Fax

To	From
Jun Maiquis Fax: (907) 465-2974	Kenley Michaud (907) 268-3109

Date:	March 18, 2016 03:57 PM
Pages:	5 (including cover)
Re:	Upcoming Dental Anesthesia Regulations

Thanks for getting back to me Jun. In short, I'm just curious if Alaska has any similar situations as California where boards both regulate the same thing. How have they dealt with that in the past?

RECEIVED
Juneau

MAR 1 8 2016

CBPL

Hello Jun,

Thanks for getting back to me and leaving a message with your email. The dental board is changing the way they regulate sedation in the dental office. Currently its written that if a dentist wants to employ an MD anesthesiologist or CRNA, they must hold an anesthesia permit. In order to make it easier for a dentist to work with a non-dentist anesthesia provider, the board has discussed removing any regulation for a CRNA or MD anesthesiologist in the dental office. Another option that has been mentioned is used by other states in the lower 48, including California. I pasted the corresponding section of the California dental practice act below as well as the link to the associated section, for your reference. As a quick summary. The California dental board will issue a permit to a licensed physician to practice general anesthesia or sedation in the dental office. This allows the dental board some oversight as to who is providing anesthesia to dental patients. And if necessary the dental board can revoke a dental permit and refer information to the medical board for evaluation of unprofessional conduct.

The question is, does Alaska have any regulations similar to this in other situations. In this case, the physician and nurse anesthetist receive their license to provide anesthesia from the associated medical or dental board. The dental board has no power over those licenses, but will issue a permit when they want to practice in a dental office. This affords the dental board the ability to oversee the safety of their stewardship, the dental patients.

My second question is, do you see any issues with structuring the sedation regulations in a similar manner as California? This type of structure directly provides the board with the most information about who is practicing in the dental office and thus allows them to directly affect dental patient safety.

Thanks for taking a look at this, I know the board wants to get some regulations out in the next few months and your help is really appreciated. Take care and I hope to hear from you soon.

Kenley Michaud, DDS
Northern Lights Dental Anesthesia

http://www.dbc.ca.gov/lawsregs/laws.shtml

http://www.leginfo.ca.gov/cgi-bin/displaycode?section=bpc&group=01001-02000&file=1646-1646.9

BUSINESS AND PROFESSIONS CODE SECTION 1646-1646.9

1646. "General anesthesia," as used in this article, means a controlled state of depressed consciousness or unconsciousness, accompanied by partial or complete loss of protective reflexes, produced by a pharmacologic or nonpharmacologic method, or a combination thereof.

1646.1. (a) No dentist shall administer or order the administration of general anesthesia on an outpatient basis for dental patients unless the dentist either possesses a current license in good standing to practice dentistry in this state and holds a valid general anesthesia permit issued by the board or possesses a current permit under Section 1638 or 1640 and holds a valid general anesthesia permit issued by the board.

(b) No dentist shall order the administration of general

anesthesia unless the dentist is physically within the dental office at the time of the administration.

(c) A general anesthesia permit shall expire on the date provided in Section 1715 which next occurs after its issuance, unless it is renewed as provided in this article.

(d) This article does not apply to the administration of local anesthesia or to conscious-patient sedation.

1646.2. (a) A dentist who desires to administer or order the administration of general anesthesia shall apply to the board on an application form prescribed by the board. The dentist must submit an application fee and produce evidence showing that he or she has successfully completed a minimum of one year of advanced training in anesthesiology and related academic subjects approved by the board, or equivalent training or experience approved by the board, beyond the undergraduate school level.

(b) The application for a permit shall include documentation that equipment and drugs required by the board are on the premises.

1646.3. Any dentist holding a permit shall maintain medical history, physical evaluation, and general anesthesia records as required by board regulations.

1646.4. (a) Prior to the issuance or renewal of a permit for the use of general anesthesia, the board may, at its discretion, require an onsite inspection and evaluation of the licentiate and the facility, equipment, personnel, and procedures utilized by the licentiate. The permit of any dentist who has failed an onsite inspection and evaluation shall be automatically suspended 30 days after the date on which the board notifies the dentist of the failure, unless within that time period the dentist has retaken and passed an onsite inspection and evaluation. Every dentist issued a permit under this article shall have an onsite inspection and evaluation at least once every five years. Refusal to submit to an inspection shall result in automatic denial or revocation of the permit.

(b) The board may contract with public or private organizations or individuals expert in dental outpatient general anesthesia to perform onsite inspections and evaluations. The board may not, however, delegate its authority to issue permits or to determine the persons or facilities to be inspected.

1646.5. A permittee shall be required to complete 24 hours of approved courses of study related to general anesthesia as a condition of renewal of a permit. Those courses of study shall be credited toward any continuing education required by the board pursuant to Section 1645.

1646.6. (a) The application fee for a permit or renewal under this

article shall not exceed the amount prescribed in Section 1724.

(b) The fee for an onsite inspection shall not exceed the amount prescribed in Section 1724.

(c) It is the intent of the Legislature that fees established pursuant to this section be equivalent to administration and enforcement costs incurred by the board in carrying out this article.

(d) At the discretion of the board, the fee for onsite inspection may be collected and retained by a contractor engaged pursuant to subdivision (b) of Section 1646.4.

1646.7. (a) A violation of this article constitutes unprofessional conduct and is grounds for the revocation or suspension of the dentist's permit, license, or both, or the dentist may be reprimanded or placed on probation.

