



Medical Quality Assurance Commission
WAC 246-919-601 – Safe and effective analgesia and anesthesia
administration in office-based surgical settings.
Allopathic Physicians
Rule changes effective September 28, 2017

Following a June 28, 2017 public hearing, the Medical Quality Assurance Commission (commission) amended the current rules, WAC 246-919-601, regarding Safe and effective analgesia and anesthesia administration in office-based surgical settings. The final rulemaking order was filed with the Code Reviser's Office on August 28, 2017, as WSR #17-13-032. These changes will become effective on September 28, 2017.

The adopted rule clarifies and updates requirements for allopathic physicians performing office-based surgery in facilities that are accredited or certified by accrediting entities approved by the commission. The adopted rule eliminates the list of accrediting entities in rule and instead will allow the commission the ability to add or delete accrediting entities based on criteria established in the adopted rule for approving accrediting entities. This will also allow the commission to post on their website and disseminate to providers and stakeholders a current list of approved entities whenever the list is amended. The rule also clarifies when a physician may perform procedures in a non-accredited facility that is actively seeking accreditation, and identifies the physician's responsibilities should the facility not maintain their accreditation.

Included with this notification is the final rulemaking document (CR-103) that was filed with the Code Reviser's Office, which contains the rulemaking order and the new rule text. Also attached is the summary of comments received from the public.

This message contains three attachments:

1. A summary of the comments received and the commission's responses to those comments.

2. The final rulemaking document (CR-103P) that was filed with the Office of the Code Reviser, which contains the rulemaking order.
3. The new rule text.

The laws and procedures for petitioning the amendment or repeal of an adopted rule are under [RCW 34.05.330](#).

For continued updates on rule development, interested parties are encouraged to subscribe to the [commission's Rules email list](#).

For more information, please contact Daidria Underwood, Program Manager, Medical Quality Assurance Commission at (360) 236-2727 or by email at daidria.underwood@doh.wa.gov.



RULE-MAKING ORDER PERMANENT RULE ONLY

CR-103P (August 2017) (Implements RCW 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: August 28, 2017

TIME: 4:23 PM

WSR 17-18-032

Agency: Department of Health- Medical Quality Assurance Commission

Effective date of rule:

Permanent Rules

31 days after filing.

Other (specify) (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

Yes No If Yes, explain:

Purpose: WAC 246-919-601 (Allopathic Physicians)--Safe and effective analgesia and anesthesia administration in office-based surgical settings. The adopted rule clarifies and updates requirements for allopathic physicians performing office-based surgery in facilities that are accredited or certified by accrediting entities approved by the Medical Quality Assurance Commission (commission). The adopted rule eliminates the list of accrediting entities in rule and instead will allow the commission the ability to add or delete accrediting entities based on criteria established in the adopted rule for approving accrediting entities. This will also allow the commission to post on their website and disseminate to providers and stakeholders a current list of approved entities whenever the list is amended. The rule also clarifies when a physician may perform procedures in a non-accredited facility that is actively seeking accreditation, and identifies the physician's responsibilities should the facility not maintain their accreditation.

Citation of rules affected by this order:

New: None

Repealed: None

Amended: WAC 246-919-601

Suspended: None

Statutory authority for adoption: RCW 18.71.017

Other authority:

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 17-11-118 on 05/23/2017 (date).

Describe any changes other than editing from proposed to adopted version: None

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name: Daidria Amelia Underwood

Address: PO Box 47866, Olympia, WA 98605-7866

Phone: (360) 236-2727

Fax: (360) 236-2795

TTY: (360) 833-6388 or 711

Email: daidria.underwood@doh.wa.gov

Web site:

Other:

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

Federal statute:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>

The number of sections adopted at the request of a nongovernmental entity:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted in the agency's own initiative:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>0</u>	Amended	<u>1</u>	Repealed	<u>0</u>
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The number of sections adopted using:

Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>0</u>	Amended	<u>1</u>	Repealed	<u>0</u>

Date adopted: 08/28/2017

Name: Melanie de Leon

Title: Executive Director

Signature:



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.

