WAC 246-922-650 Safe and effective analgesia and anesthesia administration in office-based settings. (1) Purpose. The purpose of this rule is to promote and establish consistent standards, continuing competency, and to promote patient safety. The podiatric medical board establishes the following rule for physicians licensed under chapter 18.22 RCW who perform surgical procedures and use analgesia or sedation in office-based settings. This rule does not apply to any office-based procedures performed with the use of general anesthesia.

(2) Definitions. The following terms used in this subsection apply throughout this rule unless the context clearly indicates otherwise:

(a) "Board" means the podiatric medical board.

(b) "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.

(c) "General anesthesia" means a state of unconsciousness intentionally produced by anesthetic agents, with absence of pain sensation over the entire body, in which the patient is without protective reflexes and is unable to maintain an airway. Sedation that unintentionally progresses to the point at which the patient is without protective reflexes and is unable to maintain an airway is not considered general anesthesia.

(d) "Local infiltration" means the process of infusing a local anesthetic agent into the skin and other tissues to allow painless wound irrigation, exploration and repair, and other procedures.

(e) "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.

(f) "Minimal sedation" or "analgesia" 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 is limited to oral or intramuscular medications, or both.

(g) "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.

(h) "Office-based surgery" means any surgery or invasive medical procedure requiring analgesia or sedation, performed in a location other than a hospital, or hospital-associated surgical center licensed under chapter 70.41 RCW, or an ambulatory surgical facility licensed under chapter 70.230 RCW.

(i) "Physician" means a podiatric physician licensed under chapter 18.22 RCW.

(3) Exemptions. This rule does not apply to physicians when:

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

(b) Performing surgery in a hospital, or hospital-associated surgical center licensed under chapter 70.41 RCW, or an ambulatory surgical facility licensed under chapter 70.230 RCW;

(c) Performing surgery using general anesthesia. General anesthesia cannot be a planned event in an office-based surgery setting. Facilities in which physicians perform procedures in which general anesthesia is a planned event are regulated by rules related to hospitals, or hospital-associated surgical centers licensed under chapter 70.41 RCW, or ambulatory surgical facilities licensed under chapter 70.230 RCW.

(4) Application of rule. This rule applies to physicians practicing independently or in a group setting who perform office-based surgery employing one or more of the following levels of sedation or anesthesia:

(a) Moderate sedation or analgesia; or

(b) Deep sedation or analgesia; or

(c) Major conduction anesthesia below the ankle.

(5) Accreditation or certification. Within three hundred sixty-five calendar days of the effective date of this rule, a physician who performs a procedure under this rule must ensure that the procedure is performed in a facility that is appropriately equipped and maintained to ensure patient safety through accreditation or certification from one of the following:

(a) The Joint Commission (JC);

(b) The Accreditation Association for Ambulatory Health Care (AAAHC);

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

(d) The Centers for Medicare and Medicaid Services (CMS).

(6) Presence of an anesthesiologist or anesthetist. For procedures requiring spinal or major conduction anesthesia above the ankle, a physician authorized under chapter 18.71 or 18.57 RCW or a certified registered nurse anesthetist authorized under chapter 18.79 RCW must administer the anesthesia. Under RCW 18.22.035 (4)(b), podiatrists shall not administer spinal anesthetic or any anesthetic that renders the patient unconscious.

(7) Qualifications for administration of sedation and analgesia shall include:

(a) Completion of a continuing medical education course in conscious sedation; or

(b) Relevant training in a residency training program; or

(c) Having privileges for conscious sedation granted by a hospital medical staff.

(8) At least one licensed health care practitioner currently certified in advanced resuscitative techniques appropriate for the patient age group (e.g., advanced cardiac life support (ACLS), pediatric advanced life support (PALS) or advanced pediatric life support (APLS)) 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.

(9) Sedation assessment and management.

(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) Licensed health care practitioners intending to produce a given level of sedation should be able to "rescue" patients who enter a deeper level of sedation than intended.

(c) If a patient enters into a deeper level of sedation than planned, the licensed health care practitioner must return the patient 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.

(10) Separation of surgical and monitoring functions.

(a) The physician performing the surgical procedure must not provide the anesthesia or monitoring.

(b) The licensed health care practitioner, designated by the physician to administer intravenous medications and monitor the patient who is under moderate sedation, may assist the operating physician with minor, interruptible tasks of short duration once the patient's level of sedation and vital signs have been stabilized, provided that adequate monitoring of the patient's condition is maintained. The licensed health care practitioner who administers intravenous medications and monitors a patient under deep sedation or analgesia must not perform or assist in the surgical procedure.

(11) Emergency care and transfer protocols. A physician performing office-based surgery must ensure that in the event of a complication or emergency:

(a) All office personnel are familiar with a written and documented plan to timely and safely transfer patients to an appropriate hospital.

(b) The plan must include arrangements for emergency medical services and appropriate transfer of the patient to the hospital.

(12) Medical record. The physician performing office-based surgery must maintain a legible, complete, comprehensive and accurate medical record 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, if relevant;

(vii) Documentation of which, if any, tissues and other specimens have been submitted for histopathologic diagnosis;

(viii) Provision for continuity of post-operative care; and

(ix) Documentation of the outcome and the follow-up plan.

(b) When moderate or deep sedation, or major conduction anesthesia is used, the patient medical record must include a separate anesthesia record that documents:

(i) Type of sedation or anesthesia used;

(ii) Drugs (name and dose) and time of administration;

(iii) Documentation at regular intervals of information obtained from the intraoperative and post-operative monitoring;

(iv) Fluids administered during the procedure;

(v) Patient weight;

(vi) Level of consciousness;

(vii) Estimated blood loss;

(viii) Duration of procedure; and

(ix) Any complication or unusual events related to the procedure or sedation/anesthesia.

[Statutory Authority: RCW 18.22.015 and 18.130.050. WSR 11-01-141, § 246-922-650, filed 12/21/10, effective 1/21/11.]