(b) A violation of any provision of this article or Section 1682 is grounds for suspension or revocation of the physician's and surgeon's permit issued pursuant to this article by the Dental Board of California. The exclusive enforcement authority against a physician and surgeon by the Dental Board of California shall be to suspend or revoke the permit issued pursuant to this article. The Dental Board of California shall refer a violation of this article by a physician and surgeon to the Medical Board of California for its consideration as unprofessional conduct and further action, if deemed necessary by the Medical Board of California, pursuant to Chapter 5 (commencing with Section 2000). A suspension or revocation of a physician and surgeon's permit by the Dental Board of California pursuant to this article shall not constitute a disciplinary proceeding or action for any purpose except to permit the initiation of an investigation or disciplinary action by the Medical Board of California as authorized by Section 2220.5.

(c) The proceedings under this section shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the Dental Board of California shall have all the powers granted therein.

1646.8. Nothing in this chapter shall be construed to authorize a dentist to administer or directly supervise the administration of general anesthesia for reasons other than dental treatment, as defined in Section 1625.

1646.9. (a) Notwithstanding any other provision of law, including, but not limited to, Section 1646.1, a physician and surgeon licensed pursuant to Chapter 5 (commencing with Section 2000) may administer general anesthesia in the office of a licensed dentist for dental patients, without regard to whether the dentist possesses a permit issued pursuant to this article, if both of the following conditions are met:

(1) The physician and surgeon possesses a current license in good standing to practice medicine in this state.

(2) The physician and surgeon holds a valid general anesthesia permit issued by the Dental Board of California pursuant to

subdivision (b).

(b) (1) A physician and surgeon who desires to administer general anesthesia as set forth in subdivision (a) shall apply to the Dental Board of California on an application form prescribed by the board and shall submit all of the following:

(A) The payment of an application fee prescribed by this article.

(B) Evidence satisfactory to the Medical Board of California showing that the applicant has successfully completed a postgraduate residency training program in anesthesiology that is recognized by the American Council on Graduate Medical Education, as set forth in Section 2079.

(C) Documentation demonstrating that all equipment and drugs required by the Dental Board of California are possessed by the applicant and shall be available for use in any dental office in which he or she administers general anesthesia.

(D) Information relative to the current membership of the applicant on hospital medical staffs.

(2) Prior to issuance or renewal of a permit pursuant to this section, the Dental Board of California may, at its discretion, require an onsite inspection and evaluation of the facility, equipment, personnel, including, but not limited to, the physician and surgeon, and procedures utilized. At least one of the persons evaluating the procedures utilized by the physician and surgeon shall be a licensed physician and surgeon expert in outpatient general anesthesia who has been authorized or retained under contract by the Dental Board of California for this purpose.

(3) The permit of a physician and surgeon who has failed an onsite inspection and evaluation shall be automatically suspended 30 days after the date on which the board notifies the physician and surgeon of the failure unless within that time period the physician and surgeon has retaken and passed an onsite inspection and evaluation. Every physician and surgeon issued a permit under this article shall have an onsite inspection and evaluation at least once every six years. Refusal to submit to an inspection shall result in automatic denial or revocation of the permit.

Zimmerman, Marilyn A (CED)

From: Maiquis, Jun C (CED)
Sent: Wednesday, April 13, 2016 11:34 AM
To: Valerie Stokes
Cc: Zimmerman, Marilyn A (CED); Erkenbrack, Stacia L (CED)
Subject: RE: regulations

Follow Up Flag: Follow up
Flag Status: Completed

For you, Marilyn – see below.

From: Valerie Stokes [mailto:Valerie.Stokes@akics.org]
Sent: Wednesday, April 13, 2016 11:25 AM
To: Maiquis, Jun C (CED)
Subject: regulations

Hello Jun
We received the documentation regarding proposed changes to sedation. We have a question regarding the nitrous section. Does it apply only to Hygienists or it is a change that also applied to Dentists and courses required to continue to use nitrous oxide.
Thank you for your time and attention to this question.

Valerie Stokes RDH
AICS Dental

Zimmerman, Marilyn A (CED)

From: James Clark <jacl@gci.net>
Sent: Wednesday, April 13, 2016 1:32 PM
To: Zimmerman, Marilyn A (CED)
Subject: Regulation Changes for Anesthesia & Sedation by Dentists

Dear Ms Zimmerman,

Today I received mail notice that the regulations for Anesthesia & Sedation by Dentists were changing. Lots of regulations were cited by number, some were repealed, modified or replaced by new regulations. None of the 'Specific Changes/Proposals' were described. How can we comment on such changes without a detailed description of the changes?

Please provide a written description of the Specific Changes that have been proposed by the Alaska Board Of Dental Examiners and mail it to me at the address below. As a previous member and chairman of the Alaska Board of Dental Examiners I would appreciate your timely assistance on this matter. Thank you,

Dr James A Clark #389
3312 Princeton Way
Anchorage, AK 99508

Zimmerman, Marilyn A (CED)

From: Home <chrisrosenvall@hotmail.com>
Sent: Friday, April 15, 2016 9:28 AM
To: Zimmerman, Marilyn A (CED)
Subject: Questions about proposed sedation regulations

Follow Up Flag: Follow up
Flag Status: Completed

Greetings,
I had a couple of questions about the new sedation changes.

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

2) I completed my pediatric specialty residency about 3 years ago. I performed and assisted in over 60 oral sedation cases with children under 13. The office I work at now in Alaska does not do oral sedation (moderate sedation) but we are thinking of starting Jan 2017. 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?

Thank you,
Chris Rosenvall

Zimmerman, Marilyn A (CED)

From: Craig Lowrie <craigrlowrie@gmail.com>
Sent: Tuesday, April 19, 2016 8:11 AM
To: Zimmerman, Marilyn A (CED)
Subject: Question on Board of dental examiners Title 12 ch 28

To whom it may concern,

I have a question regarding the proposed changes by the Board of Dental Examiners Title 12 Chapter 28:

Moderate sedation as defined by the ADA is a minimally depressed level of consciousness, that retains the patients ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command.
I completed my dental education at OHSU School of Dentistry and from what I learned while in school administering a low level of NO2 is considered Mild Sedation. I want to clarify what constitutes Moderate Sedation, so that our office can be sure it does not effect us.
I have read the new regulations and on page 1 it says it does not apply to NO2 if it contains a mechanism that guarantees an oxygen concentration of at least 25 percent, but again we just want to clarify.

