

ANESTHESIA SERVICES (AS)

AS.1 ORGANIZATION

- SR.1 Anesthesia services shall be provided in an organized manner, and function under the direction of a qualified doctor of medicine or osteopathy (or other appropriately qualified practitioner in accordance with State law). The CAH is responsible for all anesthesia services administered. 485.639(c)
- SR.2 Anesthesia services shall be appropriate to the scope of the services offered. 485.639(c)

Interpretive Guidelines:

The CAH may or may not offer anesthesia/sedation services. If a CAH does provide any degree of anesthesia/sedation service to its patients, these services will be provided in an organized manner. The anesthesia/sedation services will be offered under the direction of a qualified doctor of medicine or osteopathy. This individual will be responsible for all anesthesia/sedation administered throughout the CAH.

"Anesthesia" involves the administration of a medication to produce a blunting or loss of:

- *pain perception (analgesia);*
- *voluntary and involuntary movements;*
- *autonomic function; and*
- *memory and/or consciousness,*

depending on where along the central neuraxial (brain and spinal cord) the medication is delivered.

In contrast, "analgesia" involves the use of a medication to provide relief of pain through the blocking of pain receptors in the peripheral and/or central nervous system. The patient does not lose consciousness, but does not perceive pain to the extent that may otherwise prevail.

The additional definitions below illustrate differences among the various types of anesthesia services. Not all of the definitions are considered "anesthesia." The definitions are generally based on American Society of Anesthesiologists definitions found in its most recent set of practice guidelines.¹ In addition, a visual representation of these terms is displayed on the next page.

"Anesthesia services" in a CAH subject to the anesthesia administration requirements

- *General anesthesia: a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory support 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. For example, a patient undergoing major abdominal surgery involving the removal of a portion or all of an organ would require general anesthesia in order to tolerate such an extensive surgical procedure. General anesthesia is used for those procedures when loss of consciousness is required for the safe and effective delivery of surgical services;*
- *Regional anesthesia: the delivery of anesthetic medication at a specific level of the spinal cord and/or to peripheral nerves, including epidurals and spinals and other central neuraxial nerve blocks, is used when loss of consciousness is not desired but sufficient analgesia and loss of voluntary and involuntary movement is required. Given the potential for the conversion and extension of regional to general anesthesia in certain procedures, it is*

necessary that the administration of regional and general anesthesia be delivered or supervised by the qualified practitioner.

The administration of medication via an epidural or spinal route for the purpose of analgesia, during labor and delivery, is not considered anesthesia and therefore is not subject to the anesthesia supervision requirements. However, if the obstetrician or other qualified physician attending to the patient determines that an operative delivery (i.e., C-section) of the infant is necessary, it is likely that the subsequent administration of medication is for anesthesia, as defined above, and the anesthesia supervision requirements would apply.

- *Monitored anesthesia care (MAC): anesthesia care that includes the monitoring of the patient by a practitioner who is qualified to administer anesthesia. Indications for MAC depend on the nature of the procedure, the patient's clinical condition, and/or the potential need to convert to a general or regional anesthetic. Deep sedation/analgesia is included in MAC.*
- *Deep sedation/analgesia: 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. An example of deep sedation would be a screening colonoscopy when there is a decision to use propofol, so as to decrease movement and improve visualization for this type of invasive procedure. Because of the potential for the inadvertent progression to general anesthesia in certain procedures, it is necessary that the administration of deep sedation/analgesia be delivered or supervised by a qualified practitioner as specified.*

"Anesthesia services" in a CAH NOT subject to the anesthesia administration and supervision requirements

- *Topical or local anesthesia;*
- *Minimal sedation: A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilator and cardiovascular functions are unaffected. For example, a patient undergoing an MRI or CT scan may receive minimal sedation with an oral medication to decrease the anxiety while undergoing these types of radiologic examinations;*
- *Moderate sedation/analgesia: ("Conscious Sedation"): 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. For example, a patient undergoing the reduction of a dislocated large joint (shoulder) may require this form of sedation to tolerate the procedure.*

Rescue Capacity: Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, the CAH 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.

Anesthesia services throughout the CAH (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). Areas where anesthesia services are furnished may include (but are not limited to):

- *Operating room suite(s), both inpatient and outpatient;*
- *Obstetrical suite(s);*
- *Radiology department;*

- Clinics;
- Emergency department;
- Psychiatry department (DPU);
- Outpatient surgery areas;
- Special procedures area (e.g., endoscopy suite, pain management clinic, etc.)

The CAH's medical staff establishes criteria for the qualifications for the director of the anesthesia services in accordance with State laws and acceptable standards of practice. The anesthesia service is responsible 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 that are not subject to the anesthesia administration requirements.

A well-organized anesthesia service must be integrated into the CAH's quality management system, in order to assure the provision of safe care to patients.

