ADVISORY ON GRANTING PRIVILEGES FOR DEEP SEDATION TO NON-ANESTHESIOLOGIST SEDATION PRACTITIONERS

Committee of Origin: *Ad Hoc* on Non-Anesthesiologist Privileging

(Approved by the ASA House of Delegates on October 20, 2010)

1. INTRODUCTION

The American Society of Anesthesiologists is vitally interested in the safe administration of all anesthesia services including moderate and deep sedation. As such, it has concern 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 or sedation administration. It has genuine concern that individuals, however well intentioned, who are not anesthesia professionals may not recognize that sedation and general anesthesia are on a continuum, and thus deliver levels of sedation that may, in fact, be general anesthesia without having the training and experience to respond appropriately.

ASA believes that anesthesiologist participation in all deep sedation is the best means to achieve the safest care. ASA acknowledges, however, that Medicare regulations permit some non-anesthesiologists to administer or supervise the administration of deep sedation. This advisory should not be considered as an endorsement, or absolute condemnation, of this practice by ASA but rather to serve as a potential guide to its members who may be called upon by administrators or others to provide input in this process. This document provides a framework to identify those physicians, dentists, oral surgeons or podiatrists who may potentially qualify to administer or supervise the administration of deep sedation.

This document applies only to the care of patients undergoing procedural sedation, and it may not be construed as privileges to intentionally administer general anesthesia. Unrestricted general anesthesia shall only be administered by anesthesia professionals within their scope of practice (anesthesiologists, certified registered nurse anesthetists and anesthesiologist assistants). If the patient loses consciousness and the ability to respond purposefully, the anesthesia care is a general anesthetic, irrespective of whether airway instrumentation is required.

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.

Definitions of terms appear at the end of this document. Of special note, for purposes of this document the following definitions are relevant:

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

1.2 Non-anesthesiologist Sedation Practitioner: A licensed physician (allopathic or osteopathic); or dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law; who has not completed postgraduate training in anesthesiology but is specifically trained to administer personally or to supervise the administration of deep sedation.

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2. ADVISORY

This advisory is designed to assist health care facilities in developing a program for the delineation of clinical privileges for practitioners who are not anesthesia professionals to administer sedative and analgesic drugs to establish a level of deep sedation. They are written to apply to every setting in which an internal or external privileging process is required for granting privileges to administer sedative and analgesic drugs to establish a level of deep sedation (e.g., hospital, freestanding procedure center, ambulatory surgery center, physician's or dentist's office, etc.). These recommendations do not lead to the granting of privileges to administer general anesthesia.

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

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> Note: The *Hospital Anesthesia Services Condition of Participation 42 CFR 482.52(a)* limits the administration of deep sedation to "qualified anesthesia professionals" within their scope of practice. CMS defines these personnel specifically as an anesthesiologist; non-anesthesiologist MD or DO; dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law; CRNA, and AA. See also the *Ambulatory Surgery Center Condition for Coverage 42 CFR 416.42(b)*.

Only physicians and other practitioners specifically permitted by CMS, above, who are qualified by education, training and licensure to administer deep sedation may administer deep sedation or supervise the administration of deep sedation when administered by CRNAs. Because training is procedure specific, the type and complexity of procedures for which the practitioner may administer or supervise deep sedation must be specified in the privileges granted.

Any professional who administers and monitors deep sedation must be dedicated to that task. Therefore, the non-anesthesiologist sedation practitioner who administers and monitors deep sedation must be different from the individual performing the diagnostic or therapeutic procedure (see ASA Guidelines for Sedation and Analgesia by Non-anesthesiologists).

3. EDUCATION AND TRAINING

The non-anesthesiologist sedation practitioner will have satisfactorily completed a formal training program in (1) the safe administration of sedative and analgesic 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 formally recognized part of a recently completed Accreditation Council for Graduate Medical Education (ACGME) residency or fellowship training (e.g., within two years), or may be a separate deep sedation educational program that is accredited by Accreditation Council for Continuing Medical Education (ACCME) or equivalent providers recognized for dental, oral surgical and podiatric continuing education, and that includes the didactic and performance concepts below. A knowledge-based test is necessary to objectively demonstrate the knowledge of concepts required to obtain privileges. The following subject areas will be included:

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3.1 Contents of the following ASA documents (or their more current version if subsequently modified) that will be understood by practitioners who administer sedative and analgesic drugs to establish a level of deep sedation

3.1.1 Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists. Anesthesiology 2002: 96; 1004-1017.

