PROPOSED RULE MAKING

CR-102 (June 2012)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

Agency: Department of Health- Medical Quality Assurance Commission

☒ **Preproposal Statement of Inquiry was filed as WSR** 16-20-025 **; or**
☐ **Expedited Rule Making--Proposed notice was filed as WSR _ ; or**
☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).**

☒ **Original Notice**
☐ **Supplemental Notice to WSR**
☐ **Continuance of WSR**

Title of rule and other identifying information: (Describe Subject)
WAC 246-919-601--Safe and effective analgesia and anesthesia administration in office-based surgical settings. The Medical Quality Assurance Commission (commission) is proposing amendments to modernize, clarify, and streamline requirements for physicians performing office-based surgery in facilities accredited or certified by a commission-approved accrediting entity to ensure patient safety.

Hearing location(s): Educational Service District 123
3924 West Court Street
Pasco, WA 99301

Date: 6/28/17 Time: 3:00 PM

Date of intended adoption: 06/28/2017
(Note: This is **NOT** the **effective** date)

Submit written comments to:
Name: Daidria Underwood
Address: PO Box 47866
Olympia, WA 98504-7866
e-mail: https://fortress.wa.gov/doh/policyreview
fax (360) 236-4626 by (date) 06/21/2017

Assistance for persons with disabilities: Contact
Daidria Underwood by 06/23/2017
TTY (800) 833-6388 or () 711

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
The purpose of the proposal is to clarify and update requirements for physicians performing office-based surgery in facilities that are accredited or certified and properly equipped and maintained to ensure patient safety. The proposal would allow the commission flexibility in a rapidly-changing landscape to add or delete accrediting entities from an internal list without going through a rulemaking process giving physicians more options when selecting a facility. The proposal also establishes commission criteria for approving accrediting entities; clarifies when a physician may perform procedures in a facility that is in the process of applying for accreditation; and requires a physician to immediately cease performing procedures in a facility if it loses its accreditation.

Reasons supporting proposal:
The proposal updates the rule to ensure patient safety by: (1) offering more avenues for physicians to prove their facilities meet patient safety standards; (2) creating an efficient internal review of accrediting entities seeking commission approval to give physicians more options when seeking accredited facilities to perform surgery in; (3) clarifying commission criteria for becoming an approved accrediting entity; (4) permitting physicians to perform surgery in a facility seeking accreditation; (5) prohibiting physicians from performing surgery in facilities that have lost accreditation.

Statutory authority for adoption:
RCW 18.71.017

Statute being implemented:
RCW 18.71.017

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

DATE 05/23/2017

NAME (type or print)
Melanie de Leon

SIGNATURE Melanie de Leon

TITLE
Executive Director

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: May 23, 2017
TIME: 11:20 AM

WSR 17-11-118

(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) Medical Quality Assurance Commission

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting.....	Daidria Underwood	111 Israel RD SE, Tumwater, WA 98501	(360) 236-2727
Implementation....	Melanie de Leon	111 Israel RD SE, Tumwater, WA 98501	(360) 236-2755
Enforcement.....	Melanie de Leon	111 Israel RD SE, Tumwater, WA 98501	(360) 236-2755

Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?

☐ 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: Daidria Underwood
Address: PO Box 47866
Olympia, WA 98504-7866

phone (360) 236-2727
fax (360) 236-2795
e-mail daidria.underwood@doh.wa.gov

☐ No: Please explain:

AMENDATORY SECTION (Amending WSR 10-16-109, filed 8/2/10, effective 9/2/10)

WAC 246-919-601 Safe and effective analgesia and anesthesia administration in office-based surgical settings. (1) Purpose. The purpose of this rule is to promote and establish consistent standards, continuing competency, and to promote patient safety. The medical quality assurance commission 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 context clearly indicates otherwise:

(a) "Commission" means the medical quality assurance commission.

(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, 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" 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, including, but not limited to, local infiltration for tumescent liposuction, performed in a loca-

tion 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 individual licensed under chapter 18.71 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 utilizing general anesthesia. Facilities in which physicians perform procedures in which general anesthesia is a planned event are regulated by rules related to hospital or hospital-associated surgical center licensed under chapter 70.41 RCW, or an ambulatory surgical facility licensed under chapter 70.230 RCW.

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

(i) Is licensed both as a physician under chapter 18.71 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) 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;~~

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

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

~~(d) The Centers for Medicare and Medicaid Services; 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 commission.

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

(i) Standards pertaining to patient care, recordkeeping, equipment, personnel, facilities and other related matters that are in ac-

cordance with acceptable and prevailing standards of care as determined by the commission;

(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 commission-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 commission-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;

(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., ACLS, PALS or 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" a patient who enters 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, 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) The 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 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.