

Secretary of State
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PERMANENT ADMINISTRATIVE RULES

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Date prior to or same as filing date

Oregon Medical Board

OAR Chapter 847

Agency and Division

Administrative Rules Chapter Number

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to become effective **upon filing**. Rulemaking Notice was published in the **August 2013** Oregon Bulletin.**
Date upon filing or later Month and Year

RULE CAPTION

Defines office-based procedures and clarifies provider qualifications and requirements

Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

RULEMAKING ACTION

List each rule number separately (000-000-0000)

ADOPT: OAR 847-017-0003; 847-017-0008; 847-017-0037

Secure approval of new rule numbers (Adopted or Renumbered rules) with the Administrative Rules Unit prior to filing.

AMEND: OAR 847-017-0000; 847-017-0005; 847-017-0010; 847-017-0015; 847-017-0020; 847-017-0025; 847-017-0030; 847-017-0035; 847-017-0040

REPEAL:

RENUMBER:

AMEND & RENUMBER:

Stat. Auth.: **ORS 677.265, 679.255**

Other Auth.:

Stats. Implemented: **OAR 677.060, 677.085, 677.097, 677.265**

RULE SUMMARY

The rule amendments classify levels of office-based surgeries and set forth the corresponding requirements; reorganize and add new definitions; establish a standard of practice for licensees performing office-based surgery; set forth requirements for office-based surgery facilities; clarify the assessment and informed consent procedures prior to the performance of an office-based surgery; clarify the requirements for patient medical records; expand the emergency care and transfer protocol requirements; require reporting of specified office-based surgical adverse events; and contain general grammar and language housekeeping changes.

Kathleen Haley, Executive Director

Authorized Signer

Printed name

Date

*With this original, file one photocopy of certificate, one paper copy of rules listed in Rulemaking Actions, and electronic copy of rules. **The Oregon Bulletin is published the 1st of each month and updates rules found in the OAR Compilation. For publication in Bulletin, rule and notice filings must be submitted by 5:00 pm on the 15th day of the preceding month unless this deadline falls on a weekend or legal holiday, when filings are accepted until 5:00 pm on the preceding workday.

ARC 930-2005

OREGON ADMINISTRATIVE RULES
CHAPTER 847, DIVISION 017 – OREGON MEDICAL BOARD
PROPOSED RULES CHANGES
FINAL REVIEW – OCTOBER 2013

The proposed rule amendments classify levels of office-based surgeries and set forth the corresponding requirements, reorganize and add new definitions, establish a standard of practice for licensees performing office-based surgery, set forth requirements for where a licensee may perform office-based surgery, clarify the assessment and informed consent procedures prior to the performance of an office-based surgery, clarify the requirements for patient medical records, expand the emergency care and transfer protocol requirements, require reporting of specified office-based surgical adverse events, and contain general grammar and language housekeeping changes.

847-017-0000

Preamble

Licensees of the Oregon Medical Board providing office-based invasive procedures are accountable for the welfare and safety of their patients **and responsible for ensuring that the performance of these procedures meets the standard of care.**

Stat. Auth.: ORS 677.265

Stats. Implemented: ORS 677.085, 677.097, 677.265

847-017-0003

Classification of Office-Based Surgery

Office-based surgeries are classified by complexity.

(1) Level I are minor surgical procedures performed without anesthesia or under topical, local, or minor conduction block anesthesia not involving drug-induced alteration of consciousness, other than minimal sedation utilizing preoperative oral anxiolytic medications.

(a) The licensee must pursue continuing medical education in the field for which the services are being provided and in the proper drug dosages, management of toxicity, and hypersensitivity to local anesthetic and other drugs.

(b) The licensee must maintain active basic life support (BLS) certification.

(2) Level II are minor or major surgical procedures performed under moderate sedation/analgesia, such as oral, parenteral, or intravenous sedation or under analgesic or dissociative drugs.