Thank you for your time,
Craig R. Lowrie, DMD

Zimmerman, Marilyn A (CED)

From: Eric Nordstrom <ericnordstrom1@gmail.com>
Sent: Thursday, April 21, 2016 11:43 PM
To: Zimmerman, Marilyn A (CED)
Subject: Board of Dentistry Sedation Changes

Marilyn,

I wanted to both introduce myself and offer some feedback on the proposed changes to sedation regulations by the Board of Dentistry. I am sure that you are receiving numerous emails, so I will not comment on every area at this time that I see as presenting issues, but rather those in which I have intimate knowledge of practice and which may compromise the safety of the public. When I examine the proposals, it seems to me that the Board must have taken significant input into changes from those in the dental anesthesiology field. It seems that there has been a bias towards accommodating their group. It is my belief that for these practitioners to provide deep or general anesthesia--they should be held to the same standard as everyone else. If the Board is going to require a Medical Anesthesiologist to be Board Certified or Board Eligible to provide deep or general anesthesia for a dentist, it should be the same for the dental anesthesiologist. And yet the proposal is more onerous to the practitioner who has actual formal Medical Training as well as a longer residency program recognized by the AMA. The problem with this requirement of course is that dental anesthesiology is not a recognized specialty by the ADA. In addition to this, it is my belief that anyone who is providing deep or general anesthesia--should be required to have an affiliation with a local hospital and Active Staff Membership. It seems inappropriate to me that a practitioner could have a complication with anesthesia, that might require admission to a hospital and have no input or ability to follow that patient during hospital admission. (Granted, anyone who provides sedation could have a complication--but deep or general anesthesia has higher probability). This is required of me as a Board Certified Oral and Maxillofacial Surgeon and this is a requirement of a Board Certified Medical Anesthesiologist. Conveniently dental anesthesiology is able to meet all of the requirements for a Deep or General Sedation permit, and is lumped in with our specialty as outlined within paragraphs of the proposed changes--but they are not a Specialty of Dentistry recognized by the American Dental Association, nor are they eligible for hospital privileges as an anesthesiologist. I question how well a dental field can regulate its providers without the recognition and oversight that comes with being a specialty recognized by the American Dental Association.

Thank you for your consideration of these points,

Eric Nordstrom DDS, MD
907-222-5052

Zimmerman, Marilyn A (CED)

From: Eric Nordstrom <ericnordstrom1@gmail.com>
Sent: Thursday, April 21, 2016 11:59 PM
To: Zimmerman, Marilyn A (CED)
Subject: Sedation Regulations

Marilyn,

I have a comment on another proposed regulation. It seems to be too generalized to have a requirement that every 2 years to maintain a deep sedation/general anesthesia permit--that permit holder must have 8 hrs of CE in Airway Management. This might be a good idea for the general dentist who is not doing a lot of sedations every year as a refresher--but as an Oral and Maxillofacial surgeon, I have extensive training in airway management, surgical airways, and I practice maintaining airways multiple times a day with deep and general anesthesia. My colleagues in the specialty here in Alaska do the same. I am an advocate of continuing education, but there is time better spent for an Oral and Maxillofacial surgeon than to take a class to review something that is done by me and my colleagues hundreds of hours per year already. Maybe this would be better to have a requirement if under 50 cases per year are performed or some other substantial number?

Thank you,

Eric Nordstrom DDS, MD
907-222-5052

Zimmerman, Marilyn A (CED)

From: April Whitmire-Polis <april_whitmire@hotmail.com>
Sent: Friday, April 22, 2016 7:53 AM
To: marilyn.zimmerman@slaska.gov
Subject: N2O Sedation

Hello,

I am a RHD, will the N20 certification will I be able to use N20 without the dentist being on site. Can I use it when he's gone?

April Whitmire-Polis

Sent from my iPhone

Zimmerman, Marilyn A (CED)

From: Jay Marley DDS <docmarley@alaska.net>
Sent: Friday, April 22, 2016 1:04 PM
To: Zimmerman, Marilyn A (CED)
Subject: letter to AK board regarding regulation changes
Attachments: letter to AK board regarding regulation changes.pdf

Please accept, review and present my comments to the board members regarding the proposed changes by the AK state dental board.
Sincerely,
Jay Marley DDS
907.238.8909
Homer, AK

Homer Dental Clinic, LLC
W. Jay Marley, Jr., DDS
4252 Hohe Street
Homer, Alaska 99603
Phone: 907-235-8909
Fax: 907-235-8517

To: Alaska State Board of Dental Examiners

Having reviewed the proposed changes to anesthesia and parenteral sedation permits for dentists by the Alaska Board of Dental Examiners there are some very concerning items that need to be addressed. The safety of our patients and access to care should come before any other aspect of these proposed regulations. Restricting the number of providers by adding a slew of new regulations to maintain a moderate conscious sedation permit will only decrease access to care. Unfortunately, many patients fear dental care and without safe sedation techniques available they will avoid care altogether. The comments in this letter refer to the 35+ page document that completely describes what it is proposed, not the 3 page document that was sent to dental license holders.

Under 12 AAC 28.005 on page 3 of the proposed changes it is stated that moderate sedation should only be provided to ASA III patients after a physician's consult unless they are an oral surgeon (OS) or dentist anesthesiologist (DA). In which case, the OS or DA may treat the patient after making their own assessment. While it is true that both of these specialties have advanced training to provide deep sedation and general anesthesia most are not accredited as physicians and lack the qualifications to make a medical diagnosis unless they have a medical doctorate (MD) degree. If it is necessary for the safety of the ASA III patient to have a medical consultation for the general dentist with a moderate parenteral sedation permit then it is equally necessary that an OS or DA lacking an MD degree do the same.

