Significant Analysis
for Rules Concerning Administration of Anesthetic Agents for Dental Procedures WAC 246-817-701, 710, 720, 722, 724, 730, 740, 745, 755, 760, 770, 772, 774, 776, 778, and 780;
Repealed WAC 246-817-170, 175, 180, and 750

Briefly describe the proposed rule.

Amendments to chapter 246-817 WAC relating to administration of anesthetic agents for dental procedures update these rules to ensure that dentists obtain adequate education and are able to respond to sedation related emergencies. The proposed rule package includes 17 sections. These sections define appropriate education and training, facility, equipment, and practice standards for dentists providing sedation and general anesthesia.

Why we are proposing the rule?

The proposed rule package changes the regulation of administration of anesthetic agents from the "method" of sedation to the "level" of sedation. The benefits of the proposed rule package increases patient safety, updates current industry standards and terminology, and lowers emergency and hospital admissions related to dental anesthetic procedures.

Who is impacted by the rule and how are they impacted?

Dentists, dental hygienists, expanded function dental auxiliaries, dental assistants and anesthesia monitors are all impacted by the proposed rule package.

The rule:

- Makes housekeeping and other non-significant language changes;
    - Add and clarify definitions of terms used in the rules.
    - Restructure the new and existing language in a more user-friendly format.
    - Combine redundant language into single sections where appropriate.
    - Make changes to incorporate plain-talk where appropriate.
- Establishes standards for dentists that administer anesthesia based on level of patient response, rather than only on drugs used to sedate the patient.
- Requires all dental offices that administer anesthesia to have a defibrillator and dental offices providing general anesthesia to have a defibrillator in a location that is reachable within 60 seconds.
- Gives identified dental staff 45 days from hire to obtain training and current certification in health care provider – basic life support (BLS).
- Requires dentists to have additional equipment necessary to respond to sedation related emergencies when providing minimal to deep sedation.
- Requires minimum levels of sedation specific training and continuing education for dentists providing minimal sedation to deep sedation.

- Enhances recordkeeping and patient monitoring requirements for dentists providing minimal to deep sedation.
- Allows dentists to use a designated anesthesia provider without requiring a anesthesia permit of the dentist.
- Enhances the mandatory reporting requirements.

Is a Significant Analysis required for this rule?

Yes

Staff for the Dental Quality Assurance Commission assessed each of the proposed sections in the rule package. It was determined that the sections identified in the table below were not significant. The significant sections are analyzed in Part C. below.

WAC #	**Title**	**Subject**	**Reason why rule is not significant**
246-817-710	Definitions	Identifies definitions for WACs 246-817-701 through 246-817-795	Does not add or change any regulatory program or policy
246-817-730	Local Anesthesia		Rule language was removed from this WAC and moved to WAC 246-817-724 so all equipment and recording keeping is consolidated into one WAC
246-817-774	Permitting/renewal requirements		Rule language was moved here from WAC 246-817-170, 760 and 770
246-817-776	Discharge criteria for all levels of sedating/general anesthesia		Rule language was moved here from WAC 246-817-760 and 770
REPEALED			
246-817-170	Applications – Permits – Renewals	Provides application, permit, and renewal process	Rule language was incorporated into new section WAC 246-817-755, 760, 770, and 774, no changes
246-817-175	Conscious Sedation with parenteral or		Rule language was incorporated into

	multiple oral agents – Education and training		WAC 246-817-755 and 760, no changes
246-817-180	General Anesthesia (including deep sedation) – Education and training		Rule language was incorporated into WAC 246-817-770. Changes are considered in 770
246-817-750	Conscious Sedation with an oral agent		Rule language was incorporated into WAC 246-817-740 and 745, Changes are considered in 740 and 745.

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

RCW 18.32.640 allows the commission to adopt rules governing the administration of sedation and general anesthesia by licensed dentists, including training, education, equipment, and issuance of permits.

RCW 18.32.0365 allows the commission to adopt rules governing the practice dentistry and licensing of dentists.

RCW 18.32.002 indicates it is the purpose of the commission established in RCW 18.32.0351 to regulate the competency and quality of professional health care providers under its jurisdiction by establishing, monitoring, and enforcing qualifications for licensure, continuing education, consistent standards of practice, continuing competency mechanisms, and discipline. Rules, policies, and procedures developed by the commission must promote the delivery of quality health care to the residents of the state.

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.

