Interpretive Guidelines Implementation Template

Templates and resources are now available to help anesthesiologists comply with the new CMS Interpretive Guidelines for the hospital Conditions of Participation.

Scope of Anesthesia Services

Anesthesia services throughout the hospital (including all departments in all campuses and off-site locations where anesthesia services are provided) must be organized into one anesthesia service, under the direction of a qualified doctor of medicine (MD) or doctor of osteopathy (DO). (§482.52) (See position requirements in companion document.) Such anesthesia services are divided into two categories**.** The definitions of these categories are generally based on American Society of Anesthesiologists definitions found in its most recent set of practice guidelines (Anesthesiology 2002; 96:1004-17). (§482.52)

1- "Anesthesia", specifically including

- General anesthesia.
- Regional anesthesia.
- Monitored anesthesia care (MAC).
  Deep sedation/analgesia is included in MAC. An example of deep sedation would be a screening colonoscopy when there is a decision to use propofol. (§482.52)

General anesthesia, regional anesthesia and monitored anesthesia, including deep sedation/analgesia, may only be administered by:
• A qualified anesthesiologist;
• An MD or DO (other than an anesthesiologist);
• A dentist, oral surgeon or podiatrist who is qualified to administer anesthesia under State law;
• A CRNA who is supervised by the operating practitioner or by an anesthesiologist who is immediately available if needed; or
• An anesthesiologist's assistant under the supervision of an anesthesiologist who is immediately available if needed. (§482.52(a))

Administration by an MD/DO/dentist/oral surgeon/podiatrist
The hospital's anesthesia services policies must address the circumstances under which an MD or DO who is not an anesthesiologist, a dentist, oral surgeon or podiatrist is permitted to administer anesthesia. In the case of a dentist, oral surgeon or podiatrist, administration of anesthesia must be permissible under State law and comply with all State requirements concerning qualifications. Hospitals should conform to generally accepted standards of anesthesia care when establishing policies governing anesthesia administration by these types of practitioners as well as MDs or DOs who are not anesthesiologists. (§482.52(a))

Administration by a CRNA
Unless the hospital is located in a State that has chosen to opt out of the CRNA supervision requirements, a CRNA administering general, regional and monitored anesthesia must be supervised either by the operating practitioner who is performing the procedure, or by an anesthesiologist who is immediately available.

Hospitals should conform to generally accepted standards of anesthesia care when establishing policies for supervision by the operating practitioner. An anesthesiologist is considered "immediately available" when needed by a CRNA under the anesthesiologist's supervision only if he/she is physically located within the same area as the CRNA, e.g., in the same operative suite, or in the same labor and delivery unit, or in the same procedure room, and not otherwise occupied in a way that prevents him/her from immediately conducting hands-on intervention, if needed. (§482.52(a) and (c))

Administration by an anesthesiologist's assistant
An anesthesiologist's assistant may administer anesthesia when under the direct supervision of an anesthesiologist. The anesthesiologist must be immediately available if needed. An anesthesiologist is considered "immediately available" to assist the anesthesiologist's assistant under the anesthesiologist's supervision only if he/she is physically located within the same area as the anesthesiologist's assistant, e.g., in the same operative suite, or in the same labor and delivery unit, or in the same procedure room, and not otherwise occupied in a way that prevents him/her from immediately conducting hands-on intervention, if needed. (§482.52)

2- "Sedation/analgesia", specifically including

- Topical or local anesthesia
- Minimal sedation
- Moderate sedation/analgesia ("Conscious Sedation") (§482.52)

Who May Administer Topical/local anesthetics, Minimal sedation, Moderate sedation:
The requirements above concerning who may administer anesthesia do not apply to the administration of topical or local anesthetics, minimal sedation, or moderate sedation. However, they must be given by appropriately trained medical professionals within their scope of practice. The hospital must have policies and procedures, consistent with State scope of practice law, governing the provision of these types of anesthesia services. Further, hospitals must assure that all anesthesia services are provided in a safe, well-organized manner by qualified personnel. (§482.52(a))

Rescue Capacity
Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, hospitals must ensure that procedures are in place to rescue patients whose level of sedation becomes deeper than initially

intended, for example, patients who inadvertently enter a state of Deep Sedation/Analgesia when moderate sedation was intended. “Rescue” from a deeper level of sedation than intended requires an intervention by a practitioner with expertise in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper than intended level of sedation and returns the patient to the originally intended level of sedation. (§482.52)

