complies with current Joint Commission standards.

Additionally, ENA and ACEP have worked with numerous state boards of nursing to ensure that the scope of practices within states allows ED nurses to administer sedation (including Propofol) in the presence of an emergency physician. CRNAs and anesthesiologists are not immediately available to many EDs and adherence to CMS' interpretation would result in compromising quality patient care.

CMS criteria 482.52(a) for who may administer topical/local anesthetics, minimal sedation and moderate sedation are essentially unchanged. Therefore, we request clarification of who can administer sedation in the **emergency department**. As noted, general anesthesia/deep sedation as defined by CMS is very rarely utilized in the ED.

ACEP's clinical policy/guideline outlines the relevant clinical and scientific research on procedural sedation in the emergency department and on the use of propofol by well-trained and credentialed physicians and nurses. This clinical guideline was developed by experts on sedation and included emergency physicians, emergency nurses and anesthesiologists. This document has been posted on ACEP's website since 2006.

In addition, in February 2008, a stakeholder group representing nurses, physicians, and related health care associations released a Consensus Statement on the use of procedural sedation in the emergency department setting (copy attached). This statement was drafted to articulate the critical need for, and appropriateness of, ED nurses using procedural sedation to give patients quality of care consistent with the Six Quality Aims as defined by the Institute of Medicine (IOM).

The following examples illustrate real world experiences in the ED and show how detrimental this interpretation can be in EDs where anesthesia professionals are not available 24/7, 365 days per year.

- An emergency physician and nurse are on duty in the ED. A patient with a facial fracture who is bleeding severely arrives and requires immediate attention. The physician needs to maintain the patient's airway, while the nurse begins to administer sedation using Propofol. Requiring the physician to either wait for another physician or CRNA to administer the sedation would obviously compromise the care of the patient to the point that it may result in the demise of the patient.

- A patient presents to the ED with a dislocated hip. The hip needs to be put back in place quickly to decrease the risk of permanent damage (bone death). For this type of presentation Propofol is frequently used to quickly sedate and relax the patient so an immediate reduction can take place. If this drug can only be administered by anesthesia personnel, there is the distinct possibility that not only is the patient in danger of bone death but will be in extremis while the emergency physician and nursing staff wait for an anesthesiologist or CRNA.

- Cardioversion or electrically shocking the heart back into a normal rhythm is an example of a painful, but brief, life-saving procedure that frequently must be performed quickly. While it is recognized that Propofol can lead to deep sedation, the amount used in the ED typically only produces moderate sedation and the patient's recovery is quicker, without nausea or other deleterious effect experienced by some of the drugs used for moderate sedation.

In closing, we believe that extensive scientific research has demonstrated that propofol can be used with a very high degree of safety and effectiveness in the emergency department. Clearly, clinical outcomes with propofol equal or exceed those of other sedating drugs available to most non-anesthesiologists. The new interpretive guidance would harm patients by denying patients the benefits of this drug and forcing emergency departments across the country to use less desirable sedating agents. We suggest that CMS modify its guidance such that either the emergency department is specifically exempt from the restriction

on propofol use or the hospitals have an opportunity to allow propofol use by non-anesthesiologists as appropriate based on hospital specific conditions. We also ask that guidance concerning administration of sedation be relaxed such that it will not have a detrimental effect on those patients presenting to emergency departments with only a single physician and no anesthesiologist or CRNA available.

We therefore request a meeting with you and Dr. Straube at your earliest convenience to discuss options for clarifying this policy to better serve patients in the emergency setting.

If you have any questions about our request and comments, please contact Barbara Tomar, ACEP's Federal Affairs Director at (202) 728-0610, ext. 3017.

Sincerely,

Angela F. Gardner, MD, FACEP, President
American College of Emergency Physicians

Diane Gurney, RN,MS,CEN, President,
Emergency Nurses Association

Howard Blumstein, MD, FAAEM, President
American Academy of Emergency Medicine

cc: Barry Straube, MD