The proposed rules are needed to update existing rules with current sedation and general anesthesia education, training, facility, equipment, and practice standards. Standards for administering anesthesia can only be enforced when adopted in rule. Rules will increase patient safety and will allow the commission to regulate providers with well defined standards.

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 portions of the rule that are significant are analyzed in the numbered list below.

1. *WAC 246-817-701 Purpose – Administration of anesthetic agents for dental procedures.*

Description: The proposed rule regulates how dentists can administer varying levels of sedation and general anesthesia. It also includes a statement that the Dental Quality Assurance Commission (DQAC) is changing the structure of the anesthesia rules to be based on the "level" of sedation (i.e., local, minimal, moderate, deep, general, etc.) versus the previously used format based on category of anesthesia. They are making this change because anesthesia/sedation is a continuum and the route of administration and drug combinations can cause deeper level of sedation than anticipated. The American Society of Anesthesiologists (ASA) uses and refers to the level of sedation in their standards.

The proposed rule establishes a new requirement for practitioners to be able to rescue patients that enter a deeper level of sedation than the practitioner intended.

The proposed rule establishes a requirement for anesthesia providers to provide 24-hour on-call availability following an anesthesia procedure.

The proposed rule restates RCW 18.260.040 that dental assistants and expanded function dental auxiliaries may not administer general or local anesthesia, including intravenous sedation.

Cost/Benefit Analysis: The benefits outweigh the costs because it is not always possible to predict how a patient is going to respond to anesthetic agents and practitioners need to be able to rescue that patient. There are no costs associated with this section.

2. *WAC 246-817-720 Basic life support requirements.*

Description: The proposed rule requires all dental staff providing direct patient care to have a current health care provider basic life support (BLS) certification (the previous rule only required BLS certification for dental offices that use anesthesia). It also clarifies the type of BLS certification to be health care provider level. The proposed rule also allows an addition 15 days, for a new total of 45 days to complete, for new staff to complete the training.

Cost/Benefit Analysis: There are a variety of courses and locations available to obtain health care provider BLS certification. The average cost of a seven hour course is $250. Dental staff may have already received BLS training. Dental staff may incur the cost of the training. The benefits of this section outweigh the costs because of the improvement of the overall dental care system by having all health care providers certified in providing BLS. This level of protection will increase the ability to provide emergency care to patients, which could save lives.

3. *WAC 246-817-722 Defibrillator.*

Description: The proposed rule requires all dental offices that administer anesthetic to have a defibrillator or automated external defibrillator (AED) in their office. The existing rule only required dental offices that provide general anesthesia to have a defibrillator or AED.

Cost/Benefit Analysis: It is not always possible to predict how a patient is going to respond to anesthetic agents and practitioners need to be able to rescue that patient. A defibrillator or AED is a tool that has proven to assist when responding to an emergency. According to the American Red Cross, the average cost of a defibrillator or AED is $2,300. There are a variety of types, models and distributors available to obtain a defibrillator or AED. There are a variety of courses and locations to obtain defibrillator or AED training. The benefits outweigh the costs of requiring a defibrillator or AED training because of the added protection to address emergency care to patients, including the ability to bring a patient back to life.

4. *WAC 246-817-724 Recordkeeping, equipment and emergency medications or drugs required in all sites where anesthetic agents of any kind are administered.*

Description: The proposed rule requires dentists to record a patient's medical history, a patient evaluation, note all medications and dosages used, and lists specific equipment and medications needed. Dentists must also note if the patient has an adverse reaction to medications.

The proposed rule is in existing WAC language. It now consolidates the minimum equipment and recordkeeping requirements for all levels of sedation into one single WAC. The existing rule requires dental offices that perform general anesthesia to have the following minimum equipment (stethoscope, bronchodilator drug, the antihistaminic drug, and anti-anaphylactic agents). The equipment and drugs are now required for all dental offices that use anesthesia agents.

Cost/Benefit Analysis: The average cost of a stethoscope is $200 but we estimate that 99% of licensed dentists already have one. The average cost of emergency drugs is $10 each. The benefits outweigh the costs because the dentists will be better prepared to respond to emergencies, which could save patient lives. Dentists that do not currently have a stethoscope or the emergency drugs will incur an approximate cost of $230.

5. *WAC 246-817-740 "Minimal sedation by inhalation" (to include but not limited to nitrous oxide).*

Description: The proposed rule uses the term “minimal sedation by inhalation” rather than “nitrous oxide sedation” which is currently used. Dentists must now make a notation in the patient’s chart if they use any nitrous oxide, oxygen or any other inhalation sedation. If the agent used is nitrous oxide, the chart must say “N2O used.” Other agents require a dose record noting the time each agent was used.