Director of Anesthesia Services Job Description

Anesthesiology is the practice of medicine including, but not limited to, preoperative patient evaluation, anesthetic planning, intraoperative and postoperative care and the management of systems and personnel to support these activities. In addition, anesthesiology involved perioperative consultation, the prevention and management of untoward perioperative patient conditions, the treatment of acute and chronic pain, and the care of critically ill patients. This care is personally provided by or directed by the anesthesiologist. Thus, it is essential that hospitals use the following criteria in determining qualifications for the director of anesthesia services.

The Centers for Medicare and Medicaid Services (CMS) hospital Conditions of Participation and their applicable interpretive guidelines require that a hospital identify a director of anesthesia services. Such director must possess the following attributes:

- Degree of doctor of medicine (M.D.) or osteopathy (D.O.) (§482.52)
- Authority and responsibility for directing the administration of all anesthesia throughout the hospital (including all departments in all campuses and off-site locations where anesthesia services are provided) (§482.52)
    - All anesthesia services are defined by CMS, and responsiblity includes both “anesthesia” and “sedation/analgesia” services (§482.52). CMS definitions can be found in the companion document “Scope of Anesthesia Services”.
    - Delivery of anesthesia services consistent with recognized standards for anesthesia care may include (§482.52(b)):
        - Patient consent;
        - Infection control measures;
        - Safety practices in all anesthetizing areas;
        - Protocol for supportive life functions, e.g., cardiac and respiratory emergencies;
        - Reporting requirements;
        - Documentation requirements;
        - Equipment requirements, as well as the monitoring, inspection, testing, and maintenance of anesthesia equipment in the hospital’s biomedical equipment program.
        - Delineation of pre- and post-anesthesia staff responsibilities

- Responsibility for planning, directing and supervising all activities of the anesthesia service (§482.52)
- Responsibility for establishing staffing schedules (§482.52)
- Responsibility for evaluating the quality and appropriateness of the anesthesia patient care (§482.52)

In developing the job description, a hospital should refer to the following additional criteria for the director of anesthesia services recommended by the American Society of Anesthesiologists. The director of anesthesia services should have:

- Successfully completed a training program in anesthesiology accredited by the Accreditation Council for Graduate Medical Education (ACGME), the American Osteopathic Association (AOA) or equivalent organization
- Current, full and unrestricted license to practice medicine in the State, Territory or Commonwealth of the United States or in the District of Columbia where the hospital or facility is located.
- Current, unrestricted DEA registration (schedules II-IV) or no history of revocation of DEA registration (schedules II-IV) within the past five years.
- Permanent certification by the American Board of Anesthesiology (ABA) or current recertification within the time interval required by the ABA.
- Compliance with the ABA Maintenance of Certification in Anesthesiology Program (MOCA).
- Current Physician's Recognition Award of the American Medical Association or completion of 100 hours of continuing medical education (CME) over two years, of which 40 hours are in category 1 of the Accreditation Council for Continuing Medical Education (ACCME).
- Compliance with relevant state or institutional requirements for CME.
- At least 50 percent of CME hours in the primary specialty of practice.
- Demonstration of competence in advanced life support.
- Agreement in writing to abide by the ASA "Guidelines for the Ethical Practice of Anesthesiology."

Policies and Procedures Governing Anesthesia Privileging in Hospitals

***Hospitals must review and revise with legal counsel and ensure compliance with State and federal laws and regulations. ASA intends these documents as references to help hospitals design their own policies and procedures and does not intend, warrant, or hold out these documents as legal advice.*

Purpose

The purpose of these policies and procedures is to establish the standards and expectations for all patients receiving anesthesia services, including but not limited to, topical or local anesthesia, minimal sedation, moderate

sedation/analgesia, deep sedation/analgesia, regional anesthesia and general anesthesia, in _____ hospital. These policies and procedures apply to all locations in the hospital where anesthesia services are administered, including but not limited to the Operating room suite (both inpatient and outpatient), Emergency Department, Critical Care areas, Obstetrical Suite, Radiology department, Psychiatry department, Recovery Rooms, Clinics, Outpatient surgery areas, and Special procedure areas, e.g. Endoscopy Suite and Pain Management Clinics, and including all departments in all campuses and off-site locations where anesthesia services are provided. (§482.52 and 482.52(a))