On page 4 (h) disallows the use of any sedating medication prior to the arrival of the pediatric patient age 12 or under. With this proposed language the use of mild antihistamines like diphenhydramine or hydroxyzine would be prohibited prior to arrival of the patient. These medications can be very safe and effective for mild pediatric sedation when combined with N20 but require an hour or more for onset. As we all know, a child going bonkers for over an hour in the office waiting for medication to work can be extremely challenging.

Page 5 (j) is unclear as to what level of CPR training is needed by which personnel and for which level of sedation/anesthesia. For moderate conscious sedation, the provider of the sedation/anesthesia should

be trained in ACLS, however, it is not necessary to train staff involved in direct patient care at that level. Staff should maintain current BLS standards through the American Heart Association. In doing so, there is always an ACLS provider in the room with the patient who is capable of handling the advanced situations that may arise and directing the BLS trained staff to carry out the necessary tasks.

Conversely, with deep sedation and general anesthesia the stakes are higher and the patient will quit breathing quite intentionally. Page 8 (7) should require that the provider and the second person to monitor the deep sedation/general anesthesia are both trained and current in ACLS. One cannot properly monitor DS/GA without depth of knowledge in pulse oximetry, capnography, and ECG rhythms.

It is beyond comprehension that, in dentistry, the state of Alaska still allows a provider with a DS/GA permit to provide both the anesthesia and the dental care. There is no other profession in all of health care that permits for such risk. As is seen in any other medical setting, there should be a separate and qualified provider of the DS/GA such as an MD anesthesiologist, a certified nurse anesthetist or a dentist anesthesiologist.

Page 11 (h) (2) should clarify that the provider shall include a 24 hour emergency phone number that provides direct contact with office staff, not a third party answering service. These answering services never know anything and valuable time is lost playing the "Don't call me, I'll call you" game.

On page 13 12AAC 28.015 (a) needs to clarify the terms of N2O usage on children. As it appears, no minimal sedation will be allowed on children 12 and under without a moderate conscious sedation permit. It is unclear as to whether a pediatric moderate sedation permit or an adult moderate sedation permit would be necessary. N20 provides safe minimal sedation for children and should not be restricted by a sedation permit as there is no evidence to support that need.

(d) On page 13 should not try to list individual drugs (examples are fine) but instead clarify that any medication labeled as a general anesthetic according to its package insert is prohibited from use in moderate conscious sedation.

Page 16 (5) requires an intravenous (IV) line for any parenteral sedation. Parenteral sedation includes sublingual (SL) and intramuscular (IM). That means that under this proposed statute the use of SL and IM techniques would be prohibited without first starting an IV line. The very reason for using SL and IM techniques is that, in some cases, the sedation will either be minimal or a vein is very difficult to find. SL and IM are well prescribed techniques that have an application in dentistry and need to be preserved as such.

On page 17 (h) (10) under these new requirements end-tidal CO2 (ETCO2) monitoring for moderate conscious sedation will be mandatory. Although ETCO2 is highly effective in general anesthesia it is not so in moderate conscious sedation. For ETCO2 to work properly all expired air must be sampled by the sensor. In healthcare settings where the nose and mouth can be covered with a mask or the patient is intubated with an endotracheal tube (or similar sealed airway device) ETCO2 can be very accurate and helpful in determining the quality of respiration and circulation. In patients that occasionally mouth breathe or even cough during a moderate conscious sedation procedure (where only the nasal air is sampled), it will appear they are in respiratory arrest with many false alarms. The added cost of ETCO2 equipment and its ineffectiveness in moderate conscious sedation, where the patient maintains their own airway, make it completely unnecessary, cumbersome and inhibit access to quality care.

A much more affordable and effective way of monitoring the patient's physical state in moderate conscious sedation, in addition to 3-lead ECG and pulse oximetry, is with a pre-cordial/tracheal stethoscope placed over the trachea. The doctor can then hear the airway in their earpiece and continuously monitor for good respiratory sounds, wheezing, or obstruction. This provides faster and more accurate information to assure that our sedated patients maintain a patent airway, do not obstruct and do not experience oxygen desaturation.

Page 18 (i) (14) requires a muscle relaxant. This should be clarified to show the intention. Requiring moderate conscious sedation providers to keep a drug such as succinylcholine in their inventory may create more serious problems than it solves. If ever used, it will induce paralysis and respiratory arrest requiring airway support, rescue breathing and intubation. This drug is unnecessary for moderate conscious sedation when the medications used for the sedation are delivered in titration form. Titration is the prescribed technique for their administration.

Page 19 (k) (1) requires an excessive amount of continuing education to maintain a moderate conscious sedation permit. During ACLS renewal airway management is discussed and performed while taking the practical megacode test. Selection of an orally managed airway (OMA) or Laryngeal Mask Airway (LMA) should be an uncomplicated and simple selection process for each patient. The placement of an OMA or LMA is rather simple as well and does not require an extended training program. Although we currently stock Endotracheal Tubes (ET) I am not aware of a single moderate conscious sedation provider that would choose to place one in an emergency situation. In addition, the requirement for 12 hours of CE relating to the fields of sedation ads up to at least 3 days of classes every two years to maintain a permit. While education is important, the requirements for CE under this section are absurd considering much of this is reviewed in ACLS recurrent training. It is further ridiculous that if such a requirement existed it would disallow the use ACLS training time toward its fulfillment.

Page 25 (g) states that the board will have the right to inspect a practitioner's facility. This is fine but it should be the State Dental Board for ALL providers and not farmed out for the oral surgeons to their own organization. That is a double standard that we don't need.