The proposed rule establishes a new requirement for practitioners to indicate, in patient chart, the type of inhalation sedation, the required dose and time each concentration/agent was used. Nitrous oxide must be recorded as “N2O uses.”

Cost/Benefit Analysis: The benefits of patient safety outweigh the costs because there are no costs associated with this section. This process of noting type and dosage on anesthesia agents is standard practice.

6. WAC 246-817-745 “Minimal sedation.”

Description: The proposed rule establishes:

A. Initial minimum training for dentists that want to administer minimal sedation (14 hours for oral agents and 21 hours for any type of agent or combination of agents). The 14 hour training requirement is not new for this level of sedation. The 21 hour requirement reduces the original training requirement of 60 hours.

B. Procedures for administering the agents:

i) Dentists may administer oral sedative agents in the treatment setting or prescribe for the patient prior to the appointment. This is not a new requirement, it clarifies practice standard.

ii) A second individual must be in the office premise that is able to immediately respond to any request by the person administering the drug. This is not a new requirement.

iii) The patient must be continuously observed while in the office under the influence of the drug. This is not a new requirement.

iv) Dentists must be able to rescue patients that enter a deeper level of sedation than the practitioner intended. This is not a new requirement, it clarifies practice standard.

v) Dentists must keep reversal agents, if they are available, for sedative drugs and other specified equipment. This is a new requirement for this level of sedation.

vi) Dentists must indicate in patient chart the type of inhalation sedation, the required dose and time each concentration/agent was used. Nitrous oxide must be recorded as “N2O uses.” This is not a new requirement, it clarifies practice standard.

vii) Dentists must take seven hours of continuing education courses (in addition to the minimum initial education course work described in A. above) every five years. This is not a new requirement/

viii) Dentists must take a continuing education for BLS or advanced cardiovascular life support (ACLS) in addition to the already required seven hours. This is a new requirement.

Cost/Benefit Analysis: The average cost of a seven hour minimal sedation course is $400 to $800. The average cost of a BLS or ACLS course is $250. The commission recognizes that there are costs associated with purchasing drugs and other specified equipment. The average cost of the required reversal agents is $10 per dose. Therefore, the department considers that a nominal cost. The benefits outweigh the costs of BLS or ACLS certification and an additional seven hour course because the benefits increase emergency care to the patients and ensure appropriate education and training of the practitioner.

7. WAC 246-817-755 Moderate sedation.

Description: The proposed rule establishes:

A. Seven hours of minimum training for dentists to administer moderate sedation in addition to the required 21 hours for minimal sedation. The 7 hour training requirement is not new for this level of sedation. This level of sedation will require 28 hours (21 hours of minimal sedation and 7 hours of moderate sedation) which reduces the original training requirement of 60 hours.

B. Procedures for administering the agents:

i) Dentists may administer oral sedative agents in the treatment setting or prescribe for the patient prior to the appointment. This is not a new requirement.

ii) A second individual must be in the office premise that is able to immediately respond to any request by the person administering the drug. This is not a new requirement.

iii) The patient must be continuously observed while in the office under the influence of the drug. This is not a new requirement.

iv) Dentists must be able to rescue patients that enter a deeper level of sedation than the practitioner intended. This is not a new requirement, it clarifies practice standard.

v) Dentists must keep reversal agents, if they are available, for sedative drugs and other specified equipment. This is not a new requirement.

vi) Dentists must indicate in patient chart the type of inhalation sedation, the required dose and time each concentration/agent was used. Nitrous oxide must be recorded as “N2O uses.” This is not a new requirement, it clarifies practice standard.

vii) Dentists must take seven hours of continuing education courses (in addition to the minimum initial education course work described above) every five years. This is not a new requirement. It reduces education hours for this level of sedation.

viii) Dentists must take a continuing education for BLS or advanced cardiovascular life support (ACLS) in addition to the already required seven hours. This is a new requirement.

C. A dentist must obtain a conscious sedation permit to administer this level of sedation. This is not a new requirement.