Information

Our hospital is vitally interested in the safe administration of all anesthesia services. Anesthesiology is the practice of medicine. The Department of Anesthesia has the responsibility and authority, through its Director, for developing policies and procedures governing the provision of all categories of anesthesia services, including specifying the minimum qualifications for each category of practitioner who is permitted to provide anesthesia services. (§482.52) The hospital's governing body approves the specific anesthesia service privileges, including type and complexity of procedures, for each practitioner who furnishes anesthesia services, addressing the type of supervision required, if applicable.

When a hospital permits operating practitioners to supervise a CRNA administering anesthesia, the medical staff bylaws or rules and regulations must specify for each category of operating practitioner, the type and complexity of procedures that category of practitioner may supervise. However, individual operating practitioners do not need to be granted specific privileges to supervise a CRNA. (§482.52(a) and (c))

Clinical privileges in anesthesiology are granted to physicians and other providers qualified to administer anesthesia who are qualified by training to render patients insensible to pain and to minimize stress during surgical, obstetrical and certain medical procedures. Clinical privileges are also granted to practitioners who are not anesthesia professionals to administer sedative and analgesic drugs to establish a level of moderate or minimal sedation. Analgesia and anesthesia comprise a continuum of states ranging from minimal sedation to general anesthesia;. CMS adds the category of topical and local analgesia (§482.52). The following are definitions of various levels of sedation/analgesia and anesthesia as defined by the American Society of Anesthesiologists:

- Minimal Sedation (Anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes and ventilatory and cardiovascular functions are unaffected. (§482.52)

- Moderate Sedation/Analgesia is a drug-induced depression of consciousness during which patients respond purposefully (reflex withdrawal from a painful stimulus is NOT considered a purposeful response) 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. (§482.52)

- Deep Sedation/Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully (reflex withdrawal from a painful stimulus is NOT considered a purposeful response) 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. (§482.52)

- 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 or neuromuscular function. Cardiovascular function may be impaired. (§482.52) If the patient loses consciousness and the ability to respond purposefully, the anesthesia care is a general anesthetic, irrespective of whether airway instrumentation if required.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Rescue requires an intervention by a practitioner with expertise in airway management and advanced life support. (§482.52) Individuals administering Moderate Sedation/Analgesia should be able to rescue patients who enter a state of Deep Sedation/Analgesia, while those administering Deep Sedation/Analgesia should be able to rescue patients who enter a state of General Anesthesia.

Responsibility for implementation of this policy is assigned to the Director of the Anesthesia Department.

Policy

Minimal Sedation

Pursuant to State scope of practice laws and regulations, minimal sedation and local anesthetics must be administered by a qualified anesthesia provider or a licensed registered nurse, advanced practice nurse or physician assistant (PA) who is trained in compliance with all relevant local, institutional, state and/or national standards, policies or guidelines to administer prescribed sedating and analgesic medications and monitor patients during minimal sedation ("anxiolysis"). Sedation nurses and sedation physician assistants may only work under the direct supervision of a properly trained and privileged medical doctor (M.D. or D.O.).

The supervising doctor is responsible for all aspects involved in the continuum of care – pre-, intra-, and post-procedure. While a patient is sedated, the responsible doctor must be physically present and immediately available in the procedure suite. Although the supervising doctor is primarily responsible for pre-procedure patient evaluation, supervised sedation practitioners must be trained adequately in pre-procedure patient evaluation to recognize when risk may be increased, and related policies and procedures must allow sedation practitioners to decline to participate in specific cases if they feel uncomfortable in terms of any perceived threat to quality of care or patient safety.

Moderate Sedation

Pursuant to State scope of practice laws and regulations, moderate sedation must be administered by a qualified anesthesia provider, or a licensed registered nurse, advanced practice nurse or physician assistant (PA) who is trained in compliance with all relevant local, institutional, state and/or national standards, policies or guidelines to administer prescribed sedating and analgesic medications and monitor patients during moderate sedation. Sedation nurses and sedation physician assistants may only work under the direct supervision of a properly trained and privileged medical doctor (M.D. or D.O.). [If State law allows and hospital chooses] Physicians, dentists and podiatrists who are qualified by education, training and licensure to administer moderate sedation may supervise the administration of moderate sedation. Related policies and procedures must allow supervised sedation practitioners to decline to participate in specific cases if they feel uncomfortable in terms of any perceived threat to quality of care or patient safety.

