

WSR 22-21-129

PROPOSED RULES

DEPARTMENT OF HEALTH

(Board of Osteopathic Medicine and Surgery)

[Filed October 18, 2022, 5:41 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 21-11-025.

Title of Rule and Other Identifying Information: WAC 246-853-650 Safe and effective analgesia and anesthesia administration in office-based settings. The board of osteopathic medicine and surgery (board) is proposing rule amendments to remain consistent with the recent Washington medical commission (WMC) updates and best practices.

Hearing Location(s): On December 2, 2022, at 9:00 a.m. The board will hold a virtual public hearing, without a physical meeting space. This promotes social distancing and the safety of the citizens of Washington state.

Register in advance for this Zoom webinar https://us02web.zoom.us/webinar/register/WN_c4Spj75mQfSTVSl0a0I9FA.

After registering, you will receive a confirmation email containing information about joining the webinar.

Date of Intended Adoption: December 2, 2022.

Submit Written Comments to: Becky McElhiney, P.O. Box 47852, Olympia, WA 98504-7852, email <https://fortress.wa.gov/doh/policyreview>, fax 360-236-2850, by November 23, 2022.

Assistance for Persons with Disabilities: Contact Becky McElhiney, phone 360-236-4766, fax 360-236-2901, TTY 711, email osteopathic@doh.wa.gov, by November 23, 2022.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The board is proposing updates to align with best practices. The proposed rule updates mirror the updates made by WMC. The amended rules would benefit the public's health by ensuring participating providers are informed and regulated by current national industry and best practice standards.

Reasons Supporting Proposal: WMC recently updated their rules regarding the provision of safe and effective analgesia and anesthesia administration in office-based surgical settings. The proposed rule amendments align the current rules with amendments made by WMC to clarify best practice expectations. These changes include clarifying definitions, exemption while performing surgery under general anesthesia, exemption for anesthesia in a dental office, criteria for approval of an accrediting entity for facilities, and required resuscitation techniques. The board works to remain consistent with WMC rules, as osteopathic physicians and allopathic physicians regularly provide similar care in the same settings. The proposed rule updates mirror the updates made by WMC.

Statutory Authority for Adoption: RCW 18.57.005 and 18.130.050.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Department of health, board of osteopathic medicine and surgery, governmental.

Name of Agency Personnel Responsible for Drafting, Implementation, and Enforcement: Becky McElhiney, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-4766.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Becky McElhiney, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-236-4766, fax 360-236-2901, TTY 711, email osteopathic@doh.wa.gov.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(4).

Explanation of exemptions: The proposed amendments do not impact businesses.

Scope of exemption for rule proposal:

Is fully exempt.

October 18, 2022

Alex Sobel, DO

Chairperson

OTS-3304.3

AMENDATORY SECTION (Amending WSR 11-01-117, filed 12/17/10, effective 1/17/11)

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 chapter 18.57 RCW who perform surgical procedures and use anesthesia, analgesia or sedation in office-based settings.

(2) Definitions. The ~~((following terms used))~~ definitions in this subsection apply throughout this ~~((rule))~~ section unless the ~~((text))~~ context clearly ~~((indicates))~~ requires 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 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, and cardiovascular function may be impaired. Sedation that unintentionally progresses to the point at which the ~~((patient))~~ 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 in-

jected 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, intranasal, or intramuscular medications (~~(~~r~~ 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, including, but not limited to, local infiltration for tumescent liposuction, performed in a location other than a hospital (~~(~~r~~)~~) 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)~~) utilizing or administering general anesthesia. Facilities in which physicians administer general anesthesia or perform procedures in which general anesthesia is a planned event are regulated by rules related to a hospital (~~(~~s~~)~~) or hospital-associated surgical center (~~(~~s~~)~~) licensed under chapter 70.41 RCW, (~~(~~r~~)~~) an ambulatory surgical (~~(~~facilities~~)~~) facility licensed under chapter 70.230 RCW, or a dental office under WAC 246-853-655.

(d) Administering deep sedation or general anesthesia to a patient in a dental office under WAC 246-853-655.

(e) 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)~~) their 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) 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) Planned Parenthood Federation of America or the National Abortion Federation, for facilities limited to office-based surgery for abortion or abortion-related services.)~~ an accrediting entity approved by the board.

(b) The board may approve an accrediting entity that demonstrates to the satisfaction of the board that it has all of the following:

(i) Standards pertaining to patient care, recordkeeping, equipment, personnel, facilities and other related matters that are in accordance with acceptable and prevailing standards of care as determined by the board;

(ii) Processes that assure a fair and timely review and decision on any applications for accreditation or renewals thereof;

(iii) Processes that assure a fair and timely review and resolution of any complaints received concerning accredited or certified facilities; and

(iv) Resources sufficient to allow the accrediting entity to fulfill its duties in a timely manner.

(c) A physician may perform procedures under this rule in a facility that is not accredited or certified, provided that the facility has submitted an application for accreditation by a board-approved accrediting entity, and that the facility is appropriately equipped and maintained to ensure patient safety such that the facility meets the accreditation standards. If the facility is not accredited or certified within one year of the physician's performance of the first procedure under this rule, the physician must cease performing procedures under this rule until the facility is accredited or certified.

(d) If a facility loses its accreditation or certification and is no longer accredited or certified by at least one board-approved entity, the physician shall immediately cease performing procedures under this rule in that facility.

(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; ~~((e))~~

(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. Certification in advanced resuscitative techniques includes, but is not limited to, advanced cardiac life support (ACLS), pediatric advanced life support (PALS), or advanced pediatric life support (APLS).

(9) Sedation ~~((7))~~ 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))~~ (a) 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" a patient ~~((s))~~ who enters a deeper level of sedation than intended.

~~((e))~~ (b) 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 ~~((7))~~ and blood pressure are within acceptable values. A physician who returns a patient to a lighter level of sedation in accordance with this subsection ~~((e))~~ (9) (b) 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 all of the following:

(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) The type of sedation or anesthesia used;

(ii) (~~Drugs (name and dose)~~) Name, dose, and time of administration of drugs;

(iii) Documentation at regular intervals of information obtained from the 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.

[Statutory Authority: RCW 18.57.005 and 18.130.050. WSR 11-01-117, § 246-853-650, filed 12/17/10, effective 1/17/11.]