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**
☐ **Continuance of WSR**

Title of rule and other identifying information: (Describe Subject)
New WAC 246-853-650 - adding a new section for office-based surgery standards

Hearing location(s): St. Francis Hospital
34515 9th Avenue South
Federal Way, Washington 98003

Date: March 19, 2010 Time: 9:00 a.m.

Date of intended adoption: 03/19/2010
(Note: This is **NOT** the **effective** date)

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) 03/05/2010

Assistance for persons with disabilities: Contact
Erin Obenland by 03/05/2010
TTY (800) 833-6388 or () 711

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
Rules are needed to establish consistant standards for osteopathic physicians who administer sedation in an office-based setting. The proposed rule will help promote patient safety in an office-based surgery (OBS) setting by defining types of sedation that may be used, requiring compliance with certification standards, by requiring them to demonstrate qualifications and competency, requiring one provider is currently certified in advanced resuscitative techniques, return patients who enter a deeper level of sedation than intended to a lighter level of sedation as quickly as possible, separate surgical and monitoring functions, create written emergency protocols and maintain legible, complete and accurate medical records.

Reasons supporting proposal:
The Board of Osteopathic Medicine and Surgery (board) is proposing this rule because currently there is no direct regulation for office-based surgery settings. Engrossed Substitute HB 1414 (2009) amended RCW 18.57.005 and allows the board to adopt rules governing the administration of sedation and anesthesia. Rules are needed to establish enforceable standards to reduce the risk of substandard care, inappropriate anesthesia, infections, and serious complications by osteopathic physicians in an office-based surgery setting.

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 01/29/2010

NAME (type or print)
Blake Maresh

SIGNATURE

TITLE
Executive Director

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: January 29, 2010
TIME: 4:50 PM

WSR 10-04-066

(COMPLETE REVERSE SIDE)

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

None

Name of proponent: (person or organization) Department of Health - Board of Osteopathic Medicine and Surgery

☐ 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: Department of Health
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 Office-based surgery standards. (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 those physicians licensed under this chapter who perform surgical procedures and use 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 patent is without protective reflexes and is unable to maintain an airway is not considered general anesthesia.

(d) "Local infiltration" means the process of infusing local anesthetic agent into the skin and other tissues to allow painless wound irrigation, exploration and repair, foreign puncture, 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 unsupplemented oral and intramuscular medications.

(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 licensed hospital, hospital-associated surgical center, or ambulatory surgical facility.

(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.

(b) Performing surgery in a licensed hospital, a hospital-associated surgical center, or an ambulatory surgical facility.

(c) Performing surgery using general anesthesia. General anesthesia cannot be a planned event in an office-based surgery setting. Facilities where physicians do procedures involving general anesthesia are regulated by rules related to licensed hospitals, hospital-associated surgical centers, and ambulatory surgical facilities.

(d) Performing oral and maxillofacial surgery, 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 their specialty.

(4) Application of rules. 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 one hundred eighty 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 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); or

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

(6) Competency. A physician performing office-based surgery using a form of sedation or anesthesia in subsection (4) of this section must be competent and qualified to perform the operative procedure and to provide sedation and analgesia.

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

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

(b) Relevant training in a residency training program;

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

(8) Resuscitative preparedness. At least one provider who is 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) Physicians 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 unintentionally enters into a deeper level of sedation than planned, the provider 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 performing the anesthesia or monitoring 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 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;

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

(viii) Provision for continuity of postoperative care;

(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.