All providers of moderate sedation are required to have at least the following knowledge and competencies:

- Proper medication dosages, administration techniques, adverse reactions and counter interventions
- Airway management and basic life support techniques
- Ability to assess total patient care, including but not limited to respiratory rate, oxygen saturation, blood pressure, cardiac rate and level of consciousness

Because we have patient safety as our top priority, it is the policy of this organization to follow the ASA's 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 amended on October 18, 2006). See Appendix A for the policy, which is hereby incorporated and adopted by this organization.

Deep Sedation

Pursuant to State scope of practice laws and regulations, and due to the significant risk that patients may enter a state of general anesthesia, deep sedation must be administered only by practitioners who are qualified to administer deep sedation or appropriately supervised anesthesia professionals.

Because we have patient safety as our top priority, it is the policy of this organization to follow the ASA's Statement on Granting Privileges to Non-Anesthesiologist Practitioners for Personally Administering Deep Sedation or Supervising Deep Sedation by Individuals who are not Anesthesia Professionals (Approved by the ASA House of Delegates on October 18, 2006). See Appendix B for the policy, which is hereby incorporated and adopted by this organization.

General and Regional Anesthesia

Pursuant to State scope of practice laws and regulations, general anesthesia must be administered only by practitioners who are qualified to administer general anesthesia or under the direct supervision of qualified anesthesia professionals such as CRNAs and anesthesiologist assistants.

Pursuant to State scope of practice laws and regulations, neuraxial regional anesthesia must be administered only by practitioners who are qualified to administer general anesthesia or under the direct supervision of qualified anesthesia professionals such as CRNAs, anesthesiologist assistants and appropriately supervised trainees.

APPENDIX A

STATEMENT ON GRANTING PRIVILEGES FOR ADMINISTRATION OF MODERATE SEDATION TO PRACTITIONERS WHO ARE NOT ANESTHESIA PROFESSIONALS

Committee of Origin: Ad Hoc Committee on Credentialing

(Approved by the ASA House of Delegates on October 25, 2005, and amended on October 18, 2006)

The American Society of Anesthesiologists is vitally interested in the safe administration of anesthesia. 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 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 are, in fact, general anesthesia without having the training and experience to recognize this state and respond appropriately.

The intent of this statement is to suggest a framework for granting privileges that will help ensure competence of individuals who administer or supervise the administration of moderate sedation. Only physicians, dentists or podiatrists who are qualified by education, training and licensure to administer moderate sedation should supervise the administration of moderate sedation. This statement can be used by any facility—hospital, ambulatory care or physician's, dentist's or podiatrist's office—in which an internal or external credentialing process is required for administration of sedative and analgesic drugs to establish a level of moderate sedation.

REFERENCES

ASA has produced many documents over the years related to the topic addressed by this statement, among them the following:

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)

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

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

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

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)

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)

The Ad Hoc Committee on Sedation Credentialing Guidelines for Nonanesthesiologists took the contents of the above documents into consideration when developing this statement.

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

Nonanesthesiologist Sedation Practitioner: A licensed physician (allopathic or osteopathic), dentist or podiatrist who has not completed postgraduate training in anesthesiology but is specifically trained to personally administer or supervise the administration of moderate sedation.

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

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).

STATEMENT

The following statement is 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 and analgesic drugs to establish a level of moderate sedation. (Moderate sedation is also known as "conscious sedation.") The statement is written to apply to every setting in which an internal or external credentialing process is required for granting privileges to administer sedative and analgesic drugs to establish a level of moderate sedation (e.g., hospital, freestanding procedure center, ambulatory surgery center, physician's, dentist's or podiatrist's office, etc.). The statement is not intended nor should it be applied to the granting of privileges to administer deep sedation or 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. NONANESTHESIOLOGIST SEDATION PRACTITIONERS

Only physicians, dentists or podiatrists who are qualified by education, training and licensure to administer moderate sedation should supervise the administration of moderate sedation. Nonanesthesiologist sedation practitioners may directly supervise patient monitoring and the administration of sedative and analgesic 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 nonanesthesiologist sedation practitioner who is to supervise or personally administer medications for moderate sedation should have satisfactorily completed a formal training program in: (1) the safe administration of sedative and analgesic drugs used to establish a level of moderate 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 and analgesic drugs to establish a level of moderate sedation:

- *Practice Guidelines for Sedation and Analgesia by Nonanesthesiologists*
- *Continuum of Depth of Sedation – Definition of General Anesthesia and Levels of Sedation/Analgesia*

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 moderate sedation.

