CSA GUIDELINES FOR DEEP SEDATION BY NON-ANESTHESIOLOGISTS

The California Society of Anesthesiologists (CSA) is committed to the safe administration of anesthesia. Because of our concern, the CSA may provide clinical guidance for any system or set of practices, used either by its members or the members of other disciplines that would adversely affect the safety of anesthesia administration. California anesthesiologists, as members of medical staffs, are routinely asked, because of their knowledge and expertise to assume responsibility for credentialing and oversight of all sedation administered in their facilities. They therefore may be charged with or asked to advise about credentialing of non-anesthesiologists for deep sedation.

Deep sedation is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

The CSA believes that in a stable, intubated, and ventilated patient, deep sedation may be completely appropriate. The delivery of clinical care is the shared responsibility of many practitioners, and we recognize that other critical care specialists are trained and skilled in managing the care of unconscious patients. The intent of this document is to suggest a framework to identify individuals who may qualify to administer or supervise the administration of deep sedation. Only physicians or dentists who are qualified by education, training and licensure to administer deep sedation should supervise the administration of deep sedation. When deep sedation is intended, there is a significant risk that patients may slip into a state of general anesthesia (from which they cannot be aroused by painful or repeated stimulation). Therefore, individuals requesting privileges to administer deep sedation must demonstrate their ability to (1) recognize that a patient has entered a state of general anesthesia and (2) maintain a patient's vital functions until the patient has been returned to an appropriate level of sedation. This capability of recognizing and rescuing patients from general anesthesia does not imply that the practitioner is qualified to intentionally administer general anesthesia.

These guidelines may be used by any facility—hospital, ambulatory care center or physician's or dentist's office—in which an internal or external credentialing process is required for administration of sedative, analgesic or anesthetic drugs to establish a level of deep sedation, and are intended to improve patient safety in recognition of the current practice in California.

DEFINITIONS

Anesthesia Professional: An anesthesiologist, anesthesiologist assistant (AA), or certified registered nurse anesthetist (CRNA).

Non-anesthesiologist Sedation Practitioner: A licensed physician (allopathic or osteopathic) or dentist who has not completed postgraduate training in anesthesiology but is

specifically trained to administer personally or to supervise the administration of deep sedation.

Supervised Sedation Professional: A licensed registered nurse, advanced practice nurse or physician assistant who is trained to administer medications and monitor patients during deep sedation under the direct supervision of an anesthesiologist or a non-anesthesiologist sedation practitioner**.**

Credentialing: The process of documenting and reviewing a practitioner's credentials.

Credentials: The professional qualifications of a practitioner including education, training, experience and performance.

Privileges: The clinical activities within a health care organization that a practitioner is permitted to perform based on the practitioner's credentials.

Guidelines: A set of recommended practices that should be considered but permit discretion by the user as to whether they should be applied under any particular set of circumstances.

*** Moderate Sedation:** "Moderate Sedation/Analgesia ("Conscious Sedation") is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained."

* **Deep Sedation:** "Deep Sedation/Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained."

*** Rescue:** "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 of sedation."

*** General Anesthesia:** "General Anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired."

*The definitions marked with an asterisk are extracted verbatim from "*Continuum of Depth of Sedation – Definition of General Anesthesia and Levels of Sedation/Analgesia" (Approved by ASA House of Delegates on October 13, 1999, and amended on October 27, 2004).*

GUIDELINES

The following guidelines are designed to assist health care organizations develop a program for the delineation of clinical privileges for practitioners who are not anesthesia professionals to administer sedative, analgesic or anesthetic drugs to establish a level of deep sedation. The guidelines are written to apply to every setting in which an internal or external

credentialing process is required for granting privileges to administer sedative, analgesic or anesthetic drugs to establish a level of deep sedation (e.g., hospital, freestanding procedure center, ambulatory surgery center, physician's or dentist's office, etc.). The guidelines are not intended nor should they be applied to the granting of privileges to administer general anesthesia.

