TITLE 844 MEDICAL LICENSING BOARD OF INDIANA

Final Rule
LSA Document #07-842(F)

DIGEST

Adds 844 IAC 5-5 to establish standards for procedures performed in office-based settings that require moderate sedation/analgesia, deep sedation/analgesia, general anesthesia, or regional anesthesia. Effective 30 days after filing with the Publisher.

844 IAC 5-5

SECTION 1. 844 IAC 5-5 IS ADDED TO READ AS FOLLOWS:

Rule 5. Standards for Procedures Performed in Office-Based Settings That Require Moderate Sedation/Analgesia, Deep Sedation/Analgesia, General Anesthesia, or Regional Anesthesia

844 IAC 5-5-1 Purpose

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 1. This rule establishes standards for procedures performed in office-based settings that require:
(1) moderate sedation/analgesia;
(2) deep sedation/analgesia;
(3) general anesthesia; or
(4) regional anesthesia.

(Medical Licensing Board of Indiana; 844 IAC 5-5-1; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-2 Application of rule

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 2. Except as provided in section 15 of this rule, this rule does not apply to:
(1) local anesthesia;
(2) topical anesthesia;
(3) superficial nerve blocks; or
(4) minimal sedation/anxiolysis.

(Medical Licensing Board of Indiana; 844 IAC 5-5-2; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-3 "Accreditation agency" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 3. As used in this rule, "accreditation agency" means a public or private organization that is approved to issue certificates of accreditation to office-based settings by the board under this rule.

(Medical Licensing Board of Indiana; 844 IAC 5-5-3; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-4 "American Society of Anesthesiologists (ASA) Physical Status Classification System" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 4. As used in this rule, "American Society of Anesthesiologists (ASA) Physical Status Classification System" refers to the following classifications:
(1) P1 - A normal healthy patient.
(2) P2 - A patient with mild systemic disease.
(3) P3 - A patient with severe systemic disease.
(4) P4 - A patient with severe systemic disease that is a constant threat to life.
(5) P5 - A moribund patient who is not expected to survive without the operation.
(6) P6 - A declared brain-dead patient whose organs are being removed for donor purposes.

(Medical Licensing Board of Indiana; 844 IAC 5-5-4; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-5 "Anesthesia" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 5. As used in this rule, "anesthesia" includes the following:
(1) Moderate sedation/analgesia.
(2) Deep sedation/analgesia.
(3) General anesthesia.
(4) Regional anesthesia.

(Medical Licensing Board of Indiana; 844 IAC 5-5-5; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-6 "Deep sedation/analgesia" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 6. (a) As used in this rule, "deep sedation/analgesia" means a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. For purposes of this rule, reflex withdrawal from a painful stimulus is not considered a purposeful response.

(b) The following are conditions that a patient under deep sedation/analgesia may experience:
(1) The ability to independently maintain ventilatory function may be impaired.
(2) Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate.
(3) Cardiovascular function is usually maintained.

(Medical Licensing Board of Indiana; 844 IAC 5-5-6; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-7 "General anesthesia" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 7. (a) As used in this rule, "general anesthesia" means a drug-induced loss of consciousness during which patients are not arousable, even by pain stimulation.

(b) The following are conditions that a patient under general anesthesia may experience:
(1) The ability to independently maintain ventilatory function is often impaired.

(2) 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.
(3) Cardiovascular function may be impaired.

(Medical Licensing Board of Indiana; 844 IAC 5-5-7; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-8 "Health care provider" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 8. As used in this rule, "health care provider" means an individual licensed or legally authorized by this state to provide health care services.

(Medical Licensing Board of Indiana; 844 IAC 5-5-8; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-9 "Immediate presence" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 9. As used in this rule, "immediate presence" means, at a minimum, that the directing practitioner must be:
(1) physically located within the office-based setting;
(2) prepared to immediately conduct hands-on intervention if needed; and
(3) not engaged in activities that could prevent the practitioner from being able to immediately intervene and conduct hands-on interventions if needed.

(Medical Licensing Board of Indiana; 844 IAC 5-5-9; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-10 "Local anesthesia" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 10. As used in this rule, "local anesthesia" means a transient and reversible loss of sensation in a circumscribed portion of the body produced by:
(1) a local anesthetic agent; or
(2) cooling a circumscribed area of the skin.
The term includes subcutaneous infiltration of an agent.

(Medical Licensing Board of Indiana; 844 IAC 5-5-10; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-11 "Minimal sedation/anxiolysis" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 11. As used in this rule, "minimal sedation/anxiolysis" means a drug-induced state during which a patient responds normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are usually not affected.