Medical Quality Assurance Commission
Safe and Effective Analgesia and Anesthesia Administration in
Office-Based Surgical Settings
WAC 246-919-601

Summary of comments and testimony received on proposed rules

Adopted Amendments to WAC 246-919-601

The Medical Quality Assurance Commission (commission) has adopted rule amendments to clarify and update requirements for physicians performing office-based surgery in facilities accredited by commission-approved accrediting entities to ensure facilities are properly equipped and maintained for patient safety.

The adopted rule will allow the commission to add or delete accrediting entities based on criteria established in the rule for approving accrediting entities. This will also enable the commission to post on their website a current list of approved entities, and disseminate an updated list to providers and stakeholders more efficiently and expediently.

The adopted rule amendments accomplish four goals in regards to WAC 246-919-601:

1. Eliminates the list of accrediting entities existing in rule. The adopted rule will allow the commission to add or delete accrediting entities based on criteria established in the adopted rule for approving accrediting entities. This will allow the commission to post on the commission's website and disseminate to providers and stakeholders a current list of approved entities.
2. Describes how the commission will approve accrediting entities. The adopted rule will allow the commission to add or delete accrediting entities based on criteria established in the adopted rule for approving accrediting entities.
3. Clarifies when a physician may perform procedures in a non-accredited facility that is actively seeking accreditation from a commission-approved accrediting entity.
4. Explains the physician's responsibility should the facility not maintain their accreditation.

Reasons for Adopting These Rules:

WAC 246-919-601—Safe and effective analgesia and anesthesia administration in office-based surgical settings amendments were adopted by the commission to modernize, clarify, and streamline requirements for allopathic physicians performing office-based surgery in facilities accredited or certified by a commission-approved accrediting entity to ensure patient safety. Rules were also adopted in response to a petitioner's request to have their accrediting

organization included on the commission's list of approved entities in WAC 246-919-601, which resulted in the commission considering, proposing, and adopting amendments to rule to allow the commission to add or delete accrediting entities based on criteria established in the adopted rule rather than maintain a list in rule. The adopted rule now establishes criteria for commission-approval of an accrediting entity, and therefore the list of approved accrediting entities can be moved from the text of the existing rule and maintained by the commission internally. All those entities currently approved will remain on the commission's approved list as long as they continue to meet the criteria established in the adopted rule.

Language Changes Made from the Proposal to the Adopted Rules:

No changes were made in the adopted rule from the text of the proposed rule as published in the Washington State Register.

Summary of Comments and Testimony Received:

The summary of comments and testimonies includes those comments received for proposed rules for WAC 246-919-601—Safe and effective analgesia and anesthesia administration in office-based surgical settings, filed as WSR #17-11-118.

Removal from Rule the List of Accrediting Entities

Public comment #1: The commission received several comments from those accrediting entities that are currently listed in WAC 246-919-601(5) as being approved by the commission. They expressed concern that the deletion of the rule language that removed their organization from the list in rule meant they would no longer be considered commission-approved and therefore would be disqualified as an accrediting entity for physicians and office-based surgical settings seeking accreditation.

Commission response #1: Current commission-approved accrediting entities will still be approved and will be listed on the internal list that the commission will update and maintain as needed. This list will be available on the commission's website, as well as by email upon request. Once the commission responded with this explanation, and it was clear that those accrediting entities would not lose their status of being commission-approved, there were no additional concerns expressed regarding this issue during the public testimony portion of the public hearing. The adopted rule establishes criteria for approving accrediting entities, which allows the commission to add or delete accrediting entities from the internal list. As long as an accrediting entity continues to meet the criteria established in the adopted rule, they will remain on the commission's approved list that will be published on the commission's website and disseminated to providers and stakeholders on an ongoing basis. As a result, the commission did not make the requested change.

Retain List of Accrediting Entities in Rule

Public comment #2: The commission received several suggestions to retain the list of five accrediting entities in rule at the time of the public hearing, and subsequently add a sixth accrediting entity-- and any subsequent petitioners seeking commission approval—to the internal commission list of approved accrediting entities.

