CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal **(Advance Copy)** **Date:**

SUBJECT: Revised Appendix A, Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: Clarification is provided for various provisions of 42 CFR 482.52, concerning anesthesia services.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/§482.52 Condition: Anesthesia Services
R	Appendix A/§482.52(b)(1) Standard: Delivery of Services, Pre-anesthesia Evaluation
R	Appendix A/§482.52(b)(3) Standard: Delivery of Services, Postanesthesia Evaluation

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

A-1000

(Rev.)

§482.52 Condition of Participation: Anesthesia Services

If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

Interpretive Guidelines §482.52

The provision of anesthesia services is an optional hospital service. However, if a hospital provides any degree of anesthesia service to its patients, the hospital must comply with all the requirements of this Condition of Participation (CoP).

"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.

Anesthesia exists along a continuum. For some medications there is no bright line that distinguishes when their pharmacological properties bring about the physiologic transition from the analgesic to the anesthetic effects. Furthermore, each individual patient may respond differently to different types of medications. The additional definitions below illustrate distinctions among the various types of "anesthesia services" that may be offered by a hospital. These definitions are generally based on American Society of Anesthesiologists definitions found in its most recent set of practice guidelines (*Anesthesiology 2002; 96:1004-17*).

- **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 a practitioner as specified in 42 CFR 482.52(a).

- **Monitored anesthesia care (MAC)**: anesthesia care that includes the monitoring of the patient by a practitioner who is qualified to administer anesthesia as defined by the regulations at §482.52(a). 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. 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 practitioner as specified in 42 CFR 482.52(a).

- **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. CMS, consistent with ASA guidelines, does not define moderate or conscious sedation as anesthesia (71FR 68690-1).

- **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. This is also not anesthesia.

- **Topical or local anesthesia**; *the application or injection of a drug or combination of drugs to stop or prevent a painful sensation to a circumscribed area of the body where a painful procedure is to be performed. There are generally no systemic effects of these medications, which also are not anesthesia, despite the name.*

Rescue Capacity. *As stated above,* because *the level of* sedation *of a patient receiving anesthesia services* is a continuum, it is not always possible to predict how an individual patient will respond. Further, no clear boundary exists between some of these services. 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. *(Rescue capacity is not only required as an essential component of anesthesia services, but is also consistent with the requirements under the Patients' Rights standard at §482.13(c)(2), guaranteeing patients care in a safe setting.)*

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.

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;
- Outpatient surgery areas;
- Special procedures area*s* (e.g., endoscopy suite, pain management clinic, etc.)

The anesthesia services must be under the direction of one individual who is a qualified doctor of medicine (MD) or doctor of osteopathy (DO). Consistent with the requirement at §482.12(a)(4) for it to approve medical staff bylaws, rules and regulations, the hospital's governing body approves, after considering the medical staff's recommendations, medical staff rules and regulations establishing criteria for the qualifications for the director of the anesthesia services. Such criteria must be consistent with State laws and acceptable standards of practice.

As previously mentioned, there is often no bright line, i.e., no clear boundary, between anesthesia and analgesia. This is particularly the case with moderate versus deep sedation, but also with respect to labor epidurals. However, the anesthesia services CoP establishes certain requirements that apply only when anesthesia is administered. Consequently, each hospital that provides anesthesia services must establish policies and procedures, based on nationally recognized guidelines, that address whether specific clinical situations involve anesthesia versus analgesia. (It is important to note that anesthesia services are usually an integral part of "surgery," as we have defined that term in our guidance. Because the surgical services CoP at §482.51 requires provision of surgical services in accordance with acceptable standards of practice, this provides additional support for the expectation that anesthesia services policies and procedures concerning anesthesia are based on nationally recognized guidelines.) We encourage hospitals to address whether the sedation typically provided in the emergency department or procedure rooms involves anesthesia or analgesia. In establishing such policies, the hospital is expected to take into account the characteristics of the patients served, the skill set of the clinical staff in providing the services, as well as the characteristics of the sedation medications used in the various clinical settings.