The proposed changes are vast and deeply concerning to many providers and patients alike. They far exceed what is currently recommended by the ADA. Little or nothing stands to gain for patient safety while burdensome layers of bureaucracy are added on the providers. Ultimately, this limits access to safe care which is a direct contraindication in our obligation to the public.

Providers who have problems now with their sedations are not following protocol. New regulations will have little to no effect on the scofflaws while severely limiting the vast majority of us who safely provide these sedation services to our patients. I certainly hope that any decision made by the Alaska State Dental Board will coincide with the guidelines for sedation set forth by the American Dental Association. Your decisions should be made in an unbiased way and not based on different user groups or specialties seeking to advance their own agenda.

Sincerely,

W. Jay Marley, Jr., DDS

Diplomate International Congress of Oral Implantologists

Maiquis, Jun C (CED)

From: Mary Ann Dlugosch <madlugosch@gmail.com>
Sent: Sunday, April 24, 2016 6:55 PM
To: Maiquis, Jun C (CED)
Subject: sedation and anesthesia regulation changes

Can you tell me what is the effective date for these changes? Also, If one was certified for administration of N20 many years ago with fewer hours of instruction, will one have to be recertified with the 14 hours specified in the ADA guidelines?

Thanks Jun,

Mary Ann Dlugosch, Dental Hygienist

Maiquis, Jun C (CED)

From: Mary Ann Dlugosch <madlugosch@gmail.com>
Sent: Sunday, April 24, 2016 7:07 PM
To: Erkenbrack, Stacia L (CED)
Cc: Maiquis, Jun C (CED)
Subject: dental hygienist licensing questions

Stacia, I was referred to you by Jun Maiquis to answer dental hygiene and dentist licensing questions.

1. Is an online CPR class with in-person testing acceptable for renewal of dental or dental hygiene licenses?

2. Can you tell me what is the effective date for the recent sedation and anesthesia regulation changes? Also, If one was certified for administration of N20 many years ago with fewer hours of instruction, will one have to be recertified with the 14 hours specified in the ADA guidelines? If recertification is required, what would be the date at which the training would have to be completed?

Thank you.

Mary Ann Dlugosch, Dental Hygienist

Zimmerman, Marilyn A (CED)

From: H. William Gottschalk <hwgdds@socal.rr.com>
Sent: Monday, April 25, 2016 1:22 AM
To: Zimmerman, Marilyn A (CED)
Subject: Proposed changes

Follow Up Flag: Follow up
Flag Status: Completed

Dear Marilyn,

I am writing in response to the letter I received about the proposed changes on anesthesia and sedation permits.

On Page 3;

(2) only provide patients in ASA risk category Class III moderate sedation, deep sedation, or general anesthesia if

(A) he or she has documented a consultation with their primary care physician or other medical specialist regarding potential risks and special monitoring requirements that may be necessary; or

(B) he or she is an oral and maxillofacial surgeon or dental anesthesiologist and has performed an evaluation and documented the ASA risk assessment category of the patient and any special monitoring requirements that may be necessary;

Medical consultations are indicated if the medical history warrants them. Allowing OMFS and DA's to avoid obtaining medical history and physicals, EKG's, and blood and lab tests would be inviting them to practice below the standard of care. GP's and specialists are all obligated to obtain this information to properly assess a patient's ability too tolerate sedation, anesthesia, and the procedure.

On Page 4;

The dentist is not required to make a medical examination of the patient and draw medical diagnostic conclusions; therefore, if the dentist suspects a problem and calls in a physician for an examination and evaluation, the dentist may then rely upon that conclusion and the diagnosis.

Physicians will not clear a patient for sedation and/or anesthesia, nor will they conclude that it is safe to sedate or anesthetize that patient because they do not have any control over the anesthesia provider, there is no guarantee that the anesthesia provider will not make a mistake, there is no guaranteer that the patient could have an untold reaction, and they will not assume any liability for another's doctor's treatment. Yet, GP's who perform sedation are required to obtain these consultations, but OMFS's and DA's are exempt. So why is this included in the regulations?

While returning the patient to the intended level of sedation, periodic monitoring of pulse, respiration, blood pressure, and pulse oximetry must be maintained.

Please define periodic.

On Page 5;

(m) In a proceeding of the board at which the board must determine the degree of sedation or level of consciousness of a patient, the board will base its findings on

(1) the type and dosage of medication that was administered or is proposed for administration to a patient of that physical and psychological status; and

(2) the degree of sedation or level of consciousness that should reasonably be expected to result from that type and dosage of medication.

Under what conditions will there be a proceeding of the board and how could they possibly determine the degree of sedation or level of consciousness of a patient without being present during the procedure?

On Page 7;

such as courses in Advanced Cardiac Life Support (ACLS) for Health Professionals or Pediatric Advanced Life Support (PALS) for Health Professionals

Only of a practice limits their administration of anesthesia to patients 12 years or younger, should they only be certified in PALS. For example, if a Pediatric Dentistry practice sees teenagers or handicapped adults, them must also be certified in ACLS.

baseline vital signs shall be taken and recorded prior to administration of any controlled drug at the facility and prior to discharge;

This is not possible on many pediatric or handicapped adults. There must be a provision for these exceptions.

On Page 8;

(2) patients shall have continual monitoring of their heart rate, blood pressure, and respiration. In doing so, the permittee must utilize electrocardiographic monitoring, pulse oximetry, and end-tidal carbon dioxide monitoring;

You must include a manual or automatic blood pressure monitor.

(4) a patient may not be left alone in a room and must be monitored by the sedation provider or a staff member capable of handling procedures, complications, and emergency incidents related to deep sedation and general anesthesia;

This should read that the sedation provider must be present during the entire sedation experience until it is safe to transfer that patient to a licensed professional that is capable of monitoring the patient during the recovery.