**The post-test included with the ASA Sedation/Analgesia by Nonanesthesiologists videotape (ASA Document #30503-10PPV) may be considered for this purpose.

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 nonanesthesiologist sedation practitioner should be able to recognize those patients whose medical condition suggests that sedation should be provided by an anesthesia professional.

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 and analgesic drugs the practitioner requests privileges to administer to establish a level of moderate sedation, (2) pharmacological antagonists to the sedative and analgesic drugs and (3) vasoactive drugs and antiarrhythmics.

6. The benefits and risks of supplemental oxygen.

7. Proficiency of airway management with facemask and positive pressure ventilation. This training should include appropriately supervised experience in managing the airways of patients, or qualified instruction on an airway simulator (or both).

8. Monitoring of physiologic variables, including the following:
   a. Blood pressure
   b. Respiratory rate
   c. Oxygen saturation by pulse oximetry
   d. Electrocardiographic monitoring. Education in electrocardiographic (EKG) monitoring should include instruction in the most common arrhythmias seen during sedation and anesthesia, their causes and their potential clinical implications (e.g., hypercapnia), as well as electrocardiographic signs of cardiac ischemia.
   e. Depth of sedation. The depth of sedation should be based on the ASA definitions of "moderate sedation" and "deep sedation." (See above)

f. Capnography–if moderate sedation is to be administered in settings where patients' ventilatory function cannot be directly monitored (e.g., MRI suite).

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

10. Documenting the drugs administered, the patient's physiologic condition and the depth of sedation at regular intervals throughout the period of sedation and analgesia, using a graphical, tabular or automated record.

11. If moderate sedation is to be administered in a setting where individual(s) with advanced life support skills will not be immediately available (1-5 minutes; e.g., code team), then the nonanesthesiologist sedation 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 moderate sedation to pediatric patients, the nonanesthesiologist sedation practitioner 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 and analgesic drugs to pediatric patients to establish a level of moderate sedation, the education and training requirements enumerated in #1-9 above should be appropriately tailored to qualify the practitioner to administer sedative and analgesic drugs to pediatric patients.

B. Licensure

1. The nonanesthesiologist sedation practitioner should have a current active, unrestricted medical, osteopathic, dental or podiatric 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 nonanesthesiologist 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 podiatric 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 and analgesic drugs to establish a level of moderate 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 and analgesic drugs to establish a level of moderate sedation, a process should be developed to evaluate the practitioner's performance. For recent graduates (e.g., within two years), this may be accomplished through letters of recommendation from directors

of residency or fellowship training programs which include moderate 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 moderate sedation. Alternatively, the nonanesthesiologist sedation practitioner could be proctored or supervised by a physician, dentist or podiatrist who is currently privileged to administer sedative and analgesic agents to provide moderate 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 and analgesic drugs to establish a level of moderate 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 nonanesthesiologist sedation practitioner who is currently privileged to administer sedative and analgesic agents to provide moderate sedation. The facility should establish an appropriate number of procedures that will be reviewed.

D. Performance Improvement

Credentialing in the administration of sedative and analgesic drugs to establish a level of moderate 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 monitor and evaluate patient outcomes and adverse events.

II. SUPERVISED SEDATION PROFESSIONAL

A. Education and Training

The supervised sedation professional who is granted privileges to administer sedative and analgesic drugs under supervision of a nonanesthesiologist sedation practitioner or anesthesiologist and to monitor patients during moderate 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 and analgesic 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 and analgesic drugs used to establish a level of moderate 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 nonanesthesiologist sedation practitioner or anesthesiologist. Training should include the following:

1. Contents of the following ASA documents:
   - *Practice Guidelines for Sedation and Analgesia by Nonanesthesiologists*
   - *Continuum of Depth of Sedation – Definition of General Anesthesia and Levels of Sedation/Analgesia*

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

3. The benefits and risks of supplemental oxygen.
4. Airway management with facemask and positive pressure ventilation.
5. Monitoring and recognizing abnormalities of physiologic variables, including the following:
   a. Blood pressure
   b. Respiratory rate
   c. Oxygen saturation by pulse oximetry
   d. Electrocardiographic monitoring
   e. Depth of sedation. The depth of sedation should be based on the ASA definitions of "moderate sedation" and "deep sedation." (See above)
   f. Capnography–if moderate sedation is to be administered in settings where patients' ventilatory function cannot be directly monitored.

