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You are invited to submit comments concerning the following rules, with comments due by **February 11, 2016**:

**RULES IN CHAPTER 4731-25, Ohio Administrative Code: Office-based surgery**

Chapter 4731-25 contains the rules of the Board which deal with office-based surgery.

- Rule 4731-25-01: Definition of Terms:
- *The term “Deep sedation/analgesia” is proposed to be changed to “Monitored anesthesia care.”*
  - *The term “Moderate sedation/analgesia” is proposed to be changed to “Conscious sedation.”*
- Rule 4731-25-02: General Provisions: *Terms reflect changes in definitions discussed above.*
- Rule 4731-25-03: Standards for Surgery Using Moderate Sedation/Analgesia: *Terms reflect changes in definitions discussed above.*
- Rule 4731-25-04: Standards for Surgery Using Anesthesia Services: *Terms reflect changes in definitions discussed above.*
- Rule 4731-25-05: Liposuction in the Office Setting: *Terms reflect changes in definitions discussed above.*
- Rule 4731-25-07: Accreditation of Office Settings: *Terms reflect changes in definitions discussed above.*

Please send comments to [Sallie.Debolt@med.ohio.gov](mailto:Sallie.Debolt@med.ohio.gov) by February 11, 2016.

4731-25-01

**Definition of terms.**

As used in this chapter of the Administrative Code:

- (A) "Anesthesia services" means administration of any drug or combination of drugs with the purpose of creating ~~deep sedation/analgesia~~ monitored anesthesia care, regional anesthesia or general anesthesia. Anesthesia services shall not include the administration of topical or local anesthesia or ~~moderate sedation/analgesia~~ conscious sedation;
- (B) "Certified copy of a patient record" means a copy of the patient record with a separate statement, signed by the person making the copy and notarized, attesting that the copy is a "true and accurate copy of the complete patient record";
- (C) "~~Deep sedation/analgesia~~" Monitored anesthesia care" means 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;
- (D) "General anesthesia" means 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;
- (E) "Local anesthesia" means the injection of a drug or combination of drugs to stop or prevent a painful sensation in a circumscribed area of the body where a painful procedure is to be performed. Local anesthesia includes local infiltration anesthesia, digital blocks and pudendal blocks. Local anesthesia does not involve any systemic sedation;
- (F) "Minimal sedation (anxiolysis)" means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. "Minimal sedation" shall not include sedation achieved through intravenous administration of drugs;
- (G) "Minor surgery" means surgery that can safely and comfortably be performed under topical or local anesthesia without more than minimal oral or intramuscular preoperative sedation. Minor surgery includes, but is not limited to, surgery of the skin, subcutaneous tissue and other adjacent tissue, the incision and drainage of

superficial abscesses, limited endoscopies such as proctoscopies, arthrocentesis and closed reduction of simple fractures or small joint dislocations;

- (H) "~~Moderate sedation/analgesia~~"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. Reflex withdrawal from a painful stimulus is not a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is maintained;
- (I) "Office setting" means an office or portion thereof which is utilized to provide medical and/or surgical services to the physician's own patients. Office setting does not include an office or portion thereof licensed as an ambulatory surgical facility by the department of health pursuant to division (E)(1) of section 3702.30 of the Revised Code, a hospital registered with the department of health pursuant to section 3701.07 of the Revised Code, or an emergency department located within such a hospital;
- (J) "Regional anesthesia" means the administration of a drug or combination of drugs to interrupt nerve impulses without loss of consciousness and includes epidural, caudal, spinal, axillary, stellate ganglion blocks, regional blocks (such as axillary, bier, retobulbar, peribulbar, interscalene, subarachnoid, supraclavicular, and infraclavicular), and brachial anesthesia. Regional anesthesia does not include digital or pudendal blocks;
- (K) "Special procedure" means a diagnostic or therapeutic procedure which is not surgery which requires entering the body with instruments in a potentially painful manner, or which requires the patient to be immobile, and which requires the provision of anesthesia services. Special procedures include, but are not limited to, diagnostic or therapeutic endoscopy that explores existing channels and involves no transverse of a body wall; invasive radiologic procedures; pediatric magnetic resonance imaging; manipulation under anesthesia; or endoscopic examination with the use of general anesthesia;
- (L) "Surgery" means the excision or resection, partial or complete, destruction, incision or other structural alteration of human tissue by any means, including through the use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, relieving suffering, or for aesthetic, reconstructive or cosmetic purposes, to include, but not be limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed or an open reduction of a fracture; extraction of tissue, including premature extraction of the products of conception from the uterus; and, insertion of natural or