Surveyor Guidance:

Verify that the anesthesia/sedation services are planned and organized in a manner in which these services are continuously monitored, and appropriate to the scope of services offered.

Verify that the anesthesia/sedation services are under the direction of a doctor of medicine or osteopathy (or other appropriately qualified practitioner in accordance with State law).

In most cases, the physician responsible for the direction of these services will be an anesthesiologist. In the event it is not an anesthesiologist, review the qualifications of the physician (or other appropriately qualified practitioner in accordance with State law) responsible for these services to see that he or she is qualified to do so and has been appointed by the medical staff and governing body (or individual responsible).

Review the CAH's anesthesia policies and procedures.

- Do they address who may provide anesthesia services in each setting where such services are furnished, and are these policies in compliance with the regulations?

- Do they apply in all CAH locations where anesthesia services are provided?

Verify that anesthesia services is integrated into the CAH's quality management system oversight.

AS.2 ADMINISTRATION

Anesthesia shall only be administered by the following: 485.639(c)(1)

- SR.1 A qualified anesthesiologist or a doctor of medicine or osteopathy (other than an anesthesiologist including an osteopathic practitioner recognized under section 1101(a)(7) of the Act; 485.639(c)(1)(i), 485.639(c)(1)(ii)
- SR.2 A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law; 485.639(c)(1)(iii); 485.639(c)(1)(iv)
- SR.3 A certified registered nurse anesthetist (CRNA) as defined in 42 CFR §410.69(b), who is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; 485.639(c)(1)(v)

- SR.3a State exemption: A CAH may be exempted from the requirement for physician supervision of CRNAs if the State in which the CAH is located in accordance with State law or regulation or submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law. 485.639.(e)(1)
- SR.3b The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission. 485.639.(e)(2)
- SR.4 An anesthesiologist's assistant as defined in 42 CFR §410.69(b), if approved by State law, who is under the supervision of an anesthesiologist who is immediately available if needed. 485.639(c)(1)(vi)
- SR.5 A supervised trainee in an approved educational program, as described in §413.85 or 413.86. 485.639 (c)(1)(vii)

Interpretive Guidelines:

The CAH's medical staff will define the criteria and qualifications for those physicians who have privileges for administering anesthesia/sedation in accordance with State laws and acceptable standards of practice.

SR.1 – SR.5 defines those physicians and other practitioners who can administer anesthesia/sedation.

Anesthesia Services Policies

The medical staff bylaws or rules and regulations must include criteria for determining the anesthesia service privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges, as required for any type of anesthesia services, including those not subject to the anesthesia administration requirements.. The CAH's governing body (or individual responsible) must approve the specific anesthesia service privileges for each practitioner who furnishes anesthesia services, addressing the type of supervision, if any, required. The privileges granted must be in accordance with State law and CAH policy. The type and complexity of procedures for which the practitioner may administer anesthesia must be specified in the privileges granted to the individual practitioner.

When a CAH 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.

When a CAH permits operating practitioners to supervise CRNA administering anesthesia, the medical staff must specify in the statement of privileges for each category of operating practitioner, the type and complexity of procedures they may supervise.

For those practitioners who are privileged to administer anesthesia/sedation under the direction of an anesthesiologist, review the process and practice to ensure that the supervising anesthesiologist is immediately available to intervene as necessary.

Definition: "Immediately available" means that the anesthesiologist or operating practitioner is physically located within the area in which the anesthesia/sedation is being administered, he or she is prepared to promptly conduct hands-on intervention, and is not engaged in activities that could prevent the anesthesiologist or operating practitioner from quickly intervening.

Who May Administer Anesthesia

Topical/local anesthetics, minimal sedation, moderate sedation

The requirements concerning who may administer anesthesia do not apply to the administration of topical or local anesthetics, minimal sedation, or moderate sedation. However, the CAH must have policies and procedures, consistent with State scope of practice law, governing the provision of these types of anesthesia services. Further, the CAH must assure that all anesthesia services are provided in a safe, well-organized manner by qualified personnel.

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.*

Administration by an MD/DO/dentist/oral surgeon/podiatrist

The CAH'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. The CAH 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.

Administration by a CRNA

Unless the CAH 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.

The CAH 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. If the CAH is located in a State where law or regulation permits or where the Governor has submitted a letter to CMS attesting that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law, then a CAH may permit a CRNA to administer anesthesia without operating practitioner or anesthesiologist supervision. (A list of States that have opted out of the CRNA supervision requirement may be found at http://www.cms.hhs.gov/CFCsAndCoPs/02_Spotlight.asp)

A CRNA is defined in §410.69(b) as a "...registered nurse who: (1) is licensed as a registered professional nurse by the State in which the nurse practices; (2) meets any licensure requirements the State imposes with respect to non-physician anesthetists; (3) has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and (4) meets the following criteria: (i) has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other

certification organization that may be designated by the Secretary; or (ii) is a graduate of a program described in paragraph (3) of this definition and within 24 months after that graduation meets the requirements of paragraph (4)(i) of this definition.”

