Significant Legislative Rule Analysis

WAC 246-817-760 Moderate sedation with parenteral agents

October 31, 2016
SECTION 1:
Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

The proposed rule amendments updates monitoring and equipment requirements to align with the American Dental Association (ADA), the American Academy of Pediatric Dentistry (AAPD), the American Association of Oral and Maxillofacial Surgeons (AAOMS), and the American Society of Anesthesiology (ASA) national standards currently being used by dentists. The proposed rule sets minimum patient safety standards while administering moderate sedation with parenteral agents. The propose rule also provides exemptions of specific monitoring requirements for dentists when sedating children due to previous concerns expressed by the Washington State Academy of Pediatric Dentistry (WSAPD). Pediatric dentists have a unique role assessing a fearful child, addressing the dental need and parent concerns, and successfully treating the child.

Monitoring patient vitals enhances a dentist’s ability to monitor a patient’s safety and take appropriate action. Changes in heart rate, blood pressure, respiration, and expired carbon dioxide (CO₂) are all indications that there may be a problem with a patient under sedation. Requiring all dentists administering moderate sedation with parenteral agents to monitor appropriate patient vitals follows consistent practice standards. Providing specific exemptions for dentist when sedating children is consistent with the AAPD Guidelines on Behavior Guidance for the Pediatric Dental Patient.

SECTION 2:
Is a Significant Analysis required for this rule?

Yes, as defined in RCW 34.05.328 the proposed rule requires a significant analysis. The proposed rule amendments subject a licensed dentist to a penalty or sanction for violation of rule.

SECTION 3:
Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

As stated in RCW 18.32.002, the purpose of the Washington State Dental Quality Assurance Commission (commission) established in RCW 18.32.0351 is 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.

RCW 18.32.640 authorizes the commission to adopt rules governing administration of sedation and general anesthesia by persons licensed under this chapter, including necessary training, education, equipment, and the issuance of any permits, certificates, or registration as required.

SECTION 4:

Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.

The Dental Quality Assurance Commission (commission) is proposing amendments to monitoring and equipment requirements for patient’s receiving moderate sedation with parenteral agents to ensure patient safety and to remain consistent with the recognized standard of care. Requiring all dentists administering moderate sedation with parenteral agents to monitor appropriate patient vitals are consistent practice standards. Providing specific exemptions for dentist when sedating children is consistent with the AAPD Guidelines on Behavior Guidance for the Pediatric Dental Patient.

The propose rule provides exemptions of specific monitoring requirements for dentists when sedating children due to previous concerns expressed by the Washington State Academy of Pediatric Dentistry (WSAPD). Pediatric dentists have a unique role assessing a fearful child, addressing the dental need and parent concerns, and successfully treating the child.

The commission has determined that there are no feasible alternatives to rulemaking because in order to be enforceable, administration and monitoring requirements for sedation must be in rule. If the proposed rules are not adopted, the commission will be hampered in its ability to provide clear requirements for dentist administering moderate sedation with parenteral agents.

SECTION 5:

Explain how the department determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

Rule Overview – WAC 246-817-760 Moderate sedation with parenteral agents.
The proposed rule amendments:

- Require that identified training and equipment must be age appropriate for the patient being sedated.
- Require that drugs used must be safe to render unintended loss of consciousness highly unlikely.
- Lists exceptions for requiring an intravenous infusion for pediatric patients.
- Require monitoring of expired carbon dioxide with exceptions for pediatric patients.
- Require specific equipment be available when sedating pediatric patients.
- Require end-tidal carbon dioxide monitoring with exceptions for pediatric patients.
- Require additional monitoring equipment for all dentists providing moderate sedation with parenteral agents.
- Remove health care provider basic life support certification as acceptable certification as part of continuing education.

Rule Cost/Benefit Analysis

A dentist must hold an active moderate sedation with parenteral agents permit to administer moderate sedation with parenteral agents. There are approximately 276 dentists who hold a moderate sedation with parenteral agents permit. Dentists with a moderate sedation with parenteral agents permit will be required to obtain and use an electrocardiographic monitor and end-tidal CO₂ monitor when administering moderate sedation with parenteral agents. These providers routinely provide moderate sedation with parenteral agents during a dental procedure either in a dental office or an office-based surgery setting.