The granting, reappraisal and revision of clinical privileges should be awarded on a time-limited basis in accordance with rules and regulations of the health care organization, its medical staff, organizations accrediting the health care organization and relevant local, state and federal governmental agencies.

I. NON-ANESTHESIOLOGIST SEDATION PRACTITIONERS

Only physicians or dentists who are qualified by education, training and licensure to administer deep sedation should supervise the administration of deep sedation. Because training is specialty-specific, deep sedation privileges should only be granted for procedures within the same specialty as the practitioner. Non-anesthesiologist sedation practitioners may directly supervise patient monitoring and the administration of sedative, analgesic or anesthetic medications by a supervised sedation professional. Alternatively, they may personally perform these functions, with the proviso that the individual monitoring the patient should be distinct from the individual performing the diagnostic or therapeutic procedure (see *ASA Guidelines for Sedation and Analgesia by Nonanesthesiologists*).

A. Education and Training

The non-anesthesiologist sedation practitioner who is to supervise or personally administer medications for deep sedation should have satisfactorily completed a formal training program in: (1) the safe administration of sedative, analgesic or anesthetic drugs used to establish a level of deep sedation, and (2) rescue of patients who exhibit adverse physiologic consequences of a deeper-than-intended level of sedation. This training may be a part of a recently completed residency or fellowship training (e.g., within two years), or may be a separate educational program. A knowledge-based test may be used to verify the practitioner's understanding of these concepts. The following subject areas should be included:

1. Contents of the following ASA documents that should be understood by practitioners who administer sedative, analgesic or anesthetic drugs to establish a level of deep sedation:

    - *Practice Guidelines for Sedation and Analgesia by Non-anesthesiologists*
    - *Continuum of Depth of Sedation – Definition of General Anesthesia and Levels of Sedation/Analgesia*
    - *Practice Guidelines for Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures* (Approved by ASA House of Delegates on October 21, 1998, and effective January 1, 1999)

2. Appropriate methods for obtaining informed consent through pre-procedure counseling of patients regarding risks, benefits and alternatives to the administration of sedative, analgesic or anesthetic drugs to establish a level of deep sedation.

3. Skills for obtaining the patient's medical history and performing a physical examination to assess risks and co-morbidities, including assessment of the airway for anatomic and mobility characteristics suggestive of potentially difficult airway

management. The non-anesthesiologist sedation practitioner should be able to recognize those patients whose medical condition suggests that sedation should be provided by an anesthesia professional, such as morbidly obese patients or patients with obstructive sleep apnea or non-fasting patients or those with delayed gastric emptying.

4. Assessment of the patient's risk for aspiration of gastric contents as described in the *ASA Practice Guidelines for Preoperative Fasting*: "In urgent, emergent or other situations where gastric emptying is impaired, the potential for pulmonary aspiration of gastric contents must be considered in determining (1) the target level of sedation, (2) whether the procedure should be delayed or (3) whether the trachea should be protected by intubation."

5. The pharmacology of (1) all sedative, analgesic or anesthetic drugs the practitioner requests privileges to administer to establish a level of deep sedation, (2) pharmacological antagonists to the sedative, analgesic or anesthetic drugs and (3) vasoactive drugs and antiarrhythmics.

6. The benefits and risks of supplemental oxygen.

7. Recognition of adequacy of ventilatory function: This should include experience with patients whose ventilatory drive is depressed by sedative, analgesic or anesthetic drugs as well as patients whose airways become obstructed during sedation. Non-anesthesiologist practitioners should have experience managing patients during deep sedation, and understanding of the clinical manifestations of general anesthesia so that they can ascertain when a patient has entered a state of general anesthesia and rescue the patient appropriately.

8. Proficiency in advanced airway management: This training should include appropriately supervised experience in managing the airways of patients during general anesthesia. This may be supplemented using a high-fidelity patient simulator. The nonanesthesiologist practitioner must demonstrate the ability to reliably perform the following in anesthetized patients: (1) bag-valve-mask ventilation, (2) insertion and use of oro- and nasopharyngeal airways, (3) insertion and ventilation through a laryngeal mask airway, and (4) direct laryngoscopy and endotracheal intubation.