(a) In addition to the requirements in section (1) of this rule, the licensee must:

(A) Maintain board certification or board eligibility in a specialty recognized by the American Board of Medical Specialties (ABMS), the American Osteopathic Association's Bureau of Osteopathic Specialists (AOA-BOS), the American Board of Podiatric Medicine (ABPM), the American Board of Podiatric Surgery (ABPS) or the National Commission on Certification of Physician Assistants (NCCPA), or

(B) Obtain fifty hours each year of accredited continuing medical education (CME) relevant to the Level II surgical procedures to be performed in the office-based facility. This requirement may not be satisfied with cultural competency CME or other CME that is only generally relevant to the licensee's practice.

(b) The licensee must be certified in advanced resuscitative techniques and must be on site at all times when patients are under the effects of anesthetic.

(c) The patient must be appropriately monitored as defined in 847-017-0005.

(3) Level III are major surgical procedures that require deep sedation/analgesia, general anesthesia, or regional blocks, and require support of vital bodily functions.

(a) In addition to the requirements in section (1) of this rule, the licensee must:

(A) Have staff privileges to perform the same procedure in a hospital or ambulatory surgical center, or

(B) Maintain board certification or board eligibility in an appropriate specialty recognized by the ABMS, the AOA-BOS, the ABPM, the ABPS or the NCCPA.

(b) The licensee must be certified in advanced resuscitative techniques and must be on site at all times when patients are under the effects of anesthetic.

(c) The patient must be appropriately monitored as defined in 847-017-0005.

(d) The licensee performing the procedure may not administer anesthesia other than additional local anesthesia and may not be primarily responsible for monitoring anesthesia during the procedure.

(4) Procedures or treatments involving the injection of a medication or substance for cosmetic purposes are the practice of medicine and must be performed as an office-based surgical procedure.

(5) Lipoplasty involving the removal of 500 cc or less volume of supernatant fat may be performed as a Level I surgical procedure. Office-based lipoplasty involving more than 500 cc volume of supernatant fat must be performed as a Level II or Level III surgical procedure.

(a) The performance of lipoplasty in an office-based setting may not result in the removal of more than 5% of total body weight or more than 4500 cc volume of supernatant fat removed, whichever is less.

(b) The licensee may not use more than 55 mg/kg of Lidocaine or 70 mcg/kg of epinephrine for tumescent anesthesia. The concentration of epinephrine in tumescent solutions may not exceed 1.5 mg/L.

(6) The following may not be performed in an office-based surgical facility:

(a) Procedures that may result in blood loss of more than 4% of the estimated blood volume in a patient with a normal hemoglobin;

(b) Procedures requiring intracranial, intrathoracic, or abdominal cavity entry; and

(c) Joint replacement procedures.

Stat. Auth.: ORS 677.265

Stats. Implemented: ORS 677.265

847-017-0005

Definitions

For the purpose of these rules, the following terms are defined:

(1) **“Ambulatory surgical center” has the meaning given in ORS 442.015. Nothing in OAR Chapter 847, Division 17 is meant to exempt a physician’s office from the licensure requirements in ORS 441.015 if the office meets the definition of an ambulatory surgical center in ORS 442.015. A physician’s office that meets the definition of an ambulatory surgical center must comply with OAR Chapter 333, Division 76.** [“Advanced Cardiac Life

Support (ACLS) trained” means that a practitioner has successfully completed and maintains certification with advanced resuscitative techniques appropriate to the practitioner’s field of practice. For example, for those practitioners treating adult patients, training in advanced cardiac life support (ACLS) is appropriate; for those treating children, training in pediatric advanced life support (PALS) or advanced pediatric life support (APLS) is appropriate.]