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

7. Documenting the drugs administered, the patient's physiologic condition and the depth of sedation at regular intervals throughout the period of sedation and analgesia, using a graphical, tabular or automated record.

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 and analgesic drugs and to monitor patients during moderate 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 and analgesic drugs to establish a level of moderate 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 and analgesic drugs and monitoring patients during moderate 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.

Pre-Anesthesia Evaluation

A pre-anesthesia evaluation must be performed for each patient, prior to any inpatient or outpatient surgery or diagnostic or therapeutic procedure requiring anesthesia services, by a person qualified to administer anesthesia*. (§482.52(b)(1))

The pre-anesthesia evaluation/re-evaluation of the patient includes, at a minimum:

- Review of the medical history, including anesthesia, drug and allergy history;
- Interview and examination of the patient;
- Notation of anesthesia risk according to established standards of practice (e.g. ASA classification of risk);
- Identification of potential anesthesia problems, particularly those that may suggest potential complications or contraindications to the planned procedure (e.g., difficult airway, ongoing infection, limited intravascular access);
- Additional pre-anesthesia evaluation, if applicable and as required in accordance with standard practice prior to administering anesthesia (e.g., stress tests, additional specialist consultation);
- Development of the plan for the patient's anesthesia care, including the type of medications for induction, maintenance and post-operative care and discussion with the patient (or patient's representative) of the risks and benefits of the delivery of anesthesia. (§482.52(b)(1))

The patient evalaution or re-evaluation encounter for the purpose of completing this requirement must be performed and documented within 48 hours prior to the delivery of the first dose of medication(s) given for the purpose of inducing anesthesia for surgery or a procedure requiring anesthesia services. (§482.52(b)(1))

This CMS requirement for an evaluation/re-evaluation within 48 hours prior to anesthesia is separate from the Joint Commission Element of Performance 8 of

PC.03.01.03 that all patients need to be re-evaluated immediately prior to administering anesthesia.

**Qualified Anesthesia Professional:*

- *A qualified anesthesiologist;*
- *A doctor of medicine or osteopathy (other than an anesthesiologist);*
- *A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;*
- *A certified registered nurse anesthetist (CRNA), who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or*
- *An anesthesiologist's assistant who is under the supervision of an anesthesiologist who is immediately available if needed* (§482.52(b)(1))

Pre-Anesthesia Evaluation Note

The pre-anesthesia evaluation of the patient must include at a minimum:

- Review of the medical history, including anesthesia, drug and allergy history;
- Interview and examination of the patient;
- Notation of anesthesia risk according to established standards of practice (e.g. ASA classification of risk);
- Identification of potential anesthesia problems, particularly those that may suggest potential complications or contraindications to the planned procedure (e.g., difficult airway, ongoing infection, limited intravascular access);
- Additional pre-anesthesia evaluation, if applicable and as required in accordance with standard practice prior to administering anesthesia (e.g., stress tests, additional specialist consultation);
- Development of the plan for the patient's anesthesia care, including the type of medications for induction, maintenance and post-operative care and discussion with the patient (or patient's representative) of the risks and benefits of the delivery of anesthesia.
- Evaluation must be performed and completed within 48 hours prior to any inpatient or outpatient surgery or procedure requiring anesthesia services. The delivery of the first dose of medication(s) for the purpose of inducing anesthesia marks the end of the 48 hour timeframe. (§482.52(b)(1))

Pre-Anesthesia Evaluation

Date _____ Time _____

Pre-anesthesia Information:
[Pre-anesthesia data collection according to institutional practice]

- Medical History, including anesthesia, drug and allergy history
- Physical Findings

Vital signs reviewed Yes_____
Medical history reviewed Yes_____
Laboratory, imaging and consultations reviewed Yes_____
Patient interviewed and examined Yes_____
Pertinent physical findings noted:
ASA Physical Status _____
Potential anesthesia problems

_____
_____
Anesthesia Plan

_____
_____
Additional Comments

_____
_____

_____ MD___CRNA___ AA__ _____
Evaluator Signature Clinician ID

Note: Designed only for CMS compliance/participation: additional elements may be required by local, state or federal rules or regulations.