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.

An anesthesiologist's assistant is defined in §410.69(b) as a “...person who – (1) works under the direction of an anesthesiologist; (2) is in compliance with all applicable requirements of State law, including any licensure requirements the State imposes on non-physician anesthetists; and (3) is a graduate of a medical school-based anesthesiologist's assistant education program that – (A) is accredited by the Committee on Allied Health Education and Accreditation; and (B) includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.”

Surveyor Guidance:

Verify that a qualified physician is responsible for the direction of all anesthesia/sedation services offered CAH-wide. This may include, but is not limited to:

- *Surgical Services – for inpatient and outpatient surgical services (including Endoscopy and other outpatient settings);*
- *Obstetrical and Gynecological Services;*
- *Emergency Department;*
- *Medical Imaging and Nuclear Medicine Services; and,*
- *Outpatient Clinics or other settings where anesthesia/sedation services are provided.*

Review the defined scope of responsibilities or similar documentation that describes this role within the CAH. This individual will be responsible for planning, directing and monitoring all anesthesia/sedation services. The other responsibilities will encompass the implementation of staffing schedules (including on-call services).

Review the criteria and qualifications for physicians and other practitioners for attaining privileges for administering anesthesia/sedation (sample various physicians and practitioners with these privileges). This is most commonly located within the Medical Staff Bylaws or in a separate policy that governs these activities. Verify that these privileges have been granted in accordance with the physician or practitioner's scope of practice, State law, and that the criteria and qualifications include competencies, training, education and (if required) experience regarding the administration of anesthesia/sedation

Review the qualifications of individuals authorized to administer general anesthesia, regional anesthesia and monitored anesthesia, including deep sedation/analgesia to determine if they satisfy the requirements

Determine that there is documentation of current licensure or current certification status for all persons administering anesthesia.

Determine that there is documentation of current licensure and, as applicable, current certification for all persons administering anesthesia.

Determine if the state is an "opt-out state" and therefore permits CRNAs to administer anesthesia without supervision

Review the CAH's policies and procedures governing supervision of CRNA's and anesthesiologist's assistants and determine whether they comply with the regulatory requirements.

Review the qualifications of individuals authorized to furnish other anesthesia services, to determine if they are consistent with the CAH's anesthesia service policies.

AS.3 POLICIES AND PROCEDURES

SR.1 Policies on anesthesia/sedation procedures must include the delineation of pre-anesthesia and post-anesthesia responsibilities. 485.639(b)

SR.2 The policies must ensure that the following are provided for each patient:

SR.2a a pre-anesthesia or pre-sedation evaluation, to include a documented airway assessment, anesthesia risk assessment, and anesthesia drug and allergy history, by an individual qualified and privileged to administer anesthesia/sedation, immediately before or procedure requiring anesthesia services 485.639(b)(1); 485.639(b)(2)

SR.2b an intra-operative anesthesia/sedation record;

SR.2c for inpatient or outpatient surgery, a post-anesthesia evaluation for proper anesthesia recovery is completed and documented within 48 hours after surgery or prior to discharge if less than 48 hours by the individual who administers the anesthesia or, if approved by the medical staff, by any individual qualified and credentialed to administer anesthesia or as identified in AS.2 SR.3; 485.639(b)(3)

SR.2c(1) A post-anesthesia evaluation for anesthesia recovery is required and must be completed in accordance with State law and CAH policies and procedures approved by the medical staff and reflect current standards of care anytime general, regional, or monitored (this would include deep sedation/analgesia has been administered to the patient.

SR.2c(2) If the patient is discharged less than 48 hours after the procedure, completion and documentation of the post-anesthesia evaluation is still required. This is the case regardless of whether the procedure is performed on an inpatient or outpatient basis or when the patient is discharged

SR.2d for outpatient surgery, a follow-up report as defined by the medical staff.

SR.2e discharge from the CAH in the company of a responsible adult unless exempted by the clinician who performed the surgical procedure 485.639(d)

Interpretive Guidelines:

Pre-anesthesia evaluation:

A pre-anesthesia evaluation must be performed for each patient who receives general, regional or monitored anesthesia. While current practice dictates that the patient receiving moderate sedation be monitored and evaluated before, during, and after the procedure by trained practitioners, a pre-anesthesia evaluation is not required because moderate sedation is not considered to be "anesthesia", and thus is not subject to this requirement.

The evaluation must be performed by someone qualified to administer anesthesia, i.e., only by:

- A qualified anesthesiologist;