3.1.2 Continuum of Depth of Sedation; Definition of General Anesthesia and Levels of Sedation/Analgesia (ASA HOD 2004, amended 2009)

3.1.3 Standards for Basic Anesthetic Monitoring (Approved by the ASA House of Delegates on October 21, 1986, and last amended on October 25, 2005)

3.1.4 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)

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

3.3 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 will be able to recognize those patients whose medical condition requires that sedation needs to be provided by an anesthesia professional, such as morbidly obese patients, elderly patients, pregnant patients, patients with severe systemic disease, patients with obstructive sleep apnea, or patients with delayed gastric emptying.

3.4 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

3.4.1 The target level of sedation

3.4.2 Whether the procedure should be delayed

3.4.3 Whether the sedation care should be transferred to an anesthesia professional for the delivery of general anesthesia with endotracheal intubation.

3.5 The pharmacology of

3.5.1 All sedative and analgesic drugs the practitioner requests privileges to administer to establish a level of deep sedation

3.5.2 Pharmacological antagonists to the sedative and analgesic drugs

3.5.3 Vasoactive drugs and antiarrhythmics.

3.6 The benefits and risks of supplemental oxygen.

3.7 Recognition of adequacy of ventilatory function: This will include experience with patients whose ventilatory drive is depressed by sedative and analgesic drugs as well as patients whose airways become obstructed during sedation. This will also include the ability to perform capnography and understand the results of such monitoring. Non-anesthesiologist practitioners will demonstrate competency in 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.

3.8 Proficiency in advanced airway management for rescue: This training will include appropriately supervised experience to demonstrate competency in managing the airways of patients during deep sedation, and airway management using airway models as well as using high-fidelity patient simulators. The non-anesthesiologist practitioner must demonstrate the ability to reliably perform the following:

3.8.1. Bag-valve-mask ventilation

3.8.2 Insertion and use of oro- and nasopharyngeal airways

3.8.3 Insertion and ventilation through a laryngeal mask airway

3.8.4 Direct laryngoscopy and endotracheal intubation

This will include clinical experience on no less than 35 patients or equivalent simulator experience (See ACGME reference). The facility with oversight by the Director of Anesthesia Services will determine the number of cases needed to demonstrate these competencies, and may increase beyond the minimum recommended.

3.9 Monitoring of physiologic variables, including the following:

3.9.1 Blood pressure.

3.9.2 Respiratory rate.

3.9.3 Oxygen saturation by pulse oximetry with audible variable pitch pulse tone.

3.9.4 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.

3.9.5 Electrocardiographic monitoring. Education in electrocardiographic (EKG) monitoring will 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.

3.9.6 Depth of sedation. The depth of sedation will be based on the ASA definitions of "deep sedation" and "general anesthesia." (See below).

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

3.11 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.

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

3.13 Regardless of the availability of a "code team" or the equivalent, the non-anesthesiologist practitioner will have advanced life support skills and current certificate such as those required for Advanced Cardiac Life Support (ACLS). When granting privileges to administer deep sedation to pediatric patients, the non-anesthesiologist practitioner will have advanced life support skills and current certificate such as those required for Pediatric Advanced Life Support (PALS). Initial ACLS and PALS training and subsequent retraining shall be obtained from the American Heart Association or another vendor that includes "hands-on" training and skills demonstration of airway management and automated external defibrillator (AED) use.

3.14 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 oversight by the Director of Anesthesia services or their designee.

3.15 Knowledge of the current CMS Conditions of Participation regulations and their interpretive guidelines pertaining to deep sedation, including requirements for the pre-anesthesia evaluation, anesthesia intra-operative record, and post-anesthesia evaluation.

Separate privileging is required for the care of pediatric patients. When the non-anesthesiologist practitioner is granted privileges to administer sedative and analgesic drugs to pediatric patients to establish a level of deep sedation, the education and training requirements enumerated in #1-15 above will be specifically defined to qualify the practitioner to administer sedative and analgesic drugs to pediatric patients.

4. LICENSURE

4.1 The non-anesthesiologist sedation practitioner will 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.)

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

4.3 The privileging process will 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.

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

5. PERFORMANCE EVALUATION

5.1 Before granting initial privileges to administer or supervise administration of sedative and analgesic drugs to establish a level of deep sedation, a process will be developed to evaluate the practitioner's performance and competency. For recent graduates (e.g., within two years), this may be accomplished through letters of recommendation from directors of residency or fellowship training programs that include deep sedation as part of the curriculum. For those who have been in practice since completion of their training, performance evaluation may be accomplished through specific documentation of performance evaluation data transmitted from department heads or supervisors at the institution where the individual previously held 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 and analgesic agents to provide deep sedation. The Director of Anesthesia Services with oversight by the facility governing body will determine the number of cases that need to be performed in order to determine independent competency in deep sedation.

