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OFFICE BASED SURGERY RULES
MEDICAL QUALITY ASSURANCE COMMISSION

WAC 246-919-650 Office-Based Surgery Standards for Professional Conduct.

(1) Purpose. To promote and ensure consistent standards, continuing competency, and patient safety, the Medical Quality Assurance Commission establishes the following regulations for those physicians who perform surgical procedures and use analgesia or sedation in office-based settings.

(2) Definitions. The following terms used in this section shall have the same meanings set forth in this section unless the text clearly indicates otherwise:

(a) "Commission" - ~~means~~ the Medical Quality Assurance Commission.

(b) "Office-based surgery" - ~~means~~ any surgery or invasive medical procedure requiring analgesia or sedation, including but not limited to local infiltration for tumescent liposuction, performed in a location other than a hospital, a hospital-associated surgical center, or an ambulatory surgical facility licensed under RCW 70.230.

(c) "Minimal sedation" - ~~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 includes unsupplemented oral and intramuscular pre-operative medications.

(d) "Moderate Sedation or Analgesia" - ~~means~~ a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by tactile stimulation. No interventions are required to maintain a

patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

(e) "Deep sedation or 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.

(f) "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.

(g) "Major Conduction Anesthesia" - ~~means~~ the administration of a drug or combination of drugs to interrupt nerve impulses without loss of consciousness, such as epidural, caudal, or spinal anesthesia, lumbar or brachial plexus blocks, and intravenous regional anesthesia. Major conduction anesthesia does not include isolated blockade of small peripheral nerves, such as digital nerves.

~~(h) "Conscious sedation credentialed" means~~ - ~~the practitioner has completed a continuing medical education course in conscious sedation or has relevant training in a residency training program or has similar privileges granted by a hospital medical staff.~~

(h~~i~~) "Physician" - ~~means~~ an individual licensed under RCW 18.71.

(3) Application of Rules.

(a) These rules apply to physicians practicing in a singleindependently or in a group setting who perform office-based surgery employing one or more of the following levels of sedation or anesthesia:

(i) Moderate sedation or analgesia, and/or

(ii) Deep sedation or analgesia; and/or

(iii) Major conduction anesthesia.

(b) These rules do not apply to physicians who

(i) Perform surgery and medical procedures that require only minimal analgesia and sedation (anxiolysis), or infiltration of local anesthetic around peripheral nerves;.

(ii) Perform surgery in an ambulatory surgical facility licensed under RCW 70.230;.

(iii) Perform surgery utilizing general anesthesia.; Facilities where physicians do procedures involving general anesthesia and, thus, are regulated by the rules on Ambulatory Surgical Facilities in WAC 246-xxx (to be covered under proposed licensing rule **Chapter 246-XXX Ambulatory Surgical Facilities)**

(iv) Performerformractice Ooral and Mmaxillofacial Ssurgery, provided the physician is licensed both as a physician and surgeon under RCW 18.71 and as a dentist under RCW 18.32, who hold both an MD and DDS, who and complyies with Dental Quality Assurance Commission (DQAC) requirementsregulations, who and holds a valid General Anesthesia Permit, and who practices within the scope of his/her specialty.

(4) Certification or compliance with certification standards. Within 180 calendar days of the effective date of these rules, a physician who performs procedures covered by these

rules is required to ensure that the facility in which the procedures are performed is appropriately equipped and maintained to ensure patient safety through certification or accreditation in good standing from one of the following:

(a) The Centers for Medicare and Medicaid Services;

(b) The Accreditation Association for Ambulatory Health Care;

(c) The American Association for Accreditation of Ambulatory Surgery Facilities; or

(d) The Joint Commission.