Cost/Benefit Analysis: Dentist must take 7 hours of training to administer moderate sedation (note: this training is in addition to the training required for minimal sedation included in *WAC 246-817-745 "Minimal sedation"*). The average cost of a seven hour moderate sedation course is $400 to $800. The average cost of a BLS or ACLS continuing education course is $250. The dentist must also obtain a conscious sedation permit for $150 which is an existing rule requirement. The benefits outweigh the costs associated with this rule because education and training is necessary to ensure public safety. The cost will be incurred by new permit applicants.

8. WAC 246-817-760 Moderate sedation with parenteral agents.

Description: The proposed rule establishes

A. An initial 60 hours of minimum training for dentists to administer moderate sedation with parenteral agents. This is not a new training requirement.

B. A requirement for dentists to have a current and documented proficiency in advanced cardiac life support (ACLS) or pediatric advanced life support (PALS). This is a new requirement.

C. Procedures for administering the agents

i) Dentists or trained anesthesia monitors must monitor a patient at all times while administering moderate sedation with parenteral agents. This is not a new requirement.

ii) Dentists must maintain an intravenous infusion during the administration of a parenteral agent. This is not a new requirement.

iii) The operative dentists must be continuously assisted by at least one trained individual. This is not a new requirement.

iv) The dentists must monitor and record pulse, respiration, blood pressure, and blood oxygen saturation during administration of moderate sedation with parenteral agents. This is not a new requirement.

v) Dentists must be able to rescue patients that enter a deeper level of sedation than the practitioner intended. This is not a new requirement, it clarifies practice standard.

vi) Dentists must keep reversal agents, if they are available, for sedative drugs and other specified equipment. This is not a new requirement.

vii) Dentists must take eighteen hours of continuing education courses (in addition to the minimum initial education course work described above) every three years. This is not a new requirement.

viii) Dentists must take a continuing education for BLS or advanced cardiovascular life support (ACLS) or pediatric advanced life support (PALS) in addition to the already required seven hours. This is a new requirement.

D. A dentist must obtain a conscious sedation permit to administer this level of sedation. This is not a new requirement.

Cost/Benefit Analysis: The average cost of a BLS or ACLS course is $250. The dentist must obtain a conscious sedation permit for $150 which is an existing rule requirement. The benefits outweigh the costs of BLS or ACLS certification and an additional seven hour course because the benefits increase emergency care to the patients and ensure appropriate education and training of the practitioner.

9. WAC 246-817-770 General anesthesia and deep sedation.

Description: The proposed rule establishes:

A. An initial two years of minimum education requirements needed to administer general anesthesia and deep sedation. The rule includes a provision for individuals that have started the training prior to the effective date of the proposed updated rule. This is a new requirement for new permit applicants.

B. Dentists to have a current and documented proficiency in advanced cardiac life support (ACLS) or pediatric advanced life support (PALS). This is a new requirement.

C. Procedures for administering the agents

i) Dentists or trained anesthesia monitors must monitor a patient at all times while administering and during recovery of general anesthesia or deep sedation. They may not leave the immediate area. This is not a new requirement.

ii) Dentists or trained anesthesia monitors must monitor and record pulse, respiration, blood pressure, and blood oxygen saturation during administration of general anesthesia or deep sedation. Record a patient's blood pressure every five minutes and their respiratory rate every fifteen minutes. This is not a new requirement.

iii) A discharge entry must be made in patient chart of the patient's condition and the responsible party to whom the patient was discharged with. This is not a new requirement.

iv) Dentists must ensure all appropriate equipment and emergency medications are available in the facility. There is a new requirement to have a laryngeal mask airway (LMA). A defibrillator or AED must also be reached within sixty seconds. This is a new requirement.

v) Dentists must take eighteen hours of continuing education courses (in addition to the minimum initial education described above) every three years. This is not a new requirement.

The BLS continuing education requirement was removed as an acceptable course to count toward the required eighteen hours. ACLS was also indicated as unacceptable to count towards required continuing education.

Cost/Benefit Analysis: The proposed rule increases the minimum education to two years which is the national standard training currently being offered. There are no additional costs associated with the increase of education because there are no longer one year programs available. The benefit of ACLS certification and a reachable AED is the ability to provide emergency care immediately if necessary. The benefit of requiring a LMA is an alternative tool for intubation in an emergency. The average cost of an LMA is $150. The average cost of ACLS certification is $250. The benefits outweigh the costs because appropriate education and emergency equipment and training is necessary for patient safety.

10. WAC 246-817-772 Training requirements for anesthesia monitor.

Description: The proposed rule is a new section that creates "anesthesia monitor" as a newly recognized position. This section also identifies the minimum training requirements needed to become an anesthesia monitor. Some of the requirements originate from WAC 246-817-770. There is no change to the training requirements listed in existing WAC 246-817-770 although it provides an example of the type of training required.