On Page 9;

(B) endotracheal tubes and appropriate connectors, laryngeal mask airway (LMA) and other appropriate equipment necessary to do an intubation;

Should read, (B) endotracheal tubes and appropriate connectors, supra-glottic airway, and other appropriate equipment necessary to do an intubation

On Page 11;

To maintain and renew a permit to administer deep sedation or general anesthesia under this chapter, a dentist shall.....

Does this only pertain to OMFS and DA's or does this include dentists who employ CRNA's or M.D.'s to provide general anesthesia. Technically, the CRNA is practicing under the direction of their doctor. It seems that these practitioners should also be receiving periodic renewed training in anesthesia.

On Page 12;

The advanced airway management requirement is too confusing and complex. It should read, a dentist will participate in 8 hours of continuing education in advanced airway management which includes pediatric airway management if they treat patients 12 years old or younger.

provide confirmation of completed coursework within the two years prior to

submitting the renewal application from one or more of the following:
(A) ACLS from the American Heart Association; or

(B) PALS in a practice treating pediatric patients 12 years of age and under;

This provision makes it look like ACLS and PALS are interchangeable. Remove the one or more.

On Page 14;

12 AAC 28.015. Permit requirements for moderate sedation.

(6) hold and provide proof of current certification in advanced resuscitative techniques with hands-on simulated airway and megacode training for healthcare providers, including basic electrocardiographic interpretation, such as courses in ACLS for Health Professionals or PALS for Health Professionals; and

Out of nowhere, you are requiring moderate sedation providers to be ACLS and/or PALS certified. This would be beyond their requirement for monitoring standards and therefore inconsistent. An EKG is not a requirement for moderate sedation.

On Page 16;

(1) baseline vital signs shall be taken and recorded prior to administration of any controlled drug at the facility and prior to discharge;

As I mentioned on Page 7, This is not possible on many pediatric or handicapped adults. There must be a provision for these exceptions.

On Page 17;

(7) laryngeal mask airways (LMA);

This should read as supra-glottic airways (e.g. iGel, LMA, Combitube, King airway)

On Page 18;

The following should be corrected or removed;

(7) atropine- anticholinergic

(8) antiarrhythmic- remove because an EKG is not a requirement of moderate sedation

(10) nitroglycerine- should be coronary artery vasodilator

(13) 50 percent dextrose- should be 50% dextrose or other anti-hypoglycemic

(14) muscle relaxant- must be removed !

Include an anticonvulsant

On Page 20;

(3) provide confirmation of completed coursework within the two years prior to submitting the renewal application from one or more of the following:

(A) ACLS from the American Heart Association; or
(B) PALS in a practice treating pediatric patients 12 years of age and under;

Why do you require this training when an EKG is not a required monitor?

(5) complete at least 10 moderate sedation cases per calendar year.

Why is this a requirement, unless it is self-serving to some individual?

On Page 24-26;

Based upon your requirements for a dentist employing a CRNA or MD to provide deep sedation and/or general anesthesia, that dentist should also be required to obtain the 20 hours or required continuing education and advanced airway management every renewal period.

On Page 34;

The definition, (9) "moderate sedation" means a drug-induced depression of consciousness, during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained;

It is recognized that anesthesia is a continuum and moderately sedated patients can require airway intervention. Conscious patients can have partial airway obstruction (snoring) and require intervention. This is an incorrect criteria for moderate sedation.

Thank you for the opportunity to review your proposed regulation changes. I hope that my 30+ years of practicing anesthesia will be helpful to meet your goals of making Alaska a safer state for the administration of sedation and anesthesia to dental patients.

H. William Gottschalk, D.D.S.

Dentist Anesthesiologist

diplomate. A.D.B.A. and N.D.B.A.

Zimmerman, Marilyn A (CED)

From: Dr. Schultz <schultzdentistry@gmail.com>
Sent: Tuesday, April 26, 2016 2:56 PM
To: Zimmerman, Marilyn A (CED)
Subject: Proposed changes to dental regulations

Alaska Board of Dental Examiners,

As a dentist practicing in Alaska for the last 17 years, I am concerned about the proposed changes to the regulations. The changes are complex and I am concerned about the lack of time for public comments. Please allow more time and provide a forum for the providers in our state to ask questions and express concerns. These changes appear extreme in nature and will require excessive education and equipment in many cases, which I believe will limit access to care. For example, I am a general dentist treating many families with young children. Often times, the child is of an age where they are too young to cooperate for routine dental procedures. In these cases the use of nitrous oxide is very beneficial. I was trained in its use for all ages during my dental school education and have utilized it almost daily for care of my patients. If the proposed regulations are adopted, I will have to apply for a moderate sedation permit and be required to take an advanced life support class and purchase and maintain additional equipment in order to comply with the new regulations. Many providers, including myself, may not want to do this and therefore the children who could have been treated in my office will be referred elsewhere or not treated at all depending on the access to care within the community. I do not understand why the board has proposed these changes that are more extreme than the guidelines made by the ADA and AADP. Please give the dental community a chance to express our concerns and reconsider some of the proposed changes.

