



PROPOSED RULE MAKING

CR-102 (June 2004)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: Department of Health- Board of Osteopathic Medicine and Surgery

- Preproposal Statement of Inquiry was filed as WSR 07-16-141 ; or
- Expedited Rule Making--Proposed notice was filed as WSR _ ; or
- Proposal is exempt under RCW 34.05.310(4).

- Original Notice
- Supplemental Notice to WSR 10-04-066
- Continuance of WSR

Title of rule and other identifying information: (Describe Subject)

WAC 246-853-650 adding a new section for safe and effective analgesia and anesthesia administration in office-based settings (Supplemental).

Hearing location(s): Pacific NW University of Health Sciences
111 University Parkway, Iron Horse Lodge
Yakima, Washington 98901

Date: September 17, 2010

Time: 9:00 a.m.

Submit written comments to:

Name: Erin Obenland, Program Manager
Address: PO Box 47852
Olympia, Washington 98504-7852
Website: <http://www3.doh.wa.gov/policyreview/>
fax (360) 236-2406 by (date) 09/03/2010

Assistance for persons with disabilities: Contact

Erin Obenland by 09/03/2010

TTY (800) 833-6388 or () 711

Date of intended adoption: 09/17/2010

(Note: This is **NOT** the **effective** date)

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

The purpose of the proposed supplemental rule is to establish consistent standards for osteopathic physicians who administer sedation in an office-based surgery setting (OBS). The Board of Osteopathic Medicine and Surgery (board) is proposing the following amendments to the standards in the original proposal: definition of "local infiltration", definition of office-based surgery, exemptions, facility accreditation and certification, competency requirements, Advanced Cardiac Life Support requirements, sedation assessment and management requirements, and separation of surgical and monitoring functions.

Reasons supporting proposal:

The board made changes to the rules based on comments received by stakeholders and changes made by the Medical Quality Assurance Commission to OBS rules for allopathic physicians. Rules are needed to establish enforceable standards to reduce the risk of substandard care, inappropriate anesthesia, and serious complications by osteopathic physicians in OBS settings.

Statutory authority for adoption:

RCW 18.57.005; RCW 18.130.050

Statute being implemented:

Chapter 18.57 RCW

Is rule necessary because of a:

- Federal Law? Yes No
 - Federal Court Decision? Yes No
 - State Court Decision? Yes No
- If yes, CITATION:

DATE 08/04/10

NAME (type or print)
Blake Maresh

SIGNATURE

TITLE
Executive Director

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: August 04, 2010

TIME: 10:59 AM

WSR 10-16-155

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:

None

Name of proponent: (person or organization)
Surgery

Department of Health - Board of Osteopathic Medicine and

- Private
 Public
 Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Erin Obenland	310 Israel Road SE, Tumwater, WA 98501	(360) 236-4945
Implementation....Erin Obenland	310 Israel Road SE, Tumwater, WA 98501	(360) 236-4945
Enforcement.....Erin Obenland	310 Israel Road SE, Tumwater, WA 98501	(360) 236-4945

Has a small business economic impact statement been prepared under chapter 19.85 RCW?

Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name:

Address:

phone

fax

e-mail

No. Explain why no statement was prepared.

A small business economic impact statement was not prepared. The proposed rule would not impose more than minor costs on businesses in an industry.

Is a cost-benefit analysis required under RCW 34.05.328?

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name: Erin Obenland, Program Manager

Address: Board of Osteopathic Medicine and Surgery

PO Box 47852

Olympia, WA 98504-7852

phone (360) 236-4945

fax (360) 236-2406

e-mail erin.obenland@doh.wa.gov

No: Please explain:

NEW SECTION

WAC 246-853-650 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 board of osteopathic medicine and surgery establishes the following rule for physicians licensed under this chapter who perform surgical procedures and use anesthesia, analgesia or sedation in office-based settings.

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

(a) "Board" means the board of osteopathic medicine and surgery.

(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 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, including procedures such as retrobulbar or periorbital ocular blocks only when performed by a board eligible or board certified ophthalmologist. It does not include procedures in which local anesthesia is injected into areas of the body other than skin or muscle where significant cardiovascular or respiratory complications may result.

(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 maintained.

(h) "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, 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 an osteopathic physician licensed under chapter 18.57 RCW.

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

(a) Performing surgery and medical procedures that require only minimal sedation (anxiolysis), or infiltration of local anesthetic around peripheral nerves. Infiltration around peripheral nerves does not include infiltration of local anesthetic agents in an amount that exceeds the manufacturer's published recommendations.

(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. 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.

(d) Performing oral and maxillofacial surgery, and the physician:

(i) Is licensed both as a physician under chapter 18.57 RCW and as a dentist under chapter 18.32 RCW;

(ii) Complies with dental quality assurance commission regulations;

(iii) Holds a valid:

(A) Moderate sedation permit; or

(B) Moderate sedation with parenteral agents permit; or

(C) General anesthesia and deep sedation permit; and

(iv) Practices within the scope of his or her specialty.

(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.

(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 and in good standing 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);
- (d) The Centers for Medicare and Medicaid Services (CMS); or
- (e) In lieu of accreditation or certification by one of the above-listed entities, facilities limiting office-based surgery to abortions or abortion-related services may be accredited or certified by either the Planned Parenthood Federation of America or the National Abortion Federation.

(6) Competency. When an anesthesiologist or certified registered nurse anesthetist is not present, the physician performing office-based surgery and using a form of sedation defined in subsection (4) of this section must be competent and qualified both to perform the operative procedure and to oversee the administration of intravenous sedation and analgesia.

(7) Qualifications for administration of sedation and analgesia may 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) Resuscitative preparedness. 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) If an anesthesiologist or certified registered nurse anesthetist is not present, a physician 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 physician 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. A physician who returns a patient to a lighter level of sedation in accordance with this subsection (c) does not violate subsection (10) of this section.

(10) Separation of surgical and monitoring functions.

(a) The physician performing the surgical procedure must not administer the intravenous sedation, or monitor the patient.

(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 escort 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 postoperative 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 intraoperative and postoperative 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.