(Medical Licensing Board of Indiana; 844 IAC 5-5-11; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-12 "Moderate sedation/analgesia" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 12. (a) As used in this rule, "moderate sedation/analgesia" (also sometimes called "conscious sedation") means a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation.

(b) The following are conditions that a patient under moderate sedation/analgesia may experience:
(1) No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate.
(2) Cardiovascular function is usually maintained.

(Medical Licensing Board of Indiana; 844 IAC 5-5-12; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-13 "Office-based setting" defined

Authority: IC 25-22.5-2-7
Affected: IC 16-21-2; IC 25-22.5

Sec. 13. As used in this rule, "office-based setting" means any:
(1) facility;
(2) clinic;
(3) center;
(4) office; or
(5) other setting;
where procedures are performed that require moderate sedation/analgesia, deep sedation/analgesia, general anesthesia, or regional anesthesia. The term does not include a hospital operated by the federal government or a setting licensed under IC 16-21-2 as a hospital, ambulatory surgical center, abortion clinic, or birthing center.

(Medical Licensing Board of Indiana; 844 IAC 5-5-13; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-14 "Practitioner" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 14. As used in this rule, "practitioner" has the meaning set forth in 844 IAC 5-1-1(14).

(Medical Licensing Board of Indiana; 844 IAC 5-5-14; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-15 "Regional anesthesia" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 15. (a) As used in this rule, "regional anesthesia" means the administration of anesthetic agents to a patient to interrupt nerve impulses without the loss of consciousness and includes the following:
(1) Major conduction blocks, such as:
(A) epidural;
(B) spinal; and
(C) caudal;
blocks.
(2) Peripheral nerve blocks, such as:
(A) brachial;
(B) lumbar plexus;
(C) peribulbar; and

(D) retrobulbar;
blocks.
(3) Intravenous regional anesthesia, such as Bier blocks.

(b) Notwithstanding section 2 of this rule, a superficial nerve block or application of a local anesthetic agent in which the total dosage administered exceeds the recommended maximum dosage per body weight described in the manufacturer's package insert shall be considered regional anesthesia for purposes of this rule.

(Medical Licensing Board of Indiana; 844 IAC 5-5-15; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-16 "Rescue" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 16. As used in this rule, "rescue" means an intervention by a practitioner proficient in airway management and advanced life support. In rescuing a patient, the practitioner must:
(1) correct adverse physiologic consequences of the deeper-than-intended level of sedation, such as:
(A) hypoventilation;
(B) hypoxia; and
(C) hypotension; and
(2) return the patient to the originally intended level of sedation.

(Medical Licensing Board of Indiana; 844 IAC 5-5-16; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-17 "Superficial nerve block" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 17. As used in this rule, "superficial nerve block" means an agent placed in the proximity of any nerve or group of nerves outside of the vertebral canal to produce a loss of sensation in an anatomic or circumscribed area. For purposes of this rule, the term is limited to:
(1) ankle;
(2) metacarpal;
(3) digit; and
(4) paracervical;
blocks.

(Medical Licensing Board of Indiana; 844 IAC 5-5-17; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-18 "Topical anesthesia" defined

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 18. As used in this rule, "topical anesthesia" means a transient and reversible loss of sensation to a circumscribed area produced by an anesthetic agent applied directly or by spray to the skin or mucous membranes.

(Medical Licensing Board of Indiana; 844 IAC 5-5-18; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-19 Standards for procedures performed in office-based settings

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 19. (a) Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Practitioners intending to produce a given level of sedation must be able to rescue a patient whose level of sedation becomes deeper than initially intended. Practitioners administering deep sedation/analgesia in an office-based setting, or directing or supervising the administration of deep sedation/analgesia in an office-based setting, must be able to rescue patients who enter a state of general anesthesia. Practitioners administering moderate sedation/analgesia in an office-based setting, or directing or supervising the administration of moderate sedation/analgesia in an office-based setting, must be able to rescue patients who enter a state of deep sedation/analgesia.

(b) Practitioners administering regional anesthesia, or supervising or directing the administration of regional anesthesia, must be knowledgeable about the risks of regional anesthesia and the interventions required to correct any adverse physiological consequences that may occur in the administration of regional anesthesia.

(c) A health care provider may not administer or monitor an anesthetic agent containing alkylphenols in an office-based setting unless the health care provider is:
(1) trained in the administration of general anesthesia; and
(2) not involved in the conduct of the procedure.

(Medical Licensing Board of Indiana; 844 IAC 5-5-19; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-20 Accreditation required

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 20. After January 1, 2010, a practitioner may not perform or supervise a procedure that requires anesthesia in an office-based setting unless the office-based setting is accredited by an accreditation agency approved by the board under this rule.

