| Agency Name: State Medical Board of Ohio |
| Regulation/Package Title: Chapter 4731-25 rules |
| Rule Number(s): 4731-25-01, 4731-25-02, 4731-25-03, 4731-25-04, 4731-25-05, 4731-25-07 |
| Date: July 31, 2017 |

**Rule Type:**

- [ ] New
- [X] Amended
- [X] 5-Year Review
- [ ] Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.
Regulatory Intent

1. Please briefly describe the draft regulation in plain language.
   Please include the key provisions of the regulation as well as any proposed amendments.

   The rules in Chapter 4731-25 set out the standards for office based surgery and/or special procedures (hereinafter “surgery”) using anesthesia services and require accreditation by one of several nationally recognized accrediting agencies.

   Rule 4731-25-01, which defines terms used in the remainder of the chapter, is proposed to be continued without changes. Please note that paragraph (K) defines the term “special procedure.” This is in keeping with the purpose of the rules in setting standards for office based surgery and those non-surgical procedures that require the patient to receive anesthesia services. A drafting error at the time of initial adopting of the rules in Chapter 4731-25 dropped the “special” throughout the Chapter 4371-25 rules. The proposed rules being filed with CSI are amended, where appropriate, to correct this drafting error by using the term “special procedure.”

   Rule 4731-25-02, which addresses general issues in office based surgery, is proposed to be amending by changing throughout the word “procedure” to the term “special procedure.”

   Rule 4731-25-03, sets forth the standards when moderate sedation/analgesia is administered as part of the surgery or special procedure. The word “procedure” is changed to “special procedure” throughout.

   Rule 4731-25-04, OAC, sets the standards for the use of anesthesia services, which are inherently more dangerous than moderate sedation/analgesia. Also the word “procedure” is changed to “special procedure.”

   Rule 4731-25-05, which focuses on office based liposuction procedure issues, is proposed to be continued without change.

   Rule 4731-25-07, OAC, which addresses office accreditation requirements, includes the change from “procedure” to “special procedure.” It is amended to incorporate new language that recognizes that the accreditation process requires a review of surgery and special procedures performed and, therefore, authorizes the physician to perform special procedures and surgery after receiving provisional accreditation for a maximum of one year while going through the accreditation process.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.
   Revised Code Section 4731.05.

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

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4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Not applicable.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

The proposed rules set standards for physicians who provide surgery in the medical office setting. The standards are based upon the level of anesthesia that will be administered for the surgery. Standards for physicians who perform surgery in the office setting are critical to the protection of the public from inadequately trained practitioners, ill-equipped facilities, and preventable anesthesia-related incidents. They specifically do not apply when the physician performs surgery under local or topical anesthesia.

Surgeries formerly performed only in a hospital setting or licensed ambulatory surgical center are now routinely performed in a physician’s office. Such surgeries may include, but are not limited to, cosmetic procedures such as breast augmentation/reduction or liposuction; colonoscopies; hernia repairs; or knee arthroscopies. Hospitals and ambulatory surgical centers have significant oversight from accrediting bodies. In addition, ambulatory surgical centers are licensed in Ohio by the Ohio Department of Health. Moreover, hospitals and ambulatory surgical centers administer a credentialing system to thoroughly review a physician’s training and competency before granting the physician the ability to perform specific medical services and then have vigorous peer review systems for review of the physician’s practice.

However, physician’s offices are not licensed in Ohio, there is no mandatory credentialing process, and no mandatory on-going review of a physician’s practice via peer review. The proposed rules are needed to protect the public from inadequately trained practitioners, ill-equipped facilities, and preventable anesthesia-related incidents when surgery or special procedures are provided in the medical office setting.

The situation is well-described by Richard D. Urman, M.D., MBA, Nathan Punwani, BA,† and Fred E. Shapiro, D.O., as follows:

*From 1995 to 2005, the number of elective procedures performed in ambulatory settings doubled to 10 million.*3 Medical practitioners in private offices perform 10%-12% of ambulatory procedures. Many office-based providers deliver care outside of their scope of practice, a trend known as “practice drift.” These practitioners often complete weekend courses, enabling them to operate outside their specialty for certain procedures. Hospitals usually do not recognize such
certifications, so the out-of-scope procedures tend to be concentrated in the office setting. As a result, office-based proceduralists are more vulnerable to practice drift and may not be fully capable of responding to complications.


