STATEMENT ON SAFE USE OF PROPOFOL

Committee of Origin: Ambulatory Surgical Care

(Approved by the ASA House of Delegates on October 27, 2004, and amended on October 21, 2009)

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Due to the potential for rapid, profound changes in sedative/anesthetic depth and the lack of antagonist medications, agents such as propofol require special attention. Even if moderate sedation is intended, patients receiving propofol should receive care consistent with that required for deep sedation.

The Society believes that the involvement of an anesthesiologist in the care of every patient undergoing anesthesia is optimal. However, when this is not possible, non-anesthesia personnel who administer propofol should be qualified to rescue* patients whose level of sedation becomes deeper than initially intended and who enter, if briefly, a state of general anesthesia.**

- The physician responsible for the use of sedation/anesthesia should have the education and training to manage the potential medical complications of sedation/anesthesia. The physician should be proficient in airway management, have advanced life support skills appropriate for the patient population, and understand the pharmacology of the drugs used.

  The physician should be physically present throughout the sedation and remain immediately available until the patient is medically discharged from the post procedure recovery area.

- The practitioner administering propofol for sedation/anesthesia should, at a minimum, have the education and training to identify and manage the airway and cardiovascular changes which occur in a patient who enters a state of general anesthesia, as well as the ability to assist in the management of complications.

  The practitioner monitoring the patient should be present throughout the procedure and be completely dedicated to that task.

- During the administration of propofol, patients should be monitored without interruption to assess level of consciousness, and to identify early signs of hypotension, bradycardia, apnea, airway obstruction and/or oxygen desaturation. Ventilation, oxygen saturation, heart rate and blood pressure should be monitored at regular and frequent intervals. Monitoring for the presence of exhaled carbon dioxide should be utilized unless invalidated by the nature of the patient, procedure or equipment because movement of the chest will not dependably identify airway obstruction or apnea.

- Age-appropriate equipment must be immediately available for the maintenance of a patent airway, oxygen enrichment and artificial ventilation in addition to circulatory resuscitation.

* Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level. It is not appropriate to continue the procedure at an unintended level of sedation.

** The statement in the AANA-ASA Joint Statement Regarding Propofol Administration, dated April 14, 2004, that reads,

“Whenever propofol is used for sedation/anesthesia, it should be administered only by persons trained in the administration of general anesthesia, who are not simultaneously involved in these surgical or diagnostic procedures. This restriction is concordant with
specific language in the propofol package insert, and failure to follow these recommendations could put patients at increased risk of significant injury or death.”

is consistent with the principles set forth in this statement.

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The Warnings section of the drug’s package insert (Diprivan®, AstraZeneca 08/05, accessed 1-09) states that propofol used for sedation or anesthesia “should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure.” Patients should be continuously monitored, and facilities for maintenance of a patent airway, artificial ventilation, and oxygen enrichment and circulatory resuscitation must be immediately available.”

In addition, some states have prescriptive regulations concerning the administration of propofol. There are different considerations when propofol is used for sedation of intubated, ventilated patients in a critical care setting.

Fospropofol is a propofol prodrug indicated for sedation of patients undergoing diagnostic or therapeutic procedures. The Warnings section of the drug’s package insert states that fospropofol “should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the diagnostic or therapeutic procedure. Sedated patients should be continuously monitored, and facilities for maintenance of a patent airway, providing artificial ventilation, administering supplemental oxygen, and instituting cardiovascular resuscitation must be immediately available. Patients should be continuously monitored during sedation and through the recovery process for early signs of hypotension, apnea, airway obstruction, and/or oxygen desaturation.” Since fospropofol is converted to propofol after administration and carries identical warnings to propofol on its package insert, this statement applies to the safe administration of fospropofol as well.

Similar concerns apply when other intravenous induction agents such as thiopental, methohexital or etomidate are used for sedation. Administering combinations of drugs including sedatives and analgesics may increase the likelihood of adverse outcomes.

For additional information on the continuum of sedation and on sedation by non-anesthesiologists, we refer you to the American Society of Anesthesiologists’ documents “Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia” and “Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists”, ”Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners Who Are Not Anesthesia Professionals”, and “Statement on Granting Privileges to Non-Anesthesiologist Practitioners for Personally Administering Deep Sedation or Supervising Deep Sedation by Individuals Who Are Not Anesthesia Professionals”. ASA’s documents that address additional perioperative care issues are the “Guidelines for Office-Based Anesthesia,” “Guidelines for Ambulatory Anesthesia and Surgery” and “Practice Guidelines for Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration.” All ASA documents can be found on the Web site, <www.ASAhq.org>.