[~~(2) “Anesthesia, continuum of sedation:” Level of Sedation — Responsiveness Airway — Spontaneous Ventilation — Cardiovascular Function:~~

~~(A) Conscious (Moderate) Sedation/ Analgesia — Purposeful response to verbal or tactile stimulation — No intervention required — Adequate — Usually maintained;~~

~~(B) Deep Sedation/Analgesia — Purposeful response following repeated or painful stimulation 1 — Intervention may be required — May be inadequate — Usually maintained;~~

~~(C) General Anesthesia — Unarousable, even with painful stimulus — Intervention often required — Frequently inadequate — May be impaired. Reflex withdrawal from a painful stimulus is not considered a purposeful response.]~~

~~[(3) "Anesthetic agent" means any drug or combination of drugs administered with the purpose of creating conscious (moderate) sedation, deep sedation, regional anesthesia, or general anesthesia.]~~

~~[(4) "Adverse incident" means an untoward event occurring at any time within seven (7) days of any surgery, special procedure, or the administration of anesthesia agent(s) in an office setting.]~~

~~[(5) "Basic Life Support (BLS)" trained means that a practitioner has successfully completed and maintains certification in cardiopulmonary resuscitation. BLS training includes teaching the use of an automated external defibrillator (AED).]~~

(2) ~~[(6)]~~ "Board" means the Oregon Medical Board.

(3) "Certified in advanced resuscitative techniques" means that the individual is currently certified either with Advanced Cardiac Life Support (ACLS) for adults or Pediatric Advanced Life Support (PALS) or Advanced Pediatric Life Support (APLS) for children.

(4) "Deep sedation/analgesia" means the administration of a drug or drugs that produces depression of consciousness during which patients cannot be easily aroused and only 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.

(5) “Facility” has the same definition as “office.”

(6) “General anesthesia” means a drug-induced loss of consciousness during which patients are not able to be aroused, 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.

(7) “Health care personnel” means any person, licensed or unlicensed, who is directly related to the provision of health care services including, but not limited to, a physician assistant, nurse practitioner, certified registered nurse anesthetist, registered nurse, licensed practical nurse or medical assistant.

(8) “Hospital” has the meaning given in ORS 442.015.

(9) “Licensee” means an individual holding a valid license issued by the Board.

(10) “Lipoplasty” means any instrumentation under the skin through incisions for the reduction of subcutaneous volume. This includes, but is not limited to, liposuction, laser lipolysis, suction assisted lipectomy and liposculpture.

(11) [(7)] "Local anesthesia" means the administration of **a drug or drugs** [an agent] that produces a transient and reversible loss of sensation in a circumscribed portion of the body.

~~[(8) “Major conduction block anesthesia” means the injection of a local anesthetic agent in close proximity to a specific nerve or nerves to stop or prevent a painful sensation in a region of the body. Major conduction anesthesia includes, but it not limited to, all blocks and approaches to the brachial or lumbar plexus, sub arachnoid blocks, epidural and caudal blocks and regional intravenous blocks.]~~

(12) “Minimal sedation” (anxiolysis) means the administration of a drug or drugs that produces a state of consciousness that allows the patient to tolerate unpleasant medical procedures while responding normally to verbal commands. Cardiovascular or respiratory function is unaffected and defensive airway reflexes remain intact.

(13) “Minor conduction block” means the injection of local anesthesia to stop or prevent a painful sensation in a circumscribed area of the body (that is, infiltration or local nerve block), or the block of a nerve by direct pressure and refrigeration. Minor conduction blocks include but are not limited to, intercostal, retrobulbar, paravertebral, peribulbar, pudendal, and sciatic nerve and ankle blocks.

~~[(9) “Minor procedures” means surgery that can safely and comfortably be performed under topical or local anesthesia without more than minimal oral or intramuscular preoperative sedation. Minor procedures include, but are 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.]

(14) “Moderate sedation/analgesia” means the administration of a drug or drugs that produces depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by a light tactile stimulation. Reflex withdrawal from painful stimulation is NOT considered a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate.