6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The success of the rules in Chapter 4731-25 will be measured by the number of disciplinary actions the Medical Board takes for failure to follow the requirements for office based surgery.

Since adoption of the rules in 2004 the Medical Board has disciplined two physicians for violation of the rules. It filed charges against another physician but dismissed the charges based on a technicality.

**Development of the Regulation**

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

*If applicable, please include the date and medium by which the stakeholders were initially contacted.*

The proposed rules were distributed via email on January 15, 2016, to the medical organizations and associations, attorneys, lobbyists for medical related entities, and individuals who have indicated interest in Medical Board rule activities. The recipients include the Ohio State Medical Association; Ohio Osteopathic Association; Ohio Dermatological Association; Ohio Society of Anesthesiologists; Ohio Academy of Physician Assistants; Academy of Medicine of Cleveland and Northern Ohio; numerous physicians, including those who practice in specialties that regularly perform office-based surgery; Ohio Board of Nursing; lobbyists for a wide variety of medical related organizations; and health care systems.

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

One comment was received from the Ohio State Association of Nurse Anesthetists indicating that Rule 4731-25-07 requires the office to be accredited prior to any surgery
being performed, while the accreditation process requires the review of patient records from surgery performed at the office.

Language was accordingly added to proposed amended rule 4731-25-07 to require that a physician who wishes to perform surgery at an office that is not accredited must apply for accreditation and upon receipt of provisional accreditation may perform surgery in the office until full accreditation is received or for one year from the date of application, whichever is sooner.

During further review after the comment period, staff discovered that while the Chapter 4731-25 rules were meant to apply when "special procedures and surgery" are performed in the office setting, the much broader term "procedure" instead of "special procedure" was used throughout the rules. Therefore, all of the rules were amended to state "special procedure" instead of just "procedure."

9. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

The rules are consistent with the American College of Surgeons' Patient Safety Principles for Office-Based Surgery (See https://www.facs.org/education/patient-education/patient-safety/office-based-surgery); recommendations of the Federation of State Medical Boards' (http://www.fsmb.org/Content/Default/PDF/FSMB/Advocacy/2002_grpol_Outpatient_Surgery.pdf); and the appropriate state regulatory agencies of numerous other states.

The original drafting of the rules over several years in the early 2000s included the input of the Ohio State Medical Association, Ohio Dermatology Association, Ohio Osteopathic Association, Ohio State Association of Nurse Anesthetists, Ohio Society of Anesthesiologists, and others. The rules are not significantly amended from the original language.

10. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn’t the Agency consider regulatory alternatives?**

The Medical Board considers the safe practice of surgery in an office setting to be of paramount importance because office based surgeries are not otherwise regulated by any other state agency. Accordingly, the safety of the public was the primary driver of the regulations.

When originally drafted in 2001 – 2003, there was consideration of whether to set out more detailed standards in the rules. However, it was determined that requiring accreditation by one of several recognized accreditation agencies would provide more patient safety. The determination hinged upon the fact that the accrediting agencies are able to be proactive in their quality assurance processes while the Medical Board would only able to investigate
alleged violation of the standards specified in the rules if it received a complaint alleging violation of the rules.

11. Did the Agency specifically consider a performance-based regulation? Please explain. 

*Performance-based regulations define the required outcome, but don’t dictate the process the regulated stakeholders must use to achieve compliance.*

The rules are performance-based. The Chapter 4731-25 rules set forth the basics for the safe performance of office based surgery and the best practices associated with these surgeries based upon the level of consciousness the patient will have subsequent to the anesthesia received. The rules do not set out detailed standards but instead require the office to be accredited by one of several recognized accrediting bodies. Moreover, the rules provide numerous options by which a physician who wishes to perform office-based surgery may establish sufficient training and education in order to perform according to the minimal standards of care.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

No state agency regulates medical practices. The Medical Board is the only state agency that regulates physicians in the delivery of medical services such as surgery and special procedures.

Please note that the proposed rules apply only to physicians performing surgery on their own patients in their own medical offices. The rules are not duplicative of the ambulatory surgical centers or facilities rules promulgated by the Ohio Department of Health. Ambulatory surgical centers or facilities are healthcare facilities established for the performance of surgery and are not physician medical offices.

