Advisory on Granting Privileges for Deep Sedation to Non-Anesthesiologist Physicians

Committee of Origin: Quality Management and Departmental Administration

(Approved by the ASA House of Delegates on October 20, 2010 and last amended on October 25, 2017)

1. INTRODUCTION

The American Society of Anesthesiologists (ASA) is committed to improving patient safety and quality of care in the administration of all anesthesia services including moderate and deep sedation. As such, ASA 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. ASA 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 physician anesthesiologist participation in all deep sedation is the best means to achieve the safest care. ASA acknowledges, however, that Medicare regulations provide for participation in deep sedation by other anesthesia professionals (see 1.1 below) and permit some non-anesthesiologist physicians (see 1.2 below) 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, especially those serving as a facility Director of Anesthesia Services (DAS). 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 (physician anesthesiologists, nurse anesthetists and certified anesthesiologist assistants [CAAs]). 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 (see 3.15 and 6.5 below).

When deep sedation is intended, there is a significant risk that patients may slip into a state of general anesthesia (i.e. the patient can no longer 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 rescued from general anesthesia and 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: A physician anesthesiologist, certified anesthesiologist assistant (CAA), or nurse anesthetist.

1.2 Non-anesthesiologist Physician: 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 personally administer or to supervise a Centers for Medicare and Medicaid Services qualified anesthesia provider in the administration of deep sedation. See Hospital Anesthesia Services Condition of Participation 42 CFR 482.52(a) and Ambulatory Surgery Center Condition for Coverage 42 CFR 416.42(b).

2. ADVISORY

This advisory is designed to assist health care facilities in developing a program for the delineation of clinical privileges for physicians who are not anesthesia physicians 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 (e.g. two years) 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.

NON-ANESTHESIOLOGIST PHYSICIANS

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 as a physician anesthesiologist; non-anesthesiologist MD or DO; dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law; nurse anesthetist, and CAA. 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 nurse anesthetists. Because training is procedure specific, the type and complexity of procedures for which the physician may administer or supervise deep sedation must be specified in the privileges granted.

Any physician who administers and monitors deep sedation must be dedicated to that task. Therefore, the non-anesthesiologist physician 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 physician 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 includes the didactic and performance concepts below and 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. A knowledge-based test is necessary to objectively demonstrate the knowledge of concepts required to obtain privileges. The following subject areas will be included:

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


3.1.2 Continuum of Depth of Sedation; Definition of General Anesthesia and Levels of Sedation/Analgesia (Approved by the ASA House of Delegates on October 13, 1999, and last affirmed on October 15, 2014)

3.1.3 Standards for Basic Anesthetic Monitoring (Approved by the ASA House of Delegates on October 21, 1986, and last amended on October 20, 2010, and last affirmed on October 28, 2015)

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 26, 2016)

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 physician 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.

3.5 The pharmacology of

3.5.1 All sedative and analgesic drugs the physician requests privileges to administer to establish a level of deep sedation
3.5.2 Pharmacological antagonists to the sedative and analgesic drugs, if any
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 physicians 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.

3.8.1 Effective bag and mask ventilation should be sufficient for rescue, accordingly the non-anesthesiologist physician must demonstrate the ability to reliably perform the following:

3.8.1.1 Bag-valve-mask ventilation
3.8.1.2 Insertion and use of oro- and nasopharyngeal airways
3.8.2 Local privileging must ensure that the non-anesthesiologist physician can demonstrate: early recognition of the need for qualified airway backup personnel and how to immediately and reliably access services from qualified airway backup personnel when progression to techniques in 3.8.2 are indicated. The Director of Anesthesia Services defines qualified backup personnel who must be present and available on site before sedation is initiated. The non-anesthesiologist physician must demonstrate appropriate knowledge regarding indications and techniques required to perform advanced airway management:

3.8.2.1 Insertion and ventilation using a laryngeal mask airway, or

3.8.2.2 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 Adequacy of ventilation. Adequacy of ventilation will be based on the ASA Standards for Basic Anesthetic Monitoring (see below).

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

3.9.4 Capnographic monitoring. The non-anesthesiologist physician 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 physician 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 physician 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 Local privileging must ensure that the non-anesthesiologist physician have knowledge and practical understanding of the specific local systems of support and rescue within the facility. This should include but is not limited to understanding of how to immediately access services from qualified airway backup personnel.

3.15 CMS requires (Survey Procedures §482.52) a system by which adverse events related to the administration of anesthesia and analgesia, are tracked and acted upon. Accordingly, participation is required in a quality assurance system to track sedation outcomes including respiratory arrests, use of reversal agents, prolonged sedation in recovery process, larger than expected medication doses, occurrence of general anesthesia, and adverse outcomes and unusual events with oversight by the Director of Anesthesia services or their designee. All episodes of rescue by qualified airway backup personnel should be reported.

3.16 Knowledge of and compliance with 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 physician 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 physician will have a current active, unrestricted medical,
osteopathic, or dental license in the state, district or territory of practice. (Exception: physicians employed by the federal government may have a current active license in any U.S. state, district or territory.

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

4.3 Common privileging processes that may require intentional review for applicability to deep sedation prior to granting these privileges include:

4.3.1 Disclosed 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.

4.3.2 Disciplinary action recorded in the National Practitioner Data Bank (NPDB) and 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 physician’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 physician 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 physician’s performance could be reviewed by a physician anesthesiologist or a non-anesthesiologist physician 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 physician’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 physician 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 within 20% of pre-procedure vital signs
6.5.7 Episodes of rescue by qualified airway backup personnel
6.5.8 Occurrence of general anesthesia

7. DEFINITIONS

Anesthesia Professional: A physician anesthesiologist, certified anesthesiologist assistant (CAA), or nurse anesthetist.
Non-anesthesiologist Physician: 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. See Hospital Anesthesia Services
Condition of Participation 42 CFR 482.52(a) and Ambulatory Surgery Center Condition for
Coverage 42 CFR 416.42(b).

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.

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 15, 2014).

* 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 affirmed on October 15, 2014).

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, and reaffirmed on October 16, 2013)


Guidelines for Delineation of Clinical Privileges in Anesthesiology (Approved by ASA House of Delegates on October 15, 2003, and last amended on October 16, 2013)

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

Outcome Indicators for Office-Based and Ambulatory Surgery (Approved by ASA House of Delegates on October 16, 2013)


Standards for Basic Anesthetic Monitoring (Approved by the ASA House of Delegates on October 21, 1986, and last amended on October 20, 2010, and last affirmed on October 28, 2015)

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 reaffirmed on October 26, 2016)

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, and reaffirmed on October 15, 2014)

Statement on Safe Use of Propofol (Approved by ASA House of Delegates on October 27, 2004 and amended on October 15, 2014)

In addition, the following references may be considered:

ACGME Emergency Medicine residency program guidelines for number of intubations needed: https://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/110_emergency_medicine_2016.pdf