(Medical Licensing Board of Indiana; 844 IAC 5-5-20; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-21 Approval of accreditation agencies; requirements

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5-1-2

Sec. 21. In approving accreditation agencies to perform accreditation of office-based settings, the board shall ensure that the certification program, at a minimum, includes standards for the following aspects of an office-based setting's operations:
(1) Anesthesia, as follows:
(A) The level of anesthesia administered shall be appropriate for the:
(i) patient;
(ii) procedure;
(iii) clinical setting;
(iv) education and training of the personnel; and
(v) equipment available.
Practitioners shall select patients for procedures in office-based settings using anesthesia by criteria, including the American Society of Anesthesiologists (ASA) Physical Status Classification System, and so document.
(B) The choice of specific anesthetic agents and techniques shall focus on providing anesthesia that will:
(i) be safe, effective, and appropriate; and
(ii) respond to the specific needs of patients while also ensuring rapid recovery to normal function with appropriate efforts to control postoperative pain, nausea, or other side effects.
(C) A health care provider administering anesthesia shall be licensed, qualified, and working within

the provider's scope of practice. In those cases in which a nonphysician provider administers the anesthesia, the provider must be:
(i) under the direction and supervision of a practitioner as required by IC 25-22.5-1-2(a)(20); or
(ii) under the direction of and in the immediate presence of a practitioner as required by IC 25-22.5-1-2(a)(13), if the provider is a certified registered nurse anesthetist.
(D) A:
(i) health care provider who administers anesthesia; and
(ii) practitioner who:
(AA) performs a procedure that requires anesthesia; or
(BB) directs or supervises the administration of anesthesia;
in an office-based setting shall maintain current training in advanced resuscitation techniques, such as advanced cardiac life support (ACLS) or pediatric advanced life support (PALS), as applicable. At least one (1) person with ACLS or PALS training should be immediately available until the patient is discharged.
(E) In addition to the health care provider performing the procedure, sufficient numbers of qualified health care providers, each working within the individual provider's scope of practice, must be present to:
(i) evaluate the patient;
(ii) assist with the procedure;
(iii) administer and monitor the anesthesia; and
(iv) recover the patient.
Other health care providers involved in the delivery of procedures in an office-based setting that require anesthesia, at a minimum, shall maintain training in basic cardiopulmonary resuscitation.
(F) Patients who have preexisting medical or other conditions who may be at particular risk for complications shall be referred to:
(i) a hospital;
(ii) an ambulatory surgical center; or
(iii) another office-based setting appropriate for the procedure and the administration of anesthesia.
(G) The practitioner administering the anesthesia, or supervising or directing the administration of anesthesia as required by clause (C), shall do the following:
(i) Perform a preanesthetic examination and evaluation or ensure that it has been appropriately performed by a qualified health care provider.
(ii) Develop the anesthesia plan or personally review and concur with the anesthesia plan if the plan has been developed by a certified registered nurse anesthetist (CRNA).
(iii) Remain physically present during the operative period and be immediately available until the patient is discharged from anesthesia care for diagnosis, treatment, and management of complications or emergencies.
(iv) Assure provision of appropriate postanesthesia care.
(H) Patient assessment shall occur throughout the preprocedure, periprocedure, and postprocedure phases. The assessment shall:
(i) address not only physical and functional status, but also physiological and cognitive status; and
(ii) be documented in the medical record.
The procedure and anesthesia shall be properly documented in the medical record.
(I) Physiologic monitoring of patients shall be appropriate for the type of anesthesia and individual patient needs, including continuous monitoring or assessment of the following:
(i) Ventilation.
(ii) Cardiovascular status.
(iii) Body temperature.
(iv) Neuromuscular function and status.
(v) Patient positioning.
(vi) Oxygenation using a quantitative technique such as pulse oximetry.
When general anesthesia is used, equipment to assess exhaled carbon dioxide must also be available.
(J) Provisions shall be made for a reliable source of the following:
(i) Oxygen.
(ii) Suction.
(iii) Resuscitation equipment.
(iv) Emergency drugs.
(2) Procedures, as follows:
(A) Procedures shall be provided by qualified health care providers in an environment that promotes