9. Monitoring of physiologic variables, including the following:
   a. Blood pressure
   b. Respiratory rate
   c. Oxygen saturation by pulse oximetry
   d. Capnographic monitoring. The non-anesthesiologist practitioner shall be familiar with the use and interpretation of capnographic waveforms to determine the adequacy of ventilation during deep sedation
   e. Electrocardiographic monitoring. Education in electrocardiographic (EKG) monitoring should include instruction in the most common dysrhythmias seen during sedation and anesthesia, their causes and their potential clinical implications (e.g., hypercapnia), as well as electrocardiographic signs of cardiac ischemia.
   f. Depth of sedation. The depth of sedation should be based on the ASA definitions of "deep sedation" and "general anesthesia." (See above).

10. The importance of continuous use of appropriately set audible alarms on physiologic monitoring equipment.

11. Documenting the drugs administered, the patient's physiologic condition and the depth of sedation at five-minute intervals throughout the period of sedation and analgesia, using a graphical, tabular or automated record which documents all the monitored parameters including capnographic monitoring.

12. The importance of monitoring the patient through the recovery period and the inclusion of specific discharge criteria for the patient receiving sedation.

13. Regardless of the availability of a "code team" or the equivalent, the non-anesthesiologist practitioner should have advanced life support skills such as those required for American Heart Association certification in Advanced Cardiac Life Support (ACLS). When granting privileges to administer deep sedation to pediatric patients, the non-anesthesiologist practitioner should have advanced life support skills such as those required for certification in Pediatric Advanced Life Support (PALS).

14. Required participation in a quality assurance system to track adverse outcomes and unusual events including respiratory arrests, use of reversal agents, prolonged sedation in recovery process, larger than expected medication doses, and occurrence of general anesthesia, with acceptance of input and/or oversight of anesthesiologists into this process.

When the practitioner is being granted privileges to administer sedative, analgesic or anesthetic drugs to pediatric patients to establish a level of deep sedation, the education and training requirements enumerated in #1-14 above should be specifically defined to qualify the practitioner to administer sedative, analgesic or anesthetic drugs to pediatric patients.

B. Licensure

1. The non-anesthesiologist sedation practitioner should have a current active, unrestricted medical, osteopathic, or dental license in the state, district or territory of practice. (Exception: practitioners employed by the federal government may have a current active license in any U.S. state, district or territory.)

2. The non-anesthesiologist sedation practitioner should have a current unrestricted Drug Enforcement Administration (DEA) registration (schedules II-V).

3. The credentialing process should require disclosure of any disciplinary action (final judgments) against any medical, osteopathic or dental license by any state, district or territory of practice and of any sanctions by any federal agency, including Medicare/Medicaid, in the last five years.

4. Before granting or renewing privileges to administer or supervise the administration of sedative, analgesic or anesthetic drugs to establish a level of deep sedation, the health care organization should search for any disciplinary action recorded in the National Practitioner Data Bank (NPDB) and take appropriate action regarding any Adverse Action Reports.

C. Practice Pattern

1. Before granting initial privileges to administer or supervise administration of sedative, analgesic or anesthetic drugs to establish a level of deep sedation, a process should be developed to evaluate the practitioner's performance. For recent graduates (e.g., <u>within two years</u>), this may be accomplished through letters

of recommendation from directors of residency or fellowship training programs which include deep sedation as part of the curriculum. For those who have been in practice since completion of their training, this may be accomplished through communication with department heads or supervisors at the institution where the individual holds privileges to administer deep sedation. Alternatively, the non-anesthesiologist sedation practitioner could be proctored or supervised by a physician or dentist who is currently privileged to administer sedative, analgesic or anesthetic agents to provide deep sedation. The facility should establish an appropriate number of procedures to be supervised.