artificial implants. Surgery shall not include the suturing of minor lacerations;

- (M) "Topical anesthesia" means the application of a drug or combination of drugs directly or by spray to the skin or mucous membranes which is intended to produce a transient and reversible loss of sensation to a circumscribed area.
- (N) "Tumescent local anesthesia" means subcutaneous infiltration of high volumes of crystalloid fluid containing low concentrations of lidocaine and epinephrine. For purposes of this chapter of the Administrative Code, "tumescent local anesthesia" shall be considered "local anesthesia" as that term is defined in paragraph (E) of this rule.

4731-25-02

**General provisions.**

- (A) Anesthesia services in the office setting shall be provided only by physicians and osteopathic physicians licensed pursuant to Chapter 4731. of the Revised Code; podiatric physicians licensed pursuant to Chapter 4731. of the Revised Code and practicing within the scope of practice for podiatric physicians; and certified registered nurse anesthetists licensed pursuant to Chapter 4723. of the Revised Code and practicing within the scope of practice for certified registered nurse anesthetists; and only in accordance with Chapter 4731-25 of the Administrative Code.
- (B) Nothing in this chapter of the Administrative Code shall be interpreted to permit a podiatric physician to perform surgery or procedures in an office setting using general anesthesia.
- (C) Nothing in this chapter of the Administrative Code shall be interpreted to prohibit a registered nurse with the appropriate education and training from carrying out a physician's order to maintain a patient within an intensive care unit of a hospital at the level of sedation determined by the physician to be appropriate and necessary for that patient's care, so long as the patient remains within the intensive care unit with appropriate monitoring and so long as the physician's order is written in compliance with all applicable laws.
- (D) A physician or podiatric physician shall not perform on more than one patient at the same time procedures or surgery using ~~moderate sedation/analgesia~~ conscious sedation or anesthesia services.
- (E) A certified registered nurse anesthetist providing ~~moderate sedation/analgesia~~ conscious sedation or anesthesia services in the office setting shall be under the direction of a podiatric physician acting within the podiatric physician's scope of practice in accordance with section 4731.51 of the Revised Code or a physician, and, when administering anesthesia, the certified registered nurse anesthetist shall be in the immediate presence of the podiatric physician or physician. For purposes of this chapter of the Administrative Code, a physician shall not be considered to have supervised the administration and monitoring of ~~moderate sedation/analgesia~~ conscious sedation or anesthesia services if the ~~moderate sedation/analgesia~~ conscious sedation or anesthesia services were administered and monitored by a physician anesthesiologist.
- (F) "Surgery" shall not be interpreted so as to prohibit a registered nurse from performing tasks that are within the scope of practice of the registered nurse, so long as the registered nurse's activities are in accordance with Chapter 4723. of the Revised Code.

- (G) This chapter of the Administrative Code shall not apply to surgeries or special procedures in which the level of anesthesia is limited to minimal sedation as that term is defined in this chapter of the Administrative Code, or which use only local or topical anesthetic agents, and which are performed in an office setting except that liposuction procedures performed under tumescent local anesthesia shall be subject to the provisions of rules 4731-25-05 and 4731-25-06 of the Administrative Code.
- (H) Procedures or surgery utilizing ~~moderate sedation/analgesia~~ conscious sedation or anesthesia services shall be performed in the office setting only on patients who are evaluated as level P1 or P2 according to the American society of anesthesiologists physical status classification system current at the effective date of this rule.

