

Notice of Proposed Regulation Changes – Board of Dental Examiners (DEN), proposing to update various regulations relating to requirements for administering moderate sedation, deep sedation, or general anesthesia by a dentist, permit requirements, suspension or revocation of permit, on-site inspections, local anesthesia certification, administration of nitrous oxide sedation by dental hygienists, requirements for course of instruction in nitrous oxide sedation, registry, mandatory reporting, and definitions. Notice Published: April 7, 2016.

Answers to questions 1 through 6 are answers to common questions regarding proposed regulation changes. Answers to questions 7 through 9 are answers to anticipated questions specific to these proposed regulation changes. Answers to questions 10 and on are responses to questions received from the public regarding these proposed changes. The period for written comments ends May 9, 2016. To be considered, comments must be submitted by 4:30 p.m. on May 9, 2016.

### Regulatory Questions

1 4/8/2016	<b>What will these proposed regulation changes do?</b>
<b>Answer:</b> The new sedation regulations will serve to further define the practice of sedation and general anesthesia in the dental office, including but not limited to who can provide sedation and general anesthesia in the dental office, the required training in order to provide sedation and general anesthesia in the dental office, and who may receive sedation and general anesthesia in the dental office. They will also more accurately define the different levels of sedation and the requirements to gain a permit for each level. In addition, competency requirements should increase patient safety when it comes to airway management in case issues arise during sedation in the dental office. Strong mandatory reporting requirements will be added for any complications that may arise during or after sedation is done in a dental office.	
2 4/8/2016	<b>What is the public need or purpose for these proposed regulation changes?</b>
<b>Answer:</b> Updated regulations are needed so they better align with current standards of care when it comes to sedation in a dental office. Nearly all of the changes made are being done to increase public safety.	
3 4/8/2016	<b>What is the <i>positive</i> impact on the public or to a private person, business, or organization as a result of these proposed regulation changes?</b>
<b>Answer:</b> There will be a positive impact on patient safety as the standard of care for sedation is raised to levels set by the American Dental Association, American Academy of Pediatric Dentistry, and American Society of Anesthesiologist. This will increase public safety and help businesses provide a more effective and safer sedation or anesthetic to their patients.	
4 4/8/2016	<b>What <i>negative</i> impact will result from these proposed regulation changes on the public or to a private person, business, or organization?</b>
<b>Answer:</b> Having medically compromised patients go through more screening prior to sedation in a dental office is intended to increase safety. The increased requirements to provide sedation to patients 12 years old and younger are also meant to increase safety. Because pedodontists would have to obtain a moderate sedation permit, it wouldn't necessarily be a negative consequence to the public but may be onerous for the pedodontist.	
5 4/8/2016	<b>Why does the public need for this change outweigh any negative impact?</b>

**Answer:** Any perceived negative consequence for the public due to these regulation changes are far outweighed by the likely increase in public safety they should bring about.

6  
4/8/2016 | **What will the known or estimated costs of the new regulation changes be to a private person, another state agency, or a municipality?**

**Answer:** The lay public should not see any cost change secondary to enacting the proposed regulations. The dental practitioner may have an additional cost secondary to further training or updated equipment required to perform sedation. Refer to the below table:

Type of Sedation Provider	Expected Costs
Dentist administering no sedation in office	No additional cost
Dentist providing mild or nitrous oxide sedation to adults or children older than 12 years old	No additional cost
Dentist administering mild oral sedation to a child age 12 and younger	Costs of training and equipment to obtain a moderate conscious sedation permit required
Dentist with sedation permit trained to perform moderate sedation on adults	No additional cost or possible cost of monitor with capnography capability if not practicing at standard of care If sedation provider intends to provide sedation to a patient age 12 or younger, the cost for additional training will be required
Dentist with sedation permit trained to perform moderate sedation on children age 12 and younger	No additional cost or possible cost of monitor with capnography capability if not practicing at standard of care If sedation provider intends to provide sedation to an adult or patient older than 12 years old, the cost for additional training will be required
Dentist with deep sedation/general anesthesia permit	No additional cost or possible cost of monitor with capnography capability if not practicing at standard of care

7  
4/8/2016 | **Why does the Board specify specific drugs that should not be used by sedation permit holders?**

**Answer:** After defining moderate sedation, the ADA published the following note:

In accord with this particular definition, **the drugs** and/or techniques used should carry a **margin of safety wide enough to render unintended loss of consciousness unlikely**. Repeated dosing of an agent before the effects of previous dosing can be fully appreciated may result in a greater alteration of the state of consciousness than is the intent of the dentist. Further, a patient whose only response is reflex withdrawal from a painful stimulus is not considered to be in a state of moderate sedation.

