

**Significant Analysis**  
for Rule Concerning administration of sedation and anesthesia,  
WAC 246-919-601 – Safe and Effective Analgesia and Anesthesia Administration in  
Office-Based Surgical Settings.

**Briefly describe the proposed rule.**

RCW 18.71.017(2) allows the Medical Quality Assurance Commission (commission) to adopt rules governing the administration of sedation and anesthesia in the office of practitioners, including necessary training and equipment. Rules are needed to establish enforceable standards for physicians who perform office-based surgery (OBS) to reduce the risk of substandard care, inappropriate administration of anesthesia, infections, and other serious complications.

The rule will require physicians who perform office-based surgery using major conduction anesthesia, moderate sedation or analgesia or deep sedation or analgesia to:

- Obtain certification or accreditation in good standing from either the Joint Commission; the Accreditation Association for Ambulatory Health Care; the American Association for Accreditation of Ambulatory Surgery Facilities; or the Centers for Medicare and Medicaid Services;
- Be competent and qualified to perform procedures in office-based surgery.
- Return patients who enter a deeper level of sedation than intended to the lighter level of sedation as quickly as possible.
- Have at least one provider currently certified in advanced resuscitative techniques appropriate for the patient be present or immediately available with appropriate resuscitative equipment throughout the procedure and until the patient has met the criteria for discharge from the facility.
- Separate surgical and monitoring procedures so the physician performing the surgery is not the provider monitoring the anesthesia.
- Create written emergency care and transfer protocols.
- Maintain legible, complete, and accurate medical and anesthesia records for each patient.

**Is a Significant Analysis required for this rule?**

Yes.

**A. Clearly state in detail the general goals and specific objectives of the statute that the rule implements.**

RCW 18.71.017(2) authorizes the Commission to adopt rules regarding the administration of sedation and anesthesia in the offices of physicians licensed under this chapter. The rules will provide enforceable standards for office-based surgery that will reduce the risk of substandard care, inappropriate anesthesia, infections and serious complications by physicians when performing office-based surgery. The rule will also provide that patients who receive sedation and anesthesia in an office-based surgery setting are safe, monitored, and their physicians are maintaining legible, complete, comprehensive and accurate medical and anesthesia records.

**B. Determine that the rule is needed to achieve these goals and objectives, and analyze alternatives to rulemaking and the consequences of not adopting the rule.**

RCW 18.71.017(2) authorizes the Commission to adopt rules governing the administration of sedation and anesthesia when physicians perform office-based surgery. A rule is needed to set enforceable standards for practitioners conducting office-based surgery in a setting other than licensed hospitals, hospital associated surgical centers, and ambulatory surgical facilities.

**C. Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.**

The Department of Health has determined that no significant analysis is required for the following portions of the rule: **Purpose** – this only introduces what is to come later in the rule; **Definitions** – the definitions are self explanatory as to the meaning of the terms used later in the rule; **Exclusion** - this language is necessary for clarification purposes; **Application of rules** – this lists the levels of sedation or anesthesia.

The portions of the rule that are significant are analyzed in the numbered list below. As discussed above, other portions of the rule are not significant and are therefore not included in this section by section analysis.

*1. Description: Accreditation or Certification WAC 246-919-650 (5)*

The rule requires accreditation or certification of the office in which the surgery occurs. Within 180 days of the effective date of this rule, a physician who performs office-based surgery procedures covered by this rule must ensure that the facility in which the procedures are performed is appropriately equipped and maintained through certification or accreditation from one of the following accrediting entities. These entities are nationally known and accredit or certify office-based surgery settings in other states.

Name of Accreditation or Certification Entity	Cost of Accreditation or Certification
Joint Commission (JC)	<ul style="list-style-type: none"><li>• \$6,950 for three years of accreditation</li></ul>
Accrediting Association for Ambulatory Health Care (AAAHC)	<ul style="list-style-type: none"><li>• \$645 application fee</li><li>• \$3,000 - \$6,000 maximum three years accreditation</li></ul>

American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF)	<ul style="list-style-type: none"> <li>• \$1,100 annual fee</li> <li>• \$950 every three years, inspection fee for single physician office</li> </ul>
The Centers for Medicare and Medicaid Services (CMS)	CMS currently does not offer accreditation for ambulatory surgery centers, but are in the development stages. These standards will apply to physician offices that perform office-based surgery. There is no cost at this time.

Analysis: The benefit in obtaining accreditation or certification is that it promotes patient safety by requiring compliance with nationally recognized standards for the facility where office-based surgery is performed. The benefit of ensuring patient safety through compliance with national standards outweighs the cost of accreditation or certification.

2. *Description: Competency WAC 246-919-650 (6) & (7)*

A physician performing office-based surgery must be able to demonstrate competencies for the procedures being performed by completing a continuing medical education course in conscious sedation, relevant training in a residency training program, or having privileges for conscious sedation granted by a hospital.

Analysis: Physicians are currently required to complete 200 hours of continuing medical education (CME) every four years. Completing a course in conscious sedation would not be an additional cost because physicians already must complete CME. An average cost of a course for conscious sedation is \$425 for 8 hours to \$725 for 16 hours of CME.

3. *Description: Resuscitative preparedness WAC 246-919-650 (8)*

At least one provider currently certified in resuscitative techniques, e.g. advance cardiac life support (ACLS), pediatric life support (PALS), or advance pediatric life support (APLS), must be present or immediately available with appropriate resuscitative equipment throughout the procedure and until the patient has met the criteria for discharge from the facility. The cost for ACLS, PALS, or APLS ranges from \$199 to \$275 and is good for 2 to 3 years.