4731-25-03

**Standards for surgery using ~~moderate sedation/analgesia~~ conscious sedation.**

(A) A physician or podiatric physician performing procedures or surgery in the office setting during which ~~moderate—sedation/analgesia~~ conscious sedation is administered shall:

- (1) Demonstrate sufficient education, training and experience needed to conform to the minimal standards of care of similar practitioners under the same or similar circumstances by meeting at least one of the following criteria:
  - (a) Holding current privileges at a local hospital accredited by the joint commission on accreditation of healthcare organizations or the American osteopathic association or at a local ambulatory surgical facility licensed by the department of health for the procedure or surgery being performed;
  - (b) Being board certified by a specialty board recognized by the American board of medical specialties or the American osteopathic association or, if a podiatric physician, is board certified by the American board of podiatric surgery; and the surgery or procedure being performed is generally recognized as being within the usual course of practice of that specialty;
  - (c) Having successfully completed a residency training program approved by the accreditation council for graduate medical education of the American medical association or the American osteopathic association or, if a podiatric physician, having successfully completed at least a twelve month residency in podiatric surgery approved by the council on podiatric medical education; and the surgery or procedure being performed is generally recognized as being within the usual course of practice of that specialty; or
  - (d) Having successfully completed a didactic course supplemented by direct hands-on, monitored experience in the surgery or procedure being performed, and the surgery or procedure being performed is generally recognized as being within the usual course of practice of the specialty of the physician.
- (2) Have current (within the immediately previous two years) advanced cardiac life support/advanced trauma life support training, or, in the case of pediatric patients under the age of thirteen, have current (within the immediately previous two years) pediatric advanced life support training.

- (3) Ensure that assisting personnel are competent to administer and monitor ~~moderate sedation/analgesia~~ conscious sedation and to manage emergencies such as loss of airway, compromise of cardiovascular functions or anaphylaxis.
  - (4) A physician or podiatric physician performing surgeries or procedures using ~~moderate sedation/analgesia~~ conscious sedation in the office setting shall:
    - (a) Hold privileges to provide ~~moderate sedation/analgesia~~ conscious sedation from a local hospital accredited by the joint commission on accreditation of healthcare organizations or the American osteopathic association or from a local ambulatory surgical facility licensed by the department of health; or
    - (b) Have documented evidence of having completed at least five hours of category I continuing medical education relating to the delivery of ~~moderate sedation/analgesia~~ conscious sedation during the current or most recent past biennial registration period, such requirement to become effective on the one-hundred-eighty-first day following the effective date of this rule.
- (B) ~~Moderate sedation/analgesia~~ Conscious sedation may be administered in the office setting by only the following:
- (1) A physician who holds privileges to provide ~~moderate sedation/analgesia~~ conscious sedation from a local hospital accredited by the joint commission on accreditation of healthcare organizations or the American osteopathic association or from a local ambulatory surgical facility licensed by the department of health;
  - (2) A certified registered nurse anesthetist who is acting under the supervision of and in the immediate presence of a physician or podiatric physician;
  - (3) A registered nurse who is acting under the supervision and in the immediate presence of a physician or podiatric physician, provided that such registered nurse shall only administer specifically prescribed doses of drugs selected by the physician or podiatric physician who shall be continuously present in the anesthetizing location during the administration of those drugs.
- (C) The person administering and monitoring the ~~moderate sedation/analgesia~~ conscious sedation shall be at all times present in the anesthetizing location with the patient and cannot be the practitioner while performing the surgery or procedure. Further,

the person administering and monitoring the moderate sedation/analgesia shall meet the training requirements of paragraph (A)(2) of this rule.