The specifically listed drugs are examples of drugs that are classified as general anesthetics. General anesthetics are designed to produce "a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation." It is during times when a patient is unconscious when the ability to ventilate may be impaired, or cardiovascular function may be impaired. The Board believes that dentists looking to provide moderate sedation should use drugs that carry a wide margin of safety, wide enough to render unconsciousness unlikely. The Board is and has been of the opinion that using drugs such as general anesthetics, that are intended to create a loss of consciousness or general anesthesia, does not align with the guidelines set by the ADA. Proposed regulations provide examples of drugs that are general anesthetics and are not appropriate for use by a sedation permit holder.

8  
4/8/2016

**Why do I need to monitor end-tidal carbon dioxide if I'm already monitoring pulse oximetry?**

**Answer:** Both monitors are important for patient safety. One does not replace the other. Requiring end-tidal carbon dioxide monitoring brings Alaska's proposed regulations into alignment with multiple guidelines. AAOMS, ADA, AAPD, and ASA require capnography with automated apnea alarms for moderate sedation.

9  
4/8/2016

**Where can I find references to the standards of care regarding sedation for dentists?**

**Answer:** Below are links to refer to regarding the standard of care for sedation for dentists:

1. Guidelines for Teaching Pain Control and Sedation to Dentist and Dental Students. American Dental Association. Available at: [http://www.ada.org/~media/ada/about%20the%20ada/files/teaching\\_paincontrol\\_guidelines.pdf?la=en](http://www.ada.org/~media/ada/about%20the%20ada/files/teaching_paincontrol_guidelines.pdf?la=en)
2. Guidelines for the Use of Sedation and General Anesthesia by Dentists. American Dental Association. Available at: [http://www.ada.org/~media/ada/advocacy/files/%20anesthesia\\_use\\_guidelines.ashx](http://www.ada.org/~media/ada/advocacy/files/%20anesthesia_use_guidelines.ashx)
3. Guideline for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures. American Academy of Pediatric Dentistry Reference Manual. Available at: [http://www.aapd.org/media/policies\\_guidelines/g\\_sedation.pdf](http://www.aapd.org/media/policies_guidelines/g_sedation.pdf)
4. Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists. American Society of Anesthesiologists, Inc. Available at: <https://www.asahq.org/~media/sites/asahq/files/public/resources/standards-guidelines/practice-guidelines-for-sedation-and-analgesia-by-non-anesthesiologist.pdf>
5. Parameters of Care: Clinical Practice Guidelines for Oral and Maxillofacial Surgery: Anesthesia in Outpatient Facilities. American Association of Oral and Maxillofacial Surgeons. Available at: [http://www.aaoms.org/docs/govt\\_affairs/advocacy\\_white\\_papers/parcare\\_anesthesia.pdf](http://www.aaoms.org/docs/govt_affairs/advocacy_white_papers/parcare_anesthesia.pdf)

10  
4/13/2016

**Do the proposed regulation changes relating to sedation apply only to hygienists or do these changes apply to dentists as well and the courses required to continue to use nitrous oxide?**

**Answer:** The nitrous regulation changes being proposed concern only dental hygienists. 12 AAC 28.005(a)(2) of the proposed regulation changes exempt dentists from needing a permit for nitrous oxide only.

11  
4/15/2016

**If a pediatric dentist administers only nitrous oxide to patients under age 13, would they need a moderate sedation permit?**

**Answer:** No. Nitrous oxide alone for patients under age 13 is acceptable. 12 AAC 28.005(a)(2) of proposed regulations exempts dentists from needing a permit for nitrous oxide only.

12 4/15/2016	<b>I completed my pediatric specialty residency about three years ago. I performed and assisted in over 60 oral sedation cases with children under age 13. Would the cases and training I received during residency be sufficient to obtain a moderate sedation license, or would I have to undergo further training?</b>
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**Answer:** Training in moderate sedation needs to be current. 12 AAC 28.005(b) outlines training requirements.

13 4/22/2016	<b>I am a RHD. With the N20 certification, will I be able to use N20 without the dentist being onsite? Can I use it when he's gone?</b>
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**Answer:** The proposed regulation regarding supervision, 12 AAC 28.650, reads as follows:

Application to administer nitrous oxide sedation. (a) The board will issue a certification to administer nitrous oxide sedation under direct or indirect supervision to a dental hygienist licensed in this state if the hygienist ...

As outlined in the Alaska statutes, Section 08.32.190, "direct" and "indirect" supervision are defined as follows:

(3) "direct supervision" means the dentist is in the dental office, personally diagnoses the condition to be treated, personally authorizes the procedure, and before dismissal of the patient evaluates the performance of the dental hygienist;

...

(5) "indirect supervision" means a licensed dentist is in the dental facility, authorizes the procedures, and remains in the dental facility while the procedures are being performed by the dental hygienist;

...