2. Before granting ongoing privileges to administer or supervise administration of sedative, analgesic or anesthetic drugs to establish a level of deep sedation, a process should be developed to re-evaluate the practitioner's performance at regular intervals. For example, the practitioner's performance could be reviewed by an anesthesiologist or a non-anesthesiologist sedation practitioner who is currently privileged to administer sedative, analgesic or anesthetic agents to provide deep sedation. The facility should establish an appropriate number of procedures that will be reviewed.

D. Performance Improvement

Credentialing in the administration of sedative, analgesic or anesthetic drugs to establish a level of deep sedation should require active participation in an ongoing process that evaluates the practitioner's clinical performance and patient care outcomes through a formal program of continuous performance improvement.

1. The organization in which the practitioner practices should conduct peer review of its clinicians.

2. The performance improvement process should assess up-to-date knowledge as well as ongoing competence in the skills outlined in the educational and training requirements described above.

3. The performance improvement process should verify current airway management proficiency, including the ability to manage patients' airways during appropriately supervised general anesthesia using bag/mask ventilation, laryngeal mask airway and endotracheal intubation.

4. The performance improvement process should monitor and evaluate patient outcomes and adverse or unusual events.

5. The performance improvement process should have input and/or oversight of the department of anesthesiology.

II. SUPERVISED SEDATION PROFESSIONALS

A. Education and Training

The supervised sedation professional who is granted privileges to administer sedative, analgesic or anesthetic drugs under supervision of an anesthesiologist or a non-anesthesiologist sedation practitioner and to monitor patients during deep sedation can be a registered nurse who has graduated from a qualified school of nursing or a physician assistant who has graduated from an accredited physician assistant program. They may only administer sedative, analgesic or anesthetic medications on the order of an anesthesiologist or nonanesthesiologist sedation practitioner. They should have satisfactorily completed a

formal training program in 1) the safe administration of sedative, analgesic or anesthetic drugs used to establish a level of deep sedation, 2) use of reversal agents for opioids and benzodiazepines, 3) monitoring of patients' physiologic parameters during sedation, and 4) recognition of abnormalities in monitored variables that require intervention by the anesthesiologist or nonanesthesiologist sedation practitioner. Training should include the following:

1. Contents of the following ASA documents:

   - *Practice Guidelines for Sedation and Analgesia by Non-anesthesiologists*
   - *Continuum of Depth of Sedation – Definition of General Anesthesia and Levels of Sedation/Analgesia*
   - *Practice Guidelines for Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures*

2. The pharmacology of (1) all sedative, analgesic or anesthetic drugs the practitioner requests privileges to administer to establish a level of deep sedation, and (2) pharmacological antagonists to the sedative, analgesic or anesthetic drugs.

3. The benefits and risks of supplemental oxygen.

4. Recognition of adequacy of ventilatory function: This should include experience with patients whose ventilatory drive is depressed by sedative, analgesic or anesthetic drugs as well as patients whose airways become obstructed during sedation.

5. Demonstrated proficiency in positive pressure ventilation with a bag-valve-mask system: This training should include appropriately supervised experience in ventilating patients during general anesthesia.

6. Monitoring and recognizing abnormalities of physiologic variables, including the following:
   a. Blood pressure
   b. Respiratory rate
   c. Oxygen saturation by pulse oximetry
   d. Capnographic monitoring. The health professional should be familiar with the use and interpretation of capnographic waveforms to determine the adequacy of ventilation during deep sedation
   e. Electrocardiographic monitoring. Education in electrocardiographic (EKG) monitoring should include instruction in the most common dysrhythmias seen during sedation and anesthesia, their causes and their potential clinical implications (e.g., hypercapnia), as well as electrocardiographic signs of cardiac ischemia.
   f. Depth of sedation. The depth of sedation should be based on the ASA definitions of "deep sedation" and "general anesthesia." (See above)

7. The importance of continuous use of appropriately set audible alarms on all physiologic monitors.

8. Documenting the drugs administered, the patient's physiologic condition and the depth of sedation at five-minute intervals throughout the period of sedation and analgesia, using a graphical, tabular or automated record which documents all the monitored parameters including capnographic monitoring.