- (D) A violation of any provision of this rule, as determined by the board, shall constitute "a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

4731-25-04

**Standards for surgery using anesthesia services.**

- (A) A physician or podiatric physician performing special procedures or surgery in the office setting during which anesthesia services are provided shall:
- (1) Demonstrate sufficient education, training and experience needed to conform to the minimal standards of care of similar practitioners under the same or similar circumstances by meeting at least one of the following criteria:
    - (a) Holding current privileges at a local hospital accredited by the joint commission on accreditation of healthcare organizations or the American osteopathic association or at a local ambulatory surgical facility licensed by the department of health for the special procedure or surgery being performed;
    - (b) Being board certified by a specialty board recognized by the American board of medical specialties or the American osteopathic association or, if a podiatric physician, is board certified by the American board of podiatric surgery; and the surgery or procedure being performed is generally recognized as being within the usual course of practice of that specialty; or,
    - (c) Having successfully completed a residency training program approved by the accreditation council for graduate medical education of the American medical association or the American osteopathic association or, if a podiatric physician, having successfully completed at least a twelve month residency in podiatric surgery approved by the council on podiatric medical education; and the surgery or procedure being performed is generally recognized as being within the usual course of practice of that specialty.
  - (2) Have current (within the immediately previous two years) advanced cardiac life support/advanced trauma life support training or, in the case of pediatric patients under the age of thirteen, have current (within the immediately previous two years) pediatric advanced life support training.
  - (3) Ensure that assisting personnel are competent to administer and monitor anesthesia services and to manage emergencies.
  - (4) A physician or podiatric physician performing surgeries or procedures using anesthesia services in the office setting shall:
    - (a) Hold privileges to provide anesthesia services from a local hospital

accredited by the joint commission on accreditation of healthcare organizations or the American osteopathic association or from a local ambulatory surgical facility licensed by the department of health; or

- (b) Have successfully completed a residency training program approved by the accreditation council for graduate medical education of the American medical association or the American osteopathic association in anesthesia; or
- (c) Have documented evidence of having completed at least twenty hours of category I continuing medical education relating to the delivery of anesthesia services during the current or most recent past biennial registration period, such requirement to become effective on the one-hundred-eighty-first day following the effective date of this rule.

(B) Anesthesia services may be administered in the office setting by only the following:

- (1) A physician who holds privileges to provide anesthesia services from a local hospital accredited by the joint commission on accreditation of healthcare organizations or the American osteopathic association or from a local ambulatory surgical facility licensed by the department of health;
- (2) A physician who has successfully completed a residency training program approved by the accreditation council for graduate medical education of the American medical association or the American osteopathic association in anesthesia and who is actively and directly engaged in the clinical practice of medicine as an anesthesiologist;
- (3) A certified registered nurse anesthetist who is acting under the supervision and in the immediate presence of a physician or podiatric physician.

(C) The person administering and monitoring the anesthesia services shall be at all times present in the anesthetizing location with the patient and shall not function in any other capacity during the surgery or special procedure. Further, the person administering and monitoring the anesthesia services shall meet the training requirements of paragraph (A)(2) of this rule.

(D) Whenever general anesthesia is being administered to a patient in the office setting, the office shall have sufficient equipment and supplies to appropriately manage malignant hyperthermia.

- (E) A violation of any provision of this rule, as determined by the board, shall constitute "a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