(15) [(40)] "Monitor[ing]" means [~~continuous or~~] regular visual observation **and continuous physiologic measurement** of the patient [ç] as deemed appropriate by the level of sedation or recovery [ç] ~~and the use of~~ **using appropriate** instruments to measure, display, and record physiologic values, such as heart rate, blood pressure, respiration, [~~and~~] oxygen saturation, **and end tidal capnography.**

(16) [(41)] "Office" means a location, **other than a hospital or ambulatory surgical center,** at which medical or surgical services are rendered [~~and which is not subject to a jurisdiction and licensing requirements of the Oregon Department of Human Services~~].

(17) [(42)] "Office-based surgery" means the performance of any surgical or other invasive procedure requiring anesthesia, analgesia, or sedation, including cryosurgery, [~~and~~] laser surgery **and the use of lasers that penetrate the skin,** which results in patient stay of less than 24

consecutive hours [7] and is performed by a **licensee** [~~practitioner~~] in a location other than a hospital [~~-, diagnostic treatment center, free-standing~~] **or** ambulatory **surgical** [~~surgery~~] center.

[~~(13) "Governing body of the facility" means the licensee or group of licensees who establish the office-based surgery facility.~~]

(18) "PARQ conference" means a Procedures, Alternatives, Risks and Questions conference, in which the licensee performing the procedure explains in general terms the procedure or treatment to be undertaken, any alternative procedures or methods of treatment, and any risks to the procedure or treatment and allows questions from the patient.

Stat. Auth.: ORS 677.265

Stats. Implemented: ORS 677.085, 677.097, 677.265

847-017-0008

Standard of Practice

A licensee performing office-based surgery must have received appropriate training and education in the safe and effective performance of all surgical procedures performed in the office. Such training and education should include:

(1) Indications and contraindications for each procedure;

(2) Identification and selection of appropriate patients for each procedure;

(3) Identification of realistic and expected outcomes of each procedure;

(4) Selection, maintenance, and utilization of products and equipment;

(5) Appropriate technique for each procedure, including infection control and safety precautions;

(6) Pharmacological intervention specific to each procedure;

(7) Identification of complications and adverse reactions for each procedure;

(8) Standards in surgical medical care; and

(9) Emergency procedures to be used in the event of:

(a) Complications;

(b) Adverse reactions; or

(c) Equipment malfunction.

Stat. Auth.: ORS 677.265

Stats. Implemented: ORS 677.265

847-017-0010

[Patient Safety] Licensee Use of Office-Based Surgical Facilities

A licensee performing office-based surgery must ensure that the facility meets standards to ensure patient safety.

(1) **Facilities where office-based surgeries are performed must comply with all federal and state laws and regulations that affect the practice.** [~~Offices in which only minor procedures are performed do not require accreditation or the presence of ACLS-certified providers.~~]

(2) **Facilities where Level II or Level III office-based surgeries are performed must be accredited by an appropriate, Board-recognized accreditation agency, including the American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF), the Accreditation Association of Ambulatory Health Care (AAAHC), the Joint Commission, or the Institute for Medical Quality (IMQ). Facilities accredited by the Oregon Medical**

Association (OMA) prior to January 1, 2013, will continue to be recognized as accredited facilities until the accreditation period expires. [The facility in which the office based

surgeries or procedures are performed must be appropriately equipped and maintained to ensure patient safety through accreditation by an appropriate, Board-recognized, national or state organization, i.e., the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF), the American Osteopathic Association (AOA), the Institute for Medical Quality (IMQ), the Oregon Society of Oral Maxillofacial Surgeons (OSOMS), or the Oregon Medical Association (OMA). Effective August 1, 2007, for an office or facility in which office based surgeries are already being performed, the office or facility must become accredited within two years, or by August 1, 2009. When] Licensees of the Board [start] performing office-based procedures in a new **or existing** [office or] facility, **must ensure that** [the new office or] facility [must be] **is** accredited within one year of the start date of the office-based procedures being performed **or the date these rules are adopted, whichever is later**. During the period of time the facility is in the accreditation process, the facility will make changes to come into compliance with the Administrative Rules in this Division.