5.2 Before granting ongoing privileges to administer or supervise administration of sedative and analgesic drugs to establish a level of deep sedation, a process will be developed to re-evaluate the practitioner's performance at regular intervals. Re-evaluation of competency in airway management will be part of this performance evaluation. For example, the practitioner's performance could be reviewed by an anesthesiologist or a non-anesthesiologist sedation practitioner who is currently privileged to administer deep sedation. The facility will establish an appropriate number of procedures that will be reviewed.

6. PERFORMANCE IMPROVEMENT

Privileging in the administration of sedative and analgesic drugs to establish a level of deep sedation will require active participation in an ongoing process that evaluates the practitioner's clinical performance and patient care outcomes through a formal facility program of continuous performance improvement. The facility's deep sedation performance improvement program will be developed with advice from and with outcome review by the Director of Anesthesia Services.

6.1 The organization in which the practitioner practices will conduct peer review of its clinicians.

6.2 The performance improvement program will assess up-to-date knowledge as well as

ongoing competence in the skills outlined in the educational and training requirements described above.

6.3 Continuing medical education in the delivery of anesthesia services is required for renewal of privileges.

6.4 The performance improvement program will monitor and evaluate patient outcomes and adverse or unusual events.

6.5 Any of the following events will be referred to the facility quality assurance committee for evaluation and performance evaluation:

6.5.1 Unplanned admission

6.5.2 Cardiac arrest

6.5.3 Use of reversal agents

6.5.4 Use of assistance with ventilation requiring bag-valve-mask ventilation or laryngeal or endotracheal airways.

6.5.5 Prolonged periods of oxygen desaturation (<85% for 3 minutes)

6.5.6 Failure of the patient to return to 20% of pre-procedure vital signs

7. 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, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law; who has not completed postgraduate training in anesthesiology but is specifically trained to administer personally or to supervise the administration of deep sedation.

Privileges: The clinical activities within a health care organization that a practitioner is permitted to perform.

Privileging: The process of granting permission to perform certain clinical activities based on credentials, experience, and demonstrated performance

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

Credentialing: The process of obtaining, verifying, and assessing the qualifications of a practitioner to provide care or services in or for a healthcare organization.

Procedural sedation: The administration of sedative and analgesic drugs for a non-surgical diagnostic or therapeutic procedure.

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Definitions of the continuum of sedation:
* 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. It is not appropriate to continue the procedure at an unintended 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 21, 2009).
Expanded definitions of moderate and deep sedation can be found in the CMS Interpretive Guidelines.

8. REFERENCES

The American Society of Anesthesiologists has produced many documents over the years related to the topic addressed by this advisory, 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 21, 2009).

Distinguishing Monitored Anesthesia Care ("MAC") from Moderate Sedation/Analgesia (Conscious Sedation). (Approved by the ASA House of Delegates on October 27, 2004 and last amended on October 21, 2009)

Guidelines for Ambulatory Anesthesia and Surgery (Approved by ASA House of Delegates on October 11, 1973, and last amended on October 22, 2008)

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Guidelines for Delineation of Clinical Privileges in Anesthesiology (Approved by ASA House of Delegates on October 15, 1975, and last amended on October 22, 2008)

Guidelines for Office-Based Anesthesia and Surgery (Approved by ASA House of Delegates on October 13, 1999, and last affirmed on October 21, 2009)

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 Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures. Anesthesiology 1999; 90: 896-905.

Practice Guidelines for Sedation and Analgesia by Non-anesthesiologists. Anesthesiology 2002: 96; 1004-1017.

Standards for Basic Anesthetic Monitoring (Approved by the ASA House of Delegates on October 21, 1986, and last amended on October 20, 2010)

Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners Who Are Not Anesthesia Professionals (Approved by the ASA House of Delegates on October 25, 2005, and last amended on October 18, 2006)

Statement on Qualifications of Anesthesia Providers in the Office-Based Setting (Approved by ASA House of Delegates on October 13, 1999, and last amended on October 21, 2009)

Statement on Safe Use of Propofol (Approved by ASA House of Delegates on October 27, 2004 and amended on October 21, 2009)

In addition the following references may be considered:

ACGME Emergency Medicine residency program guidelines for number of intubations needed:
http://www.acgme.org/acWebsite/RRC_110/110_guidelines.asp#res

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.

Centers for Medicare and Medicaid Services Revisions to Interpretive Guidelines for Hospital Condition of Participation, December 11, 2009.
http://www.cms.gov/surveycertificationgeninfo/pmsr/itemdetail.asp?itemid=CMS1231690

Centers for Medicare and Medicaid Services Revisions to Interpretive Guidelines for Ambulatory Surgery Centers Condition for Coverage, December 30, 2009.
https://www.cms.gov/transmittals/downloads/R56SOMA.pdf