4731-25-05

**Liposuction in the office setting.**

- (A) A physician performing liposuction in the office setting shall meet the training requirements set forth in paragraph (A) of rule 4731-25-03 of the Administrative Code and must be in compliance with this rule.
- (B) Liposuction in the office setting shall be performed in compliance with rules 4731-25-03 and 4731-25-04 of the Administrative Code as appropriate to the level of sedation being administered and in compliance with the following standards:
- (1) The cannula utilized shall be no larger than 4.5 millimeters in diameter;
  - (2) The concentration of lidocaine in the solution shall not be greater than 0.1 per cent and the total dosage of lidocaine received by the patient during the procedure shall not exceed fifty milligrams per kilogram of body weight;
  - (3) The concentration of epinephrine in the solution shall not be greater than 1.5:1,000,000 and the total dosage of epinephrine received by the patient during the procedure shall not exceed fifty micrograms per kilogram of body weight;
  - (4) Intravenous access shall be maintained if the total aspirate is less than or equal to one hundred milliliters;
  - (5) If the total aspirate is more than one hundred milliliters, an intravenous line shall be running at a rate sufficient to prevent hypovolemia and must be monitored appropriately;
  - (6) Appropriate monitoring shall be performed. Such monitoring shall include:
    - (a) Recording the baseline vital signs, including blood pressure and heart rate, both preoperatively and postoperatively.
    - (b) If more than one hundred milliliters of aspirate is to be removed, a second person who is a health care professional as that term is defined in section 2305.234 of the Revised Code and who is acting within that health care professional's scope of practice shall be continuously within the room to monitor the patient. Continuous blood pressure monitoring and cardiac monitoring with pulse oximetry shall be performed and documented; supplemental oxygen shall be available.
    - (c) Patients who receive oral anxiolytics, sedatives, narcotic analgesics, ~~moderate sedation~~ conscious sedation or anesthesia services shall be

monitored postoperatively until fully recovered and ready for discharge.

- (7) Liposuction in the office setting shall be performed only on patients who are evaluated as level P1 or P2 according to the version of the American society of anesthesiologists physical status classification system current at the effective date of this rule;
- (8) Liposuction shall not be performed in an office setting in combination with other procedures except as specifically authorized in paragraph (F) of this rule.
- (C) Liposuction performed in an office setting shall not exceed four thousand five hundred milliliters of total aspirate.
- (D) Liposuction using ~~moderate sedation/analgesia~~ conscious sedation or anesthesia services performed in an office shall be accredited in accordance with rule 4731-25-07 of the Administrative Code.
- (E) The written discharge instructions given to the patient shall include specific information concerning the symptoms of lidocaine toxicity, the period of time during which such symptoms might appear and specific instructions for the patient to follow should the patient experience such symptoms.
- (F) Nothing in this rule shall be interpreted to prohibit a physician from performing in the office setting procedures involving a focused, local small liposuction that is a routine part of the main procedure, provided that the physician complies with all other applicable rules.
- (G) A violation of any provision of this rule, as determined by the board, shall constitute "a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

4731-25-07

**Accreditation of office settings.**

- (A) No physician or podiatric physician shall perform procedures or surgery using ~~moderate sedation/analgesia~~ conscious sedation or anesthesia services in an office setting unless that office setting is accredited by an accrediting agency approved by the board, except that physicians and podiatric physicians who are performing such procedures or surgeries in office settings that are not accredited on the effective date of this rule shall apply for accreditation within eighteen months of the effective date of this rule and shall receive accreditation within three years of the effective date of this rule.
- (B) Accrediting agencies approved by the board include the following:
- (1) The joint commission on accreditation of healthcare organizations;
  - (2) The accreditation association for ambulatory health care, inc.;
  - (3) The American association for accreditation of ambulatory surgery facilities, inc.;
  - (4) The healthcare facilities accreditation program of the American osteopathic association; or,
  - (5) Any other accrediting agency that demonstrates to the satisfaction of the board that it has:
    - (a) Standards pertaining to patient care, record keeping, equipment, personnel, facilities and other related matters that are in accordance with acceptable and prevailing standards of care as determined by the board;
    - (b) Processes that assure a fair and timely review and decision on any applications for accreditation or renewals thereof;
    - (c) Processes that assure a fair and timely review and resolution of any complaints received concerning accredited facilities; and
    - (d) Resources sufficient to allow the accrediting agency to fulfill its duties in a timely manner.
- (C) A violation of paragraph (A) of this rule, as determined by the board, shall constitute "a departure from, or the failure to conform to, minimal standards of care of similar

practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code