patient safety.
(B) Procedures to be undertaken shall be within the:
(i) scope of practice, training, and expertise of the health care providers; and
(ii) capabilities of the facilities.
(C) The procedure shall be of a duration and degree of complexity that will permit patients to recover and be discharged from the office-based setting in less than twenty-four (24) hours.
(D) Provisions shall be made for appropriate ancillary services on site or in another predetermined location. Ancillary services shall be provided in a safe and effective manner in accordance with accepted ethical professional practice and statutory requirements. These services include, but are not limited to:
(i) pharmacy;
(ii) laboratory;
(iii) pathology;
(iv) radiology;
(v) occupational health; and
(vi) other associated;
services.
(3) Facilities and equipment, as follows:
(A) The office-based setting shall:
(i) be clean and properly maintained and have adequate lighting and ventilation;
(ii) be equipped with the appropriate medical equipment, supplies, and pharmacological agents that are required in order to provide:
(AA) anesthesia;
(BB) recovery services;
(CC) cardiopulmonary resuscitation; and
(DD) other emergency services;
(iii) have:
(AA) appropriate firefighting equipment;
(BB) signage;
(CC) emergency power capabilities and lighting; and
(DD) an evacuation plan;
(iv) have the necessary:
(AA) personnel;
(BB) equipment; and
(CC) procedures;
to handle medical and other emergencies that may arise in connection with services provided; and
(v) comply with:
(AA) applicable federal, state, and local laws and codes and regulations, and provisions must be made to accommodate disabled individuals in compliance with the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.); and
(BB) federal and state laws and regulations regarding protection of the health and safety of employees.
(B) The space allocated for a particular function or service shall be adequate for the activities performed.
(C) In locations where anesthesia is administered, there shall be appropriate anesthesia apparatus and equipment to allow appropriate monitoring of patients. All equipment shall be maintained, tested, and inspected according to the manufacturer's specifications. Backup power sufficient to ensure patient protection in the event of an emergency shall be available. There shall be sufficient space to:
(i) accommodate all necessary equipment and personnel; and
(ii) allow for expeditious access to patients and all monitoring equipment.
(D) When anesthesia services are provided to infants and children, the required:
(i) equipment;
(ii) medications; and
(iii) resuscitative capabilities;
shall be appropriately sized for children.
(E) All equipment used in patient care, testing, or emergency situations shall be inspected, maintained, and tested:
(i) on a regular basis; and
(ii) according to manufacturers' specifications.
(F) Appropriate emergency equipment and supplies shall be readily accessible to all patient service

areas.
(G) Efforts shall be made to eliminate hazards that might lead to:
(i) slipping;
(ii) falling;
(iii) electrical shock;
(iv) burns;
(v) poisoning; or
(vi) other trauma.
(H) Procedures shall be implemented to:
(i) minimize the sources and transmission of infections; and
(ii) maintain a sanitary environment.
(I) A system shall be in place to:
(i) identify;
(ii) manage;
(iii) handle;
(iv) transport;
(v) treat; and
(vi) dispose of;
hazardous materials and wastes, whether solid, liquid, or gas.
(J) Smoking must be prohibited in all patient care areas.

(Medical Licensing Board of Indiana; 844 IAC 5-5-21; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

844 IAC 5-5-22 Practitioners requirements

Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 22. (a) A practitioner who performs a procedure that requires anesthesia in an office-based setting, or who directs or supervises the administration of anesthesia in an office-based setting, must have:
(1) admitting privileges at a nearby hospital;
(2) a transfer agreement with another practitioner who has admitting privileges at a nearby hospital; or
(3) an emergency transfer agreement with a nearby hospital.

(b) A practitioner who performs a procedure that requires anesthesia in an office-based setting, or who directs or supervises the administration of anesthesia in an office-based setting, shall ensure that a patient's informed consent for the nature and objectives of the anesthesia planned and procedure to be performed is obtained in writing before the procedure is performed. The informed consent shall be:
(1) obtained after a discussion of the risks, benefits, and alternatives; and
(2) documented in the patient's medical record.

(c) Written procedures for credible peer review to determine the appropriateness of the following shall be established and reviewed at least annually:
(1) Clinical decision making.
(2) Overall quality of care.

(d) Agreements with local emergency medical service (EMS) shall be in place for purposes of transfer of patients to the hospital in case of an emergency. EMS agreements shall be re-signed at least annually.

(e) A practitioner who performs a procedure that requires anesthesia in an office-based setting, or who directs or supervises the administration of anesthesia in an office-based setting, shall show competency by maintaining privileges at an accredited or licensed hospital or ambulatory surgical center, for the procedures they perform in the office-based setting. Alternatively, the governing body of the office-based setting is responsible for a peer review process for privileging practitioners based on nationally recognized credentialing standards.

(f) A practitioner who performs a procedure that requires anesthesia in an office-based setting, or who

directs or supervises the administration of anesthesia in an office-based setting, shall have appropriate education and training.

(Medical Licensing Board of Indiana; 844 IAC 5-5-22; filed Apr 24, 2008, 1:41 p.m.: 20080521-IR-844070842FRA)

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