Dentists with a moderate sedation with parenteral agents permit must have training appropriate for the age of the patient being sedated; if sedating an adult, adult sedation; if sedating a minor, pediatric sedation. Most moderate sedation education courses provide general sedation training. If a dentist must obtain additional training, specifically in pediatric sedation, initial education courses cost $765 to $3200.

Exceptions proposed for specific monitoring requirements when sedating children are necessary because pediatric dentists have a unique role assessing a fearful child, addressing the dental need and parent concerns, and successfully treating the child. Pediatric dentistry is a specialty of dentistry that is directly concerned with the oral health of children. Pediatric dentists undergo specific training to treat a very unique, and often times, tricky patient population. In the Guidelines on Behavior Guidance for the Pediatric Dental Patient, behavior guidance is not an application of individual techniques created to “deal” with the children, but rather a comprehensive, continuous method meant to develop and nurture the relationship between patient and doctor, which ultimately builds trust and allays fear and anxiety. Pediatric dentists expressed by allowing the exceptions to the monitoring requirements would be less traumatic for the child and parent. Additionally, this will be cost-effective for the dentist as the techniques would minimize the use of operating room time and general anesthesia.
The proposed rule is necessary to ensure patient safety while dentists administer moderate sedation with parenteral agents. If a dentist is not currently monitoring and recording a patient’s end-tidal CO₂ values, there will be a cost to purchase the equipment and complete the required record keeping of the results. If a dentist is not currently using an electrocardiograph to monitor a patient’s heart activity, there will be a cost to purchase the equipment and complete the required record keeping of the results. The benefit of being able to monitor a patient’s CO₂ levels and the heart’s electrical activity, a change of which may be the first indication that there is a problem, will enable dentists to recognize and address a unforeseen problem with the dental procedure. The cost of end-tidal CO₂ monitors range from $1000 to over $4000 depending on model, for the useful life of the model. The cost of electrocardiographic monitors range from $114 to $5000. Most dentists providing moderate sedation with parenteral agents have an electrocardiographic monitor already in their office. Pulse oximetry monitoring is required in current rule. The amended language adds the pulse oximetry monitor to the equipment list, no new cost is incurred for this amendment. Monitors are not replaced based on time of use but there are costs associated to maintaining each monitor; filters, consumable components, and bio-medical inspection every two years. The annual cost for maintenance of the monitors is nominal. In addition to the equipment costs, there will also be the nominal amount of time to complete a physical evaluation and to record the results of the CO₂ and electrocardiographic monitoring in the patient’s surgery and dental records.

The proposed rule removes health care provider basic life support (BLS) certification as an acceptable certification as part of continuing education. If a dentist not currently maintaining an advanced cardiac life support (ACLS) or pediatric advanced life support (PALS) certification, there will be a cost between $40 to $300 to maintain an ACLS or PALS certification every two years.

Enhanced patient safety outweighs the cost of monitoring, charting, and equipment necessary to monitor patient vitals. The benefit of the proposed rule provides better service to children with consistent dental sedation treatment.

SECTION 6:

Identify alternative versions of the rule that were considered, and explain how the department determined 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 state previously.

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Description of alternatives considered
One alternative listed the exceptions for intravenous infusion, expired carbon dioxide, and end-tidal carbon dioxide requirements differently. The commission re-worded the exceptions for clarity.

A second alternative did not delete the health care provider basic life support (BLS) certification option for continuing education. The commission determined that BLS certification should not be continuing education when higher level of certification is required to obtain the initial permit.

The commission has determined that the proposed rule is the lease burdensome option as it provides clear requirements for dentist administering moderate sedation with parenteral agents to ensure patient safety.

SECTION 7:
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.

SECTION 8:
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.

SECTION 9:
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.

SECTION 10:
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.