Sincerely,

Kristen J. Schultz DDS
--
Southeast Dental Group
Dr. Kristen Schultz, DDS
2220 Dunn St.
Juneau, AK 99801
Phone: (907)586-9586
Fax: (907)586-9484

Zimmerman, Marilyn A (CED)

From: Charles Cole <ccoledds@yahoo.com>
Sent: Tuesday, April 26, 2016 4:26 PM
To: Zimmerman, Marilyn A (CED)
Subject: Proposed changes on anesthesia and sedation permits

Alaska Board of Dental Examiners:
I am Charles Cole DDS license holder AA628 and am very concerned with the short period of public comment on the proposed changes to the regulations regarding sedation. The changes are lengthy and complex and deserve detailed input for the practicing dental community (license holders).
I believe the public would be better served with a slower, measured approach allowing the license holders to fully participate in the complex decisions for sedation regulation. The Boards decision to not accept public comment at the May meeting denies a forum for license holders to engage the Board and leaves dentists an opportunity to have questions answered and the board to hear concerns directly.
The proposed regulations as I interpret them will directly limit access to critical dental care, especially by Medicaid patients in the MatSu Valley. Patients requiring sedation already have a 3 to 4 month waiting period for sedation by our oral surgeons and with the increase number of qualifying Medicaid patients due to the new administrations expansion of the Medicaid enrollees, those wait times will increase.
I will not be able to care for these patients for at least 12 to 14 months while attending a residency program and upwards of $50,000.00 tuition and expenses, not to even cover lost wages for my staff while I am away. Of course these additional costs will have to be passed on to the public as increasing the cost of health care.

Some additional points which I am in agreement with

- Moderate sedation permit would now be required for GP using minimal sedation on <12yo
- Excessive education requirements for moderate sedation permit (even for pediatric specialists if graduated over 5 years ago)
- Increased permitting requirements will limit access to care
- ADA, AAPD, and AAP have guidelines already made, why is the board making changes or recommendations that are not in the guidelines?
- Capnography not yet a "standard of care", according to ADA guidelines
- Emergency medication/equipment list excessive for a practitioner whose sedation practices are limited to oral moderate conscious sedation
- Med consult required for stable ASA III patient can limit access to care
- Single dose for minimal sedation – clause should be removed because dentist may elect to give the maximum dose up front, instead of using the lowest possible dose for the therapeutic effect (Halcion used as example)

Respectfully Submitted,
Dr. Charles Cole

Zimmerman, Marilyn A (CED)

From: Clearview Dentristry <clearviewdentistry@gmail.com>
Sent: Wednesday, April 27, 2016 8:13 AM
To: Zimmerman, Marilyn A (CED)
Subject: Purposed changes to Dental Sedation regulations...

Alaska Board of Dental Examiners:
I am concerned as a license holder with the short period of public comment on the proposed changes to the regulations regarding sedation. The changes are lengthy and complex and deserve detailed input for the practicing dental community (license holders).
I believe the dentists and public would be better served with a slower, measured approach allowing the license holders to fully participate in the complex decisions for sedation regulation. The Boards decision to not accept public comment at the May meeting denies a forum for license holders to engage the Board and leaves dentists an opportunity to have questions answered and the board to hear concerns directly.
Thank you very much.
Dr. Andrew Newman
License # 101533

Zimmerman, Marilyn A (CED)

From: Singleton, James <jsingleton@SouthcentralFoundation.com>
Sent: Wednesday, April 27, 2016 10:13 AM
To: Zimmerman, Marilyn A (CED)
Subject: Sedation regulations

Dear Alaska Board of Dental Examiners

As a license holder I am concerned about the short public comment period for the proposed sedation regulation changes. The changes are significant and complex and they deserve detailed review and input from the practicing dental community (license holders).

The stated purpose of the regulation change is to protect the safety of the public. To accomplish this will require the balanced input of all license holders and must address provider differences in experience, training, and scope of practice. The Boards decision to not accept public comment at the May meeting precludes a forum for license holders to engage the Board and denies dentists an opportunity to have questions answered and the board to hear concerns directly.

Though the meetings to discuss the regulation changes thus far have been "open" they have not had representation from all dentists that utilize sedation in their practice. The perspective of one Dental Anesthesiologist does not represent or replace the perspective of the entire Alaska dental community.

The ADA, AAPD, AAP and ASDA are all national organizations with sedation guidelines designed to protect the patients of their member providers. The AAPD has a stellar safety record when their sedation guidelines have been followed. Why is the board making changes and recommendations that are not in these national guidelines? Why would the Board choose to utilize a limited local resource when national resources of proven effectiveness exist?

Excessive education requirements for moderate sedation permit (even for pediatric specialists if graduated over 5 years ago) will not necessarily improve patient safety. Experienced specialists with a history of safe sedation performance who regularly perform sedations will gain little value in additional education.

The proposed regulations do not address poor clinical judgement of the provider which is more often the cause of significant morbidity. How does the board propose to address providers with a history of poor sedation outcomes?

Capnography is not yet a "standard of care " for oral sedation according to ADA.

Emergency medication/equipment lists are excessive for a practitioner whose sedation practices are limited to oral moderate conscious sedation.

Please do not compromise the quality and effectiveness of the proposed sedation regulation changes by not allowing adequate time for detailed review and input from the practicing dental community. Thank you in advance for your consideration of this request.

James C. Singleton DDS
Associate Faculty , NYU Lutheran Medical Center
Pediatric Dental Residency Program
Alaska Native Medical Center
4315 Diplomacy Drive

Anchorage, AK 99508

Zimmerman, Marilyn A (CED)

From: Ronald Adair <radair@catg.org>
Sent: Wednesday, April 27, 2016 10:45 AM
To: Zimmerman, Marilyn A (CED)
Subject: FW: Commmets to Board on proposed regulations

Please note my comment to Dave below about adding WITHOUT Thanks, Ron Adair DDS

From: Ronald Adair [mailto:radair@catg.org]
Sent: Wednesday, April 27, 2016 10:40 AM
To: 'David Logan'
Subject: RE: Commmets to Board on proposed regulations

This is my second try to add to your letter. In the sample wording I think you should add the word without: The Boards decision to not accept public comment at the May meeting denies a forum for license holders to engage the Board and leaves dentists WITHOUT an opportunity to have questions answered and the board to hear concerns directly. Still Best Regards, Ron Adair DDS

From: David Logan [mailto:dlogan@akdental.org]
Sent: Tuesday, April 26, 2016 1:47 PM
To: Info
Subject: Commmets to Board on proposed regulations

Dear ADS Membership,

Last night's Town hall meeting was well attended, including many who joined online. Opinions varied on the Board's proposed changes to sedation regulations with most not in favor of the changes. There were two universal point of agreements, however: additional reporting requirements for adverse outcomes are needed and the Board has failed to adequately give the license holders (dentists) time or a forum to respond.