Cost/Benefit Analysis: The benefits outweigh the costs because there are no costs associated with this section.

11. WAC 246-817-778 Nondental anesthesia providers.

Description: The proposed rule establishes guidelines when a licensed dentist works with a non-dental anesthesia provider, for example; a certified registered nurse anesthetists. The proposed rule requires dentists to establish a written agreement with the nondental anesthesia provider to ensure they meet the DQAC anesthesia related requirements.

Cost/Benefit Analysis: The benefits outweigh the costs because there are no costs associated with this section. The benefit of this section is that it educates dentists about how to contract with nondental providers so they know how to comply with the rules.

12. WAC 246-817-780 Mandatory reporting of death or significant complication as a result of any dental procedure.

Description: This section establishes a requirement for dentists to report to the dental commission if one of their patients dies or has a significant complication that requires

hospitalization stay at least 24 hours long. The proposed rule also requires the dentist to notify the department within 72 hours of discovery of the incident by phone, fax, or e-mail.

Cost/Benefit Analysis: Although dentists will have to expend time and resources completing the mandatory reporting for the prescribed outcomes. The benefits outweigh the costs of this practice because the dental commission will be able to track these occurrences to determine if dentists are providing unsafe practices.

Cost Benefit Rule Package Summary

These existing rules were outdated compared to national standards. The benefit of this rule package is that it defines appropriate education and training, facility, equipment, and practice standards for dentists providing all levels of sedation and general anesthesia. These proposed rules will increase patient safety and will be enforceable with clear standards.

These proposed rules will have an economic impact on most dentists. As identified in the sectional analysis above, there are several requirements that collectively could cost a typical dentist approximately five thousand dollars to comply if they do not already have the necessary equipment and training. The benefits of this rule package outweigh the costs associated with the proposed requirements. The imposed costs are justified due to the added protection to the patients in Washington State in all aspects of oral health. Dental Quality Assurance Commission staff, therefore, concludes that the benefits of this rule outweigh the costs.

Attached is a cost summary matrix titled "Cost Summary Chart for Dental Anesthesia Rule WAC 246-817."

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.

DOH staff and the Dental Quality Assurance Commission worked closely with constituents and the public to minimize the burden of this rule. The commission established the Dental Anesthesia Committee (DAC) made up of 13 licensed dentists and one public member. The DAC met twice and held two public workshops throughout the state. The DAC provided a recommendation to the full commission and rule writing began. There were two rule writing workshops held and public comment was accepted verbally and in writing. Comments were incorporated where appropriate. The commission additionally accepted comments during the business meetings where they approved the draft rule language. In the course of these and other efforts, the following alternative version(s) of the rule were rejected:

Alternative version #1:

WAC 246-817-724 Recordkeeping, emergency medication and equipment required in all sites where anesthetic agents of any kind are administered.

(1) Dental records must contain an appropriate medical history and patient evaluation. Any adverse reactions must be recorded.

(2) Office facilities and equipment must include:

(a) Suction equipment capable of aspirating gastric contents from the mouth and pharynx.

(b) Portable oxygen delivery system including full face masks and a bag-valve-mask combination with appropriate connectors capable of delivering positive pressure, oxygen enriched ventilation to the patient. Blood pressure cuff (sphygmomanometer) of appropriate size.

(c) Stethoscope; or equivalent monitoring device.

(3) Appropriate Emergency Medications must be available.

Compared to this alternative version, the proposed rule is less burdensome for those required to comply because the rule provides a specific list of required emergency drugs to ensure compliance.

Alternative version #2:

WAC 246-817-740 ”Inhalation Minimal Sedation (to include but not limited to nitrous oxide)”

Compared to this alternate version of the title, the proposed rule title is less burdensome for those required to comply because the rule uses terminology recognized by national organizations.

Alternative version #3:

WAC 246-817-776 - Pre and post operative care. There must be direct monitoring by the anesthesia provider or a person trained in anesthesia recovery, if the patient does not meet established discharge criteria. The anesthesia provider may discharge patients provided the patient meets the discharge criteria.

Compared to this alternate version, the proposed rule is less burdensome for those required to comply because the rule was combined with the discharge cretieria for clarity and proposed rule was renumbered for formatting.

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, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule does not differ from any applicable federal regulation or 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.