(5) Competency: An office-based surgery physician must be able to demonstrate qualifications and competency for the procedures being performed. Examples of such qualifications include completion of a continuing medical education course in conscious sedation, relevant training in a residency training program, or having privileges for conscious sedation granted by a hospital medical staff. At least one physician who is currently certified in advanced resuscitative techniques appropriate for the patient age group (e.g., ACLS, PALS or APLS~~-should we define these terms in our definitions section?~~)) must be present or immediately available with age-size-appropriate resuscitative equipment throughout the procedure and until the patient has met the criteria for discharge from the facility.

(6) Assessment and management of sedation:

(a) Sedation is a continuum. Depending on the patient's response to drugs, the drugs administered, and the dose and timing of drug administration, it is possible that a deeper level of sedation will be produced than initially intended.

(b) Physicians intending to produce a given level of sedation should be able to "rescue" patients who enter a deeper level of sedation than intended.

(b) If a patient unintentionally enters into a deeper level of sedation than planned, the patient must be returned to the lighter level of sedation as quickly as possible, while closely monitoring the patient to ensure the airway is patent, the patient is breathing, and that oxygenation, the heart rate and blood pressure are within acceptable values.

(c) ~~Presence of anesthesiologist or anesthetist. If g~~General or major conduction anesthesia ~~is to~~may not be utilized unless the facility is ~~,~~ regulated by rules on Ambulatory Surgical Facilities in WAC 246-xxx, and an anesthesiologist or certified registered nurse anesthetist is~~must be~~ present.

(7) Separation of surgical and monitoring functions. The appropriately licensed practitioner administering ~~deep~~ sedation and/or monitoring the patient shall not play any ~~integral~~ role in performing, or assisting with, the surgical procedure, nor shall the surgeon play a primary role in sedating and/or monitoring the patient concurrent with performing the surgical procedure.

(8) Emergency Care and Transfer Protocols. An office-based surgery physician must ensure that in the event of a 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. The plan must include arrangements for emergency medical services and appropriate escort of the patient to the hospital.

(9) Medical record. An office-based surgeon must maintain Aa legible, complete, comprehensive and accurate medical record ~~must be maintained~~ for each patient.

(a) The medical record must include: (i) Identity of the patient; (ii) History and physical, diagnosis and plan; (iii) Appropriate lab, x-ray or other diagnostic reports; (iv)

Appropriate preanesthesia evaluation; (v) Narrative description of procedure; (vi) Pathology reports; -and (vii) Documentation of the outcome and the follow-up plan.

(b) When moderate or deep sedation, or major conduction anesthesia is provided, the patient record must include a separate anesthetic record that contains documentation of the type of sedation/anesthesia used, drugs (name 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 sedation/anesthesia.

(c) The medical records must contain documentation, at regular intervals, of information obtained from intraoperative and postoperative monitoring.

(d) The medicalpatient record must document which, if any, tissues and other specimens have been submitted for histopathologic diagnosis.

(e) The medical record must document Pprovision for continuity of post-operative care must be documented in the patient's medical chart.

(109) Reporting of Death or Significant Complication. If a death, or other life-threatening complication, or permanent injury occurs as a consequence of a procedure performed in the office facility, during or immediately after the procedure, or within 30 days from when the procedure was performed, the surgeon involved must submit a written report to the Commission within thirty days of the incident.

Thise written report must include the following:

(a) Name, age, and address of the patient.

(b) Name of the surgeon and all other personnel present during the incident.

(c) Address of the facility or office where the incident took place.

(d) Description of surgical procedure.

(e) Description of the type of sedation or anesthetic being utilized at the time of the incident.

(fe) An anesthetic record or pertinent vital sign monitoring form, including Dnames and dosages, i of any, of drugs administered to the patient.

(gf) A narrative description of the incident including approximate times, and the evolution of symptoms and untoward events.

(hg) Any Aadditional information which the Commission may require or request.

(110) Unprofessional conduct for office-based surgery. The commission will address complaints of unprofessional conduct and allegations of violations of these rules pursuant to the Medical Practice Act, RCW 18.71 and the Uniform Disciplinary Act, RCW 18.130.