The regulation at 42 CFR 482.52(a) establishes the qualifications and, where applicable, supervision requirements for personnel who administer anesthesia. However, hospital anesthesia services policies and procedures are expected to also address the minimum qualifications and supervision requirements for each category of practitioner who is permitted to provide analgesia services, particularly moderate sedation. This expectation is consistent not only with the requirement under this CoP to provide anesthesia services in a well-organized manner, but also with various provisions of the Nursing Services CoP at §482.23 and the Medical Staff CoP at §482.22 related to qualifications of personnel providing care to patients. Taken together, these regulations require the hospital to assure that any staff administering drugs for analgesia must be appropriately qualified, and that the drugs are administered in accordance with accepted standards of practice. Specifically:

- *The Medical Staff CoP at §482.22(b)(6) requires the medical staff bylaws, "Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges."*
- *The Nursing Services CoP requires at:*
  - *§482.23(b)(5) that nursing personnel be assigned to provide care based on "the specialized qualifications and competence of the nursing staff available."*
  - *§482.23(c) that, "Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, …and accepted standards of practice." And*
  - *§482.23(c)(3) , "… If … intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty."*

Finally, it is expected that the anesthesia services policies and procedures will undergo periodic re-evaluation that includes analysis of adverse events, medication errors and other quality or safety indicators related not only to anesthesia, but also to the administration of medications in clinical applications that the hospital has determined involve analgesia rather than anesthesia. This expectation is also supported by the provisions of the Quality Assessment and Performance

Improvement (QAPI) CoP at §482.21, which requires the hospital to ensure its QAPI program, "…involves all hospital departments and services…"; "…focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors...."; "…track[s] quality indicators, including adverse patient events…"; "… use[s] the data collected to monitor the effectiveness and safety of the services and quality of care…"; and "…take[s] actions aimed at performance improvement…"

Hospitals are free to develop their own specific organizational arrangements in order to deliver all anesthesia services in a well-organized manner. Although not required under the regulation to do so, a well-organized anesthesia service would develop the hospital's anesthesia policies and procedures in collaboration with several other hospital disciplines (e.g., surgery, pharmacy, nursing, safety experts, material management, etc.) that are involved in delivering these services to patients in the various areas in the hospital.

A well-organized anesthesia service must be integrated into the hospital's required Quality Assessment/Performance Improvement program, in order to assure the provision of safe care to patients.

Survey Procedures §482.52

- Request a copy of the organizational chart for anesthesia services.

- Determine that a doctor of medicine or osteopathy has the authority and responsibility for directing all anesthesia *services* throughout the hospital.

- Look for evidence *in the director's file* of the director's appointment *privileges and qualifications, consistent with the criteria adopted by the hospital's governing body*. Review the position description. Confirm that the director's responsibilities include at least the following:

  - Planning, directing, and supervising all activities of the service;

  - Evaluating the quality and appropriateness of the anesthesia *services provided to* patient*s as part of the hospital's QAPI program*;

- *Request a copy of and review the hospital's anesthesia services policies and procedures.*

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

  - *Do they indicate the necessary qualifications that each clinical practitioner must possess in order to administer anesthesia as well as moderate sedation or other forms of analgesia?*

  - *Do they address what clinical applications are considered to involve analgesia, in particular moderate sedation, rather than anesthesia, based on identifiable national*

guidelines? What are the national guidelines that they are following and how is that documented?

- *Does the hospital have a system by which adverse events related to the administration of anesthesia and analgesia, including moderate sedation, are tracked and acted upon?*

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A-1003

(Rev.)

[The policies must ensure that the following are provided for each patient:]

§482.52(b) (1) - A pre-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, performed within 48 hours prior to surgery or a procedure requiring anesthesia services.

Interpretive Guidelines §482.52(b)(1)

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 *performed by someone qualified to administer anesthesia as specified in §482.52(a)* is not required because moderate sedation is **not** considered to be "anesthesia", and thus is not subject to *that* requirement *under this regulation*.

The evaluation must be performed by someone qualified to administer anesthesia as specified in §482.52(a), i.e., only by:

- 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.

Although §482.12 (c)(1)(i) *generally* provides broad authority to physicians to delegate tasks to other qualified medical personnel, the more stringent requirements at §482.52(b)(1) do not

permit delegation of the pre-anesthesia evaluation to practitioners who are not qualified to administer anesthesia.

The pre-anesthesia evaluation must be *completed and documented* within 48 hours *immediately* 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, as defined above, marks the end of the 48 hour time frame.

In accordance with current standards of anesthesia care, *some of the individual elements contributing to the pre-anesthesia evaluation may be performed prior to the 48-hour timeframe. However, under no circumstances may these elements be performed more than 30 days prior to surgery or a procedure requiring anesthesia services. Review of these elements must be conducted, and any appropriate updates documented, within the 48-hour timeframe.*

*T*he pre-anesthesia evaluation of the patient includes, at a minimum:

Elements that must be performed within the 48-hour timeframe:

- Review of the medical history, including anesthesia, drug and allergy history; *and*
- Interview*, if possible given the patient's condition,* and examination of the patient.