13. Please describe the Agency’s plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

Notice of the proposed rules in Chapter 4731-25 will be sent to licensees and interested parties and posted on the Medical Board’s website. Medical Board staff will be available to address questions that may arise.

### Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

   a. Identify the scope of the impacted business community;
Physicians who perform office based surgery constitute the business community subject to the Chapter 4731-25 rules.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

Physicians who intend to practice office based surgery must receive accreditation of the office by one of several nationally recognized accreditation organizations. Attaining accreditation involves payment of fees and the maintenance of accreditation requires the payment of fees. Properly staffing office based surgery involves compensation for qualified personnel. Medical Board licensees who fail to follow the requirements of the office based surgery rules are subject to Medical Board license discipline.

c. Quantify the expected adverse impact from the regulation.
   The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

Accreditation fees to the Joint Commission are estimated to be approximately $10,000.00. The fee charged for the required survey of the facility and processes is $3,100 per day of the survey. The fee for maintaining accreditation is approximately $6,300 based on a fee of $2,100 per each of the three-years of accreditation. (See https://www.jointcommission.org/assets/1/18/OBS_pricing-17.pdf) Internet searches of the websites for the other accreditation bodies could find no fee information.

Licensure actions against licensees who violate the rules in Chapter 4731-25 include possible actions up to and including permanent license revocation and fines and penalties not to exceed $20,000.

Proper staffing for office-based surgery requires either an anesthesiologist or a certified registered nurse anesthetist. However, there is not a requirement that either be an employee of the physician performing the office-based surgery. The Bureau of Labor Statistics reports that the mean hourly wage for an anesthesiologist in an office setting is $128.54. (See https://www.bls.gov/oes/current/oes291061.htm) The mean hourly wage for a certified registered nurse anesthetist is $75.45. (See https://www.bls.gov/oes/current/oes291151.htm)

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?
Office based surgeries can be a hazardous endeavor for the patient, and the safety of the public outweighs the adverse business impact.

**Regulatory Flexibility**

16. **Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

No. The potential consequences to the public for not following the office based surgery rules in Chapter 4731-25 are significant, including potential harm or death. Therefore, a physician whose practice falls within the “small business” category must be held to the same standards as a physician whose medical practice is not a “small business.”

17. **How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

The rules do not require a physician to submit any paperwork. Given the potential harm to the public for noncompliance with the rules, any waiver would be inappropriate.

18. **What resources are available to assist small businesses with compliance of the regulation?**

The Medical Board provides information via email blasts to licensees and posts information on its website. Where needed, guidance documents are created to explain information that is not clear. The Medical Board staff is available via telephone and email.
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, regional anesthesia or general anesthesia. Anesthesia services shall not include the administration of topical or local anesthesia or moderate sedation/analgesia;

(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" 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" 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 special 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 special procedures or surgery using moderate sedation/analgesia or anesthesia services.

(E) A certified registered nurse anesthetist providing moderate sedation/analgesia 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 or anesthesia services if the moderate sedation/analgesia 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 Special procedures or surgery utilizing moderate sedation/analgesia 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.
Standards for surgery using moderate sedation/analgesia.

(A) A physician or podiatric physician performing special procedures or surgery in the office setting during which moderate sedation/analgesia 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 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 special 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 special 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 special 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 and to manage emergencies such as loss of
airway, compromise of cardiovascular functions or anaphylaxis.

(4) A physician or podiatric physician performing surgeries or special procedures using moderate sedation/analgesia in the office setting shall:

(a) Hold privileges to provide moderate sedation/analgesia 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 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 period.

(B) Moderate sedation/analgesia may be administered in the office setting by only the following:

(1) A physician who holds privileges to provide moderate sedation/analgesia 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 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.
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 special 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 special 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 special 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.
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 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/analgnesia 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.
Accreditation of office settings.

4731-25-07

(A) No physician or podiatric physician shall perform special procedures or surgery using moderate sedation/analgesia 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, in compliance with both of the following requirements:

(1) Prior to performing special procedures or surgery in the office setting that is not accredited, the physician or podiatric physician shall file an application for accreditation with an accrediting agency listed in paragraph (B) of this rule.

(2) Upon receipt of provisional accreditation, the physician or podiatric physician may perform special procedures or surgery in the office setting in accordance with the rules in chapter 4731-25 of the Administrative Code until full accreditation is received or for one year from the date application for accreditation was filed, whichever is sooner.

(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.