[~~(3) The licensee must be able to demonstrate qualifications and competency for the procedures performed by becoming or being board certified and maintaining board certification by a member of the American Board of Medical Specialties (ABMS). Alternatively, the governing body of the office facility is responsible for a peer review process for privileging physicians based on nationally recognized credentialing standards.~~]

~~[(4) The licensee must insure that a practitioner administering deep sedation or anesthesia and/or monitoring the patient shall not play an integral role in performing the procedure.]~~

~~[(5) At least one physician who is currently certified in advanced resuscitative techniques appropriate for the patient age group (e.g., ACLS, PALS or APLS) must be present or immediately available with age-size appropriate resuscitative equipment until the patient has met the criteria for discharge from the facility. In addition, other medical personnel with direct patient contact must at a minimum be trained in Basic Life Support (BLS).]~~

(3) ~~[(6) The governing body of the facility]~~ **Facilities where Level II or Level III office-based surgeries are performed must provide** [is responsible for providing] health care **personnel** [providers] who have appropriate education and training for administration **and monitoring** of moderate sedation/analgesia, deep sedation/analgesia, [or] general anesthesia **or regional block**.

(4) ~~[(7)]~~ A licensee who holds a MD or DO degree as well as a DDS (Doctor of Dental Surgery) or DMD (Doctor of Dental Medicine) degree and is an active member of the Oregon Society of Oral Maxillofacial Surgeons (OSOMS) may perform maxillofacial procedures in a facility approved by the OSOMS and function under the administrative rules of the Oregon Board of Dentistry, OAR chapter 818, division 026. For all procedures that are not oral maxillofacial in nature, licensees with medical and dental licenses must follow rules laid out in OAR chapter 847, Division 017.

Stat. Auth.: ORS 677.265, 679.255

Stats. Implemented: ORS 677.060, 677.265, 679.255

847-017-0015

Selection of Procedures and Patients

(1) The licensee who performs the ~~[surgical procedure]~~ **office-based surgery** ~~[and/]~~ or anesthetic **is responsible for the safety of the patient.**

(a) The licensee must evaluate and document the condition of the patient and the potential risks associated with the proposed treatment plan; ~~[-and]~~

(b) The licensee must be satisfied that the procedure to be undertaken is within the scope of practice of the health care **personnel** ~~[providers]~~, the capabilities of the facility and the condition of the patient; **and** ~~[-]~~

(c) The licensee must examine the patient immediately before the procedure to evaluate the risks of the procedure and the risks of anesthesia if applicable.

(2) Informed consent for the nature and objectives of the anesthesia planned and **office-based** surgery to be performed must be in writing and obtained from **the** patient[s] before the **office-based surgery** ~~[procedure]~~ is performed. Informed consent is only to be obtained after a ~~[discussion of the risks, benefits, and alternatives]~~ **PARQ conference** and must be documented in the medical record. **The informed consent must include a disclosure of the licensee's**

specialty board certification through the ABMS, the AOA-BOS, the ABPM, the ABPS or the NCCPA or lack thereof. The requirement for written informed consent is not necessary for minor Level I procedures limited to the skin and mucosa.

Stat. Auth.: ORS 677.265

Stats. Implemented: ORS 677.085, 677.097, 677.265

847-017-0020

Patient Medical Records

(1) A legible, complete, comprehensive and accurate medical record must be maintained for each patient evaluated or treated. The record must include:

- (a) Identity of the patient;
- (b) History and physical, diagnosis and plan;
- (c) Appropriate lab, x-ray or other diagnostic reports;

(d) Documentation of the PARQ conference;

(e) Disclosure of the licensee's specialty board certification through the ABMS, the AOA-BOS, the ABPM, the ABPS or the NCCPA or lack thereof;

(f) ~~[(d)]~~ Appropriate preanesthesia evaluation;

(g) ~~[(e)]~~ Narrative description of procedure;

(h) Intraoperative and postoperative monitoring;

(i) ~~[(f)]~~ Pathology reports;

~~[(g) Procedure code; and]~~

(j) ~~[(h)]~~ Documentation of the outcome and the follow-up plan; **and** ~~[-]~~

(k) Provision for continuity of post-procedure care.