Elements that must be reviewed and updated as necessary within 48 hours, but which may also have been performed during or within 30 days prior to the 48-hour time period, in preparation for the procedure:

- 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 *data or information*, 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.

Survey Procedures §482.52(b)(1)

- Review a sample of inpatient and outpatient medical records for patients who had surgery or a procedure requiring administration of anesthesia.

- Determine whether each patient had a pre-anesthesia evaluation by a practitioner qualified to administer anesthesia.

- Determine whether each patient's pre-anesthesia evaluation included at least the elements described above.

- Determine that the pre-anesthesia evaluation was *updated, completed and documented* within 48 hours prior to the delivery of the first dose of medication(s) given for the purpose of inducing anesthesia for the surgery or a procedure requiring anesthesia services.

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A-1005
(Rev.)

[The policies must ensure that the following are provided for each patient:]

482.52(b)(3) - A postanesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, no later than 48 hours after surgery or a procedure requiring anesthesia services. The postanesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with hospital policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care.

Interpretive Guidelines §482.52(b)(3)

A postanesthesia evaluation must be completed and documented no later than 48 hours after surgery or a procedure requiring anesthesia services. The evaluation is required any time general, regional, or monitored anesthesia has been administered to the patient. While current practice dictates that the patient receiving moderate sedation be monitored and evaluated before, during, and after the procedure by trained practitioners, a postanesthesia evaluation *performed by someone qualified to administer anesthesia as specified in §482.52(a)* is not required *under this regulation.* (71 FR 68691)

The *postanesthesia* evaluation must be completed and documented by any practitioner who is qualified to administer anesthesia*; this need not be the same practitioner who administered the anesthesia to the patient*. In accordance with §482.52(a), anesthesia must be administered only by:

- 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.

Although §482.12(c)(1)(i) provides broad authority to physicians to delegate tasks to other qualified medical personnel, the more stringent requirements of §482.52(b)(3) do not permit delegation of the postanesthesia evaluation to practitioners who are not qualified to administer anesthesia.

The calculation of the 48-hour timeframe begins at the point the patient is moved into the designated recovery area. *T*he evaluation generally *should* not be performed immediately at the point of movement from the operative area to the designated recovery area. *Rather, a*ccepted standards of anesthesia care indicate that the evaluation *should* not begin until the patient is sufficiently recovered from the acute administration of the anesthesia so as to participate in the evaluation, e.g., answer questions appropriately, perform simple tasks, etc. *While t*he evaluation *should begin* in the PACU/ICU or other designated recovery location*, it may be completed after the patient is moved to another inpatient location or, for same day surgeries, if State law and hospital policy permits, after the patient is discharged, so long as it is completed within 48 hours*. *The 48 hour timeframe for completion and documentation of the postanesthesia evaluation is an outside parameter. Individual patient risk factors may dictate that the evaluation be completed and documented sooner than 48 hours. This should be addressed by hospital policies and procedures. (71 FR 68690)*.

For those patients who are unable to participate in the postanesthesia evaluation (e.g., post-operative sedation, mechanical ventilation, etc.), a postanesthesia evaluation should be completed and documented within 48 hours with notation that the patient was unable to participate. This documentation should include the reason for the patient's inability to participate as well as expectations for recovery time, if applicable. For those patients who require long-acting regional anesthesia to ensure optimum medical care of the patient, whose acute effects will last beyond the 48-hour timeframe, a postanesthesia evaluation must still be completed and documented within 48 hours. However, there should be a notation that the patient is otherwise able to participate in the evaluation, but full recovery from regional anesthesia has not occurred and is not expected within the stipulated timeframe for the completion of the evaluation.

The elements of an adequate post-anesthesia evaluation should be clearly documented and conform to current standards of anesthesia care, including:

- 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.

Depending on the specific surgery or procedure performed, additional types of monitoring and assessment may be necessary.

Survey Procedures §482.52(b)(3)

- Review a sample of medical records for patients who had surgery or a procedure requiring general, regional or monitored anesthesia to determine whether a post anesthesia evaluation was written for each patient.
- Determine whether the evaluation was conducted by a practitioner who is qualified to administer anesthesia.
- Determine whether the evaluation was *completed and documented* within 48 hours after the surgery or procedure.
- Determine whether the appropriate elements of a postanesthesia evaluation are documented in the medical record.