Intraoperative Anesthesia Record

There must be an intraoperative anesthesia record or report for each patient who receives general, regional or monitored anesthesia. (§482.52(b)(2))

Current standard of care stipulates that an intraoperative anesthesia record, at a minimum, includes:
• Name and hospital identification number of the patient;
• Name(s) of practitioner who administered anesthesia, and as applicable, the name and profession of the supervising anesthesiologist or operating practitioner;
• Name, dosage, route and time of administration of drugs and anesthesia agents;
• Techniques(s) used and patient position(s), including the insertion/use of any intravascular or airway devices;
• Name and amounts of IV fluids, including blood or blood products if applicable;
• Timed-based documentation of vital signs as well as oxygenation and ventilation parameters;
• Any complications, adverse reactions, or problems occurring during anesthesia, including time and description of symptoms, vital signs, treatments rendered, and patient's response to treatment. (§482.52(b)(2))

Post-Anesthesia Evaluation

A postanesthesia evaluation must be completed and documented by an individual qualified to administer anesthesia*, no later than 48 hours after surgery or a procedure requiring anesthesia services. (§482.52(b)(3)). The qualified individual performing the postanesthesia evaluation need not be the same individual who administered the anesthetic.

The 48-hour timeframe begins at the point the patient is moved into the PACU/ICU or other designated recovery area. The evaluation can occur in the PACU, ICU or other designated recovery location. (§482.52(b)(3))

The elements of an adequate post-anesthesia evaluation should be clearly documented and include:

- Respiratory function, including respiratory rate, airway patency, and oxygen saturation;
- Cardiovascular function, including pulse rate and blood pressure;
- Mental status;
- Temperature;
- Pain;
- Nausea and vomiting; and
- Postoperative hydration. (§482.52(b)(3))

Depending on the specific surgery or procedure performed, additional types of monitoring and assessment may be necessary. (§482.52(b)(3))

Except in cases where post-operative sedation is necessary for the optimum medical care of the patient (e.g., ICU), the evaluation:

- may be done any time after the patient is sufficiently recovered from the acute administration of the anesthesia so as to participate in the evaluation.
- generally would not be performed immediately at the point of movement from the operative area to the designated recovery area. (§482.52(b)(3))

This CMS requirement for a post-anesthesia evaluation within 48 hours after anesthesia services is separate from the Joint Commission Element of Performance 4 of PC.03.01.07 that all patients need to be discharged from the recovery area or from the hospital, and in the absence of a qualified practitioner, patients may be discharged according to approved criteria.

*Qualified Anesthesia Professional:

- *A qualified anesthesiologist;*
- *A doctor of medicine or osteopathy (other than an anesthesiologist);*
- *A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;*

• *A certified registered nurse anesthetist (CRNA), who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or*

• *An anesthesiologist's assistant who is under the supervision of an anesthesiologist who is immediately available if needed* (§482.52(b)(3))

Post-Anesthesia Evaluation Note

The post-anesthesia evaluation must include the assessment of stability or satisfactory control of:

- Respiratory function: respiratory rate, airway patency, oxygen saturation
- Cardiovascular function: pulse rate, blood pressure, hydration status
- Temperature
- Mental status: patient participates in the evaluation
- Pain
- Nausea and vomiting (§482.52(b)(3))

Post-Anesthesia Evaluation Note

Date _____ Time _____

Vital signs in patient's normal range	Yes_____
Respiratory function stable; airway patent	Yes _____
Cardiovascular function and hydration status stable	Yes _____
Mental status recovered: patient participates in evaluation	Yes _____
Pain control satisfactory	Yes _____
Nausea and vomiting control satisfactory	Yes _____

Comments

_____

_____

_____ MD___CRNA___ AA__ _____

Evaluator Signature Clinician ID

Note: Designed only for CMS compliance/participation: additional elements may be required by local, state or federal rules or regulations.