(2) If the **office-based surgery is a Level II or Level III surgical procedure** ~~[nature of the surgery is such that analgesia/sedation, major conduction blockage, conscious (moderate) sedation, or general anesthesia are provided]~~, the patient record must include a separate anesthetic record that contains documentation of anesthetic provider, procedure, and technique employed. This must include the type of anesthesia used, drugs (type and dose) and fluids administered during the procedure, patient weight, level of consciousness, estimated blood loss,

duration of procedure, and any complication or unusual events related to the procedure or anesthesia.

~~[(3) The medical records must contain documentation of the intra-operative and post-operative monitoring required.]~~

(3) [(4)] The patient record must document if tissues and other specimens have been submitted for histopathologic diagnosis.

~~[(5) Provision for continuity of post-operative care must be documented in each patient's medical chart.]~~

(4) ~~[(6) Procedures must be established to assure]~~ **The licensee must ensure that the facility has specific and current protocols in place for** patient confidentiality and security of all patient data and information.

Stat. Auth.: ORS 677.265

Stats. Implemented: ORS 677.085, 677.097, 677.265

847-017-0025

Discharge Evaluation

The licensee performing the procedure is responsible for the determination that the patient is safe to be discharged from the office after the procedure.

Stat. Auth.: ORS 677.265

Stats. Implemented: ORS 677.085, 677.097, 677.265

847-017-0030

Emergency Care and Transfer Protocols

[The licensee is responsible for insuring that, in the event of an anesthetic, medical or surgical complication or emergency, all office personnel are familiar with a written documented] **In facilities where Level II or Level III office-based surgeries are performed, the licensee must ensure that a written plan is in place for the provision of emergency medical care as well as the safe and** timely [and safe] transfer of patients to a nearby hospital **should hospitalization be necessary.** [This plan must include arrangements for emergency medical services and appropriate escort of the patient to the hospital.]

(1) Age-appropriate emergency supplies, equipment, and medication should be provided in accordance with the scope of surgical and anesthesia services provided at the licensee's office.

(2) All office personnel must be familiar with the documented plan for arranging emergency medical services and the safe and timely transfer of patients to a nearby hospital and must be able to take necessary actions. If cardiopulmonary resuscitation (CPR) is instituted, the plan must include immediate contact with emergency medical services.

Stat. Auth.: ORS 677.265

Stats. Implemented: ORS 677.085, 677.097, 677.265

847-017-0035

Quality Assessment

(1) Office-based surgical practices must develop a system of quality assessment that effectively and efficiently strives for continuous quality improvement.

(2) Documentation of **complications and** adverse incident review must be available.

Stat. Auth.: ORS 677.265

Stats. Implemented: ORS 677.085, 677.097, 677.265

847-017-0037

Reporting Requirement

(1) Licensees performing office-based surgery must report the following complications and adverse incidents to the Board within ten business days of the event if the complication occurred within 30 days of the procedure:

(a) Surgical related death;

(b) Emergency transfer of the surgical patient to the hospital;

(c) Anesthetic or surgical event requiring cardiopulmonary resuscitation (CPR); and

(d) Unscheduled hospitalization related to the office-based surgery.

(2) Licensees performing or intending to perform office-based surgery must report any restriction, limitation, loss or denial of privileges in a hospital or accredited outpatient facility within ten business days of the restriction, limitation, loss or denial of privileges.

(3) The Board will review reports made under this rule to determine whether an investigation is necessary.

Stat. Auth.: ORS 677.265

Stats. Implemented: ORS 677.415

847-017-0040

Facility Administration and Equipment

The [~~office facility must document~~] **licensee must ensure** that specific and current arrangements are in place for obtaining laboratory, radiological, pathological and other ancillary services as may be required to support the surgical and/or anesthetic procedures undertaken.

Stat. Auth.: ORS 677.265

Stats. Implemented: ORS 677.085, 677.097, 677.265