9. Regardless of the availability of a "code team" or the equivalent, the supervised sedation professional should have advanced life support skills such as those required for American Heart Association certification in Advanced Cardiac Life Support (ACLS). When granting privileges to administer deep sedation to pediatric patients, the supervised sedation professional should have advanced life support skills such as those required for certification in Pediatric Advanced Life Support (PALS).

When the practitioner is being granted privileges to administer sedative, analgesic or anesthetic drugs to pediatric patients to establish a level of deep sedation, the education and training requirements enumerated in #1-14 above should be specifically defined to qualify the practitioner to administer sedative, analgesic or anesthetic drugs to pediatric patients.

B. Licensure

1. The supervised sedation professional should have a current active nursing license or physician assistant license or certification, in the U.S. state, district or territory of practice. (Exception: practitioners employed by the federal government may have a current active license in any U.S. state, district or territory.)

2. Before granting or renewing privileges for a supervised sedation professional to administer sedative, analgesic or anesthetic drugs and to monitor patients during deep sedation, the health care organization should search for any disciplinary action recorded in the National Practitioner Data Bank (NPDB) and take appropriate action regarding any Adverse Action Reports.

C. Practice Pattern

1. Before granting ongoing privileges to administer sedative, analgesic or anesthetic drugs to establish a level of deep sedation, a process should be developed to re-evaluate the supervised sedation professional's performance. The facility should establish performance criteria and an appropriate number of procedures to be reviewed.

D. Performance Improvement

Credentialing of supervised sedation professionals in the administration of sedative, analgesic or anesthetic drugs and monitoring patients during deep sedation should require active participation in an ongoing process that evaluates the health care professional's clinical performance and patient care outcomes through a formal program of continuous performance improvement.

1. The organization in which the practitioner practices should conduct peer review of its supervised sedation professionals.

2. The performance improvement process should assess up-to-date knowledge as well as ongoing competence in the skills outlined in the educational and training requirements described above.

REFERENCES

ASA has produced many documents over the years related to the topic addressed by these guidelines, among them the following (in alphabetical order):

AANA-ASA Joint Statement Regarding Propofol Administration (April 14, 2004)

Continuum of Depth of Sedation – Definition of General Anesthesia and Levels of Sedation/Analgesia (Approved by ASA House of Delegates on October 13, 1999, and last amended on October 27, 2004).
Guidelines for Ambulatory Anesthesia and Surgery (Approved by ASA House of Delegates on October 11, 1973, and last affirmed on October 15, 2003)

Guidelines for Delineation of Clinical Privileges in Anesthesiology (Approved by ASA House of Delegates on October 15, 1975, and last amended on October 15, 2003) *Guidelines for Office-Based Anesthesia and Surgery* (Approved by ASA House of Delegates on October 13, 1999, and last affirmed on October 27, 2004)

Outcome Indicators for Office-Based and Ambulatory Surgery (ASA Committee on Ambulatory Surgical Care and Task Force on Office-Based Anesthesia, April 2003)

Practice Guidelines for Sedation and Analgesia by Nonanesthesiologists (Approved by ASA House of Delegates on October 25, 1995, and last amended on October 17, 2001)

Statement on Qualifications of Anesthesia Providers in the Office-Based Setting (Approved by ASA House of Delegates on October 13, 1999, and last affirmed on October 27, 2004)

Statement on Safe Use of Propofol (Approved by ASA House of Delegates on October 27, 2004)

Report 614-1.3 to the 2006 ASA House of Delegates — Guidelines for Granting Privileges to Nonanesthesiologist Practitioners for Personally Administering Deep Sedation or Supervising Deep Sedation by Individuals Who are not Anesthesia Professionals (Not adopted by the ASA HOD, October 2006

In addition the following reference may be considered:

American Academy of Pediatrics, American Academy of Pediatric Dentistry, Cote CJ, Wilson S, and the Workgroup on Sedation. Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures: An Update. *Pediatrics* 2006;118:2587-2602.