Analysis: - The commission requires a physician performing office-based surgery to be certified in advanced or resuscitative techniques. This ensures immediate resuscitation to begin without delay.

The requirement to have age-appropriate resuscitative equipment is essential and is a requirement of the certification standards in WAC 246-919-650 (5). A physician working in a certified or accredited office will have appropriate training and resuscitative equipment necessary. Therefore no additional cost is required. The benefit is the public is assured that a physician working in a certified or accredited office will have appropriate training and necessary resuscitative equipment.

4. *Description: Sedation assessment and Management WAC 246-919-650 (9)* - A physician must be able to rescue patients who enter a deeper level of sedation than intended. If a patient enters into a deeper level of sedation than planned, the patient must be returned to the lighter level of sedation as quickly as possible while ensuring the patient is closely monitored, the airway is patent, the patient is breathing, and that oxygenation, the heart rate and blood pressure are within acceptable values.

Analysis: The benefit is that the physician has the ability and knowledge to bring a patient back from any state of sedation. There are no costs associated with this as the physician would already have the necessary training and knowledge.

5. Description: Separation of surgical and monitoring functions WAC 246-919-650 (10)

The physician performing the surgery may not be the same provider monitoring the anesthesia.

Analysis: – The American Society of Anesthesiologist states that anesthesiologists “are responsible for administering anesthesia to relieve pain and for managing vital life functions, including breathing, heart rhythm and blood pressure, during surgery. After surgery, they maintain the patient in a comfortable state during the recovery....”

The American Association of Nurse Anesthetists states that nurse anesthetists “must stay with a patient for the entire procedure, constantly monitoring every important function of your body and individually modifying your anesthetic to ensure your maximum safety and comfort.”

The proposed rule requires practitioners performing office-based surgery using sedation that requires monitoring to separate surgical and monitoring functions. A practitioner performing or assisting with the surgical procedure cannot be responsible for administering the anesthesia or monitoring the patient during and after the surgery.

For those practitioners who will need to hire a dedicated practitioner to administer anesthesia the department estimates it could cost approximately \$175 an hour for an anesthesiologist and approximately \$75 an hour for a certified nurse anesthetist (CRNA) to be present to administer and monitor sedation.

The benefit of separating the monitoring procedure and the surgical procedure greatly outweighs the cost because it allows the primary physician to focus on the surgery. In an emergency, the primary physician can focus solely on the surgery while the anesthesiologist will focus on the sedation level.

6. Description: Emergency care and transfer protocols WAC 246-919-650 (11)

The rule requires a physician performing office-based surgery to have a transfer protocol for the timely and safe transfer of patients to a nearby hospital. The transfer protocol must include arrangements for emergency medical services and transfer of the patient to an appropriate hospital. The physician must also ensure office personnel are trained in the transfer protocol in the event of a complication or emergency.

Analysis: The cost to develop and implement an emergency care and transfer protocol would be minimal as it would only be the initial time it would take by the physician to create a plan and train staff. The commission assumes that it will take approximately four hours to develop the protocol and that the physician will do it. The cost is approximately \$175 an hour for the physician’s time multiplied by four hours for a total cost of \$700. The commission assumes the physician will train staff during routine office staff meetings and therefore other than time there will be no cost.

The benefit of an emergency care and transfer protocol is that patients will be transferred to an appropriate hospital in a timely manner, thereby improving patient safety. The benefit of getting patient faster emergent care greatly outweighs the minimal cost incurred by the physician.

7. *Description: Medical Record and Anesthesia Record, WAC 246-853-650 (12)*

The rule will require physicians performing office-based surgery to maintain legible, complete, and accurate medical and anesthesia records for each patient.

Analysis: The rule requires a physician to put specific information regarding the surgery and anesthesia into the medical record. This is already considered the standard of care for physicians to maintain complete medical and anesthesia records for all patients. There is no additional cost of maintaining medical and anesthesia records.

**Cost Benefit Conclusion**

As described above, the proposed rule requires practitioners that perform office-based surgery using moderate sedation deep sedation or analgesia or major conduction anesthesia to satisfy several requirements: obtain accreditation or certification; demonstrate qualification and competency; be able to rescue a patient that experiences complications from anesthesia; have a provider certified in resuscitative techniques; have a designated licensed health care practitioner to administer sedation and monitor the patient; create and implement an emergency care and transfer protocol; and maintain legible, complete, and accurate medical and anesthesia records for each patient. Although individual practitioners may incur costs associated with these requirements, the overall benefit of increased patient safety outweighs these costs.

**D. Determine, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.**

The Commission met numerous times and created multiple draft versions of the rule. The Commission sent all draft rules to the interested parties for comment and worked with members of the Board of Osteopathic Medicine and Surgery, the Podiatric Medical Board and Department of Health policy staff. To minimize the burden of this rule, the Commission made the following changes to previous drafts.

- The Commission deleted a provision requiring a physician performing office-based surgery to be board-certified. The commission believed that this requirement would be potentially burdensome to the practitioner.
- The Commission deleted a provision requiring the person providing anesthesia to have hospital privileges. The commission believed that this requirement would be potentially burdensome to the practitioner.
- The Commission deleted a provision requiring the reporting of a death or significant complication. The commission believed that this requirement would be potentially burdensome and punitive to the practitioner. In addition, the facility must report deaths or adverse events to the accrediting or certifying entities.
- The Commission deleted a provision requiring a physician performing office based surgery to register with the Commission. The commission believes that registration would be

**E. Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.**

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

**F. Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.**

The rule does not impose more stringent performance requirements on private entities than on public entities.

**G. Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determines that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.**

This rule does not differ from any federal regulation or state statute.

**H. Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.**

There are no other applicable laws.