### **OREGON ADMINISTRATIVE RULES**

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### **CHAPTER 847 BOARD OF MEDICAL EXAMINERS**

#### DIVISION 17 OFFICE-BASED SURGERY OR PROCEDURES

#### § 847-017-0000 Preamble

Licensees of the Board of Medical Examiners providing office-based invasive procedures are accountable for the welfare and safety of their patients.

## § 847-017-0005 Definitions

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

- (1) "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).
- (6) "Board" means the Oregon Board of Medical Examiners.
- (7) "Local anesthesia" means the administration of 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 is not limited to, all blocks and approaches to the brachial or lumbar plexus, sub-arachnoid blocks, epidural and caudal blocks and regional intravenous 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.
- (10) "Monitoring" means continuous or regular visual observation of the patient (as deemed appropriate by the level of sedation or recovery) and the use of instruments to measure, display, and record physiologic values, such as heart rate, blood pressure, respiration, and oxygen saturation.
- (11) "Office" means a location 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.
- (12) "Office-based surgery" means the performance of any surgical or other invasive procedure requiring anesthesia, analgesia, or sedation, which results in patient stay of less than 24 consecutive hours, and is performed by a practitioner in a location other than a hospital, diagnostic treatment center, or free-standing ambulatory surgery center.
- (13) "Governing body of the facility" means the licensee or group of licensees who establish the office-based surgery facility.

## § 847-017-0010 Patient Safety

- (1) Offices in which only minor procedures are performed do not require accreditation or the presence of ACLS certified providers.
- (2) 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) 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 office or facility, the new office or facility must be accredited within one year of the start date of the office-based procedures being performed. 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).
- (6) The governing body of the facility is responsible for providing healthcare providers who have appropriate education and training for administration of moderate sedation/analgesia, deep sedation/analgesia or general anesthesia.

# § 847-017-0015 Selection of Procedures and Patients

(1) The licensee who performs the surgical procedure and/or anesthetic must evaluate and document the condition of the patient and the potential risks associated with the proposed treatment plan, and be satisfied that the procedure to be undertaken is within the

scope of practice of the health care providers, the capabilities of the facility and the condition of the patient.

(2) Informed consent for the nature and objectives of the anesthesia planned and surgery to be performed must be in writing and obtained from patients before the procedure is performed. Informed consent is only to be obtained after a discussion of the risks, benefits, and alternatives and must be documented in the medical record.

## § 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) Appropriate preanesthesia evaluation;
- (e) Narrative description of procedure;
- (f) Pathology reports;
- (g) Procedure code; and
- (h) Documentation of the outcome and the follow-up plan.
- (2) If the 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 intraoperative and postoperative monitoring required.
- (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.

(6) Procedures must be established to assure patient confidentiality and security of all patient data and information.

# § 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.

## § 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 plan for the timely and safe transfer of patients to a nearby hospital. This plan must include arrangements for emergency medical services and appropriate escort of the patient to the hospital.

## § 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 adverse incident review must be available.

### § 847-017-0040 Facility Administration and Equipment

The office facility must document 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.