Commission response #2: Establishing criteria in rule for being commission-approved as an accrediting entity allows the commission to maintain an internal list of approved entities rather than going through a lengthy rulemaking process each time a request is made by an entity to be added to the commission's list. To date, all entities on the approved list meet the criteria in the adopted rule, and as long as the entities continue to meet the criteria established in the adopted rule, they will remain on the commission-approved list. As a result, the commission did not make the requested change.

Maintain Existing Entities as Commission-Approved

Public comment #3: The commission received several comments from those accrediting entities listed in WAC 246-919-601(5) suggesting that if the list is removed from rule then the commission should automatically include those listed into the commission's internal list of approved accrediting entities.

Commission response #3: The commission agreed with this suggestion. The adopted rule establishes criteria for approving accrediting entities, which allows the commission to add or delete accrediting entities from the internal list. Those entities currently approved meet the criteria established in the adopted rule and will remain on the commission's internal list as long as they continue to meet the criteria in the adopted rule. As a result, the commission did not make the requested change as this suggestion did not require a rule change.

Confidentiality

Public comment #4: It was suggested that the commission add a provision in the rule that ensures that materials submitted by an accreditation entity will be exempt from public disclosure.

Commission response #4: The commission responded that it cannot create an exemption to the Washington Public Records Act ([chapter 42.56 RCW](#)). Trade secrets and proprietary information are already exempt from disclosure under RCW 42.56.270(11). As a result, the proposed rule was not changed at adoption.

Clarifying Criteria

Public comment #5: It was suggested that the commission consider clarifying criteria for approval, disapproval, or deletion of accreditation entities and provide broad agency notice whenever the approved list is revised.

Commission response #5: The commission responded that it has addressed the criteria for approval, disapproval, or deletion of an accrediting entity in the adopted rule amendment. The commission will provide notice via GovDelivery and on its website to providers and interested stakeholders whenever the internal list of approved entities is revised. As a result, the commission did not make the requested change.

Complaints Process

Public comment #6: “Included in the proposed standards is a requirement that the accreditation entity has ‘(iii) Processes that assure a fair and timely review and resolution of any complaints received concerning accredited or certified facilities.’ Many well- established accreditation organizations do not handle patient complaints about a provider the entity has accredited. But they do have standards that require a quality and risk-management process, audits, and an internal complaints process. The goal that we all share is to ensure that a provider has a means to evaluate the quality of its services and a patient has access to a process for a review of a complaint. Therefore, we urge the Commission to remove the requirement that an accreditation entity itself have a complaints process.”

Commission response #6: The adopted rule amendment requires the accrediting entity to ensure that the facility it is accrediting has a complaints resolution process, and does not require the accrediting entity itself to have a complaints resolution process. Accrediting entities do not resolve complaints; they merely require that facilities they are accrediting have a process for resolving complaints. The commission, therefore, did not agree with the suggestion and did not to make the requested change.

“Other Related Matters”

Public comment #7: “In the revised rule, section (i), the rule describes that an accreditation entity must have 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 commission.’ We urge the Commission to remove the general catch-all language of ‘other related matters’ and include only its specific criteria in the modified rule. We believe the process for approval will be most effective if all parties are aware of the standards for approval, and that those standards should be described in the rule.”

Commission response #7: The commission did not agree with this suggestion and responded that the rule amendment language’s list of standards is not meant to be inclusive. The commission needs to have some flexibility in deciding whether to approve accrediting entities. As a result, the commission did not make the requested change.

Performing Office-Based Surgery while in Application Status

Public comment #8: The commission received a comment that expressed concern over the language that would allow a physician to perform office-based surgery in a facility that was not yet accredited but was in application status. The comment indicated that the rule amendment states that if the facility is not accredited within one year of the physician's performance of the first procedure under the rule, the physician must cease performing procedures until the facility is accredited.

Commission response #8: The commission responded that the accreditation application process can be time-consuming and the commission feels that by allowing a physician to perform office-based surgery while the facility is in application status would allow more patient access to care, as well as not delay a provider from opening a practice. Also, the adopted amended rule states that a physician can perform office-based surgery in a facility that is in application status provided "that the facility is appropriately equipped and maintained to ensure patient safety such that the facility meets the accreditation standards." The commission decided not to make the requested change.