Currently the Board is not planning on taking public testimony at their May meeting – the only comments accepted will be those delivered in writing before the May 9th deadline.

The ADS is drafting our response letter – it will be shared before it is sent – and will concentrate on requesting a longer comment period with more involvement from the practicing community. It would be a departure for the Board but we will request they form a workgroup of Board members with other dentists from the following groups: general dentists with and without a parenteral permit and specialists with and without a parenteral permit. Certainly not every view will be represented but it should move us towards a more universal set of standards.

We also hope with revised regulations the Board will offer some insight to the reasons behind the increased level of regulation. Many last night questioned the need for such a dramatic increase in regulations and the Board owes the license holders an explanation as to why.

We are urging all ADS members to send a short note to the Board requesting the Board delay implementation of the regulations to allow for additional public comment. Sample wording and an email address are below along with a bullet point list of concerns brought up at last night's meeting that can be included. Personal responses would be even better so feel free to sample what you want and go from there.

Email comments to: Marilyn Zimmerman at **Marilyn.zimmerman@alaska.gov**

Sample wording:

Alaska Board of Dental Examiners:

I am concerned as a license holder with the short period of public comment on the proposed changes to the regulations regarding sedation. The changes are lengthy and complex and deserve detailed input for the practicing dental community (license holders).

I believe the dentists and public would be better served with a slower, measured approach allowing the license holders to fully participate in the complex decisions for sedation regulation. The Boards decision to not accept public comment at the May meeting denies a forum for license holders to engage the Board and leaves dentists an opportunity to have questions answered and the board to hear concerns directly.

Some points from Monday night to include if desired.

- Moderate sedation permit would now be required for GP using minimal sedation on <12yo

- Excessive education requirements for moderate sedation permit (even for pediatric specialists if graduated over 5 years ago)
- Increased permitting requirements will limit access to care

- ADA, AAPD, and AAP have guidelines already made, why is the board making changes or recommendations that are not in the guidelines?
- Capnography not yet a "standard of care", according to ADA guidelines
- Emergency medication/equipment list excessive for a practitioner whose sedation practices are limited to oral moderate conscious sedation
- Does it make more sense to have oral moderate conscious sedation permit separate from parenteral sedation permit?
- Med consult required for stable ASA III patient can limit access to care
- Single dose for minimal sedation – clause should be removed because dentist may elect to give the maximum dose up front, instead of using the lowest possible dose for the therapeutic effect (Halcion used as example)

Dave Logan, DDS
Executive Director, Alaska Dental Society
P:(907) 563-3003 C:(907) 723-2884
Email: dlogan@akdental.org
Website: akdental.org

"Committed to enhancing the dental profession and the health of all Alaskans"

Zimmerman, Marilyn A (CED)

From: Jonathan Woller <Jon@wollerdental.com>
Sent: Wednesday, April 27, 2016 11:46 AM
To: Zimmerman, Marilyn A (CED)
Subject: Dental Anesthesia Guidelines

To the Alaska Board of Dental Examiners,
I am a dental license holder who is concerned with the proposed re-writing of the dental anesthesia guidelines. While I agree with the board that a review and rewrite of the regulations is indicated, I believe it would not be in the best interest of the people in Alaska to put out a rushed document with limited input from license holders. Is there a dental anesthesia crisis in Alaska that warrants such a quick, sweeping and aggressive rewrite of the legislation? It seems to me the ADA is currently working through this same issue, and there are guidelines available from the American Academy of Pediatric Dentistry and the American Academy of Periodontolgy. I have to question why our dental board believes that regulations exceeding or preempting these guidelines would serve the people of Alaska well? Please don't take this as a slight to the effort you have put in to working on this document. I feel we do not have to invent the wheel on this one, and in the absence of a crisis, prudence would be to proceed in a more measured manner. There are areas whereas unintentionally we may create some barriers to care that would not serve the public well.
Thank you for you consideration.
Jonathan P. Woller, DMD

Zimmerman, Marilyn A (CED)

From: Hannah S <hannah.summerfelt@gmail.com>
Sent: Friday, April 29, 2016 6:43 AM
To: Zimmerman, Marilyn A (CED)
Subject: Changes to sedation regulations
Attachments: letter about sedation regulation changes.docx

Attached is a letter regarding the abrupt planned changes to sedation regulations.

Thank you,
Hannah Summerfelt

I am concerned as a license holder with the short period of public comment on the proposed changes to the regulations regarding sedation. The changes are lengthy and complex and deserve detailed input for the practicing dental community (license holders). Below is more detail about the change and concerns that I'm sure you'll be receiving from other dentists.

Thank you,

Hannah Summerfelt, DMD

Alaska Board of Dental Examiners

POB 110806

Juneau, AK 99811

Alaska Board of Dental Examiners

The Alaska Dental Society (ADS), representing 365 dental license holders, held a meeting of its members on April 25th to discuss the proposed changes to sedation regulations.

Opinions varied amongst our members on the overall effect of the proposed changes but there was one universal point all attendees agreed on: there has been both limited time for public comment and no forum to allow license holders or public members to speak directly to the Alaska Board of Dental Examiners (Board) regarding the changes.

The proposed changes to the regulations span 35 pages, are very complex and would introduce new permitting and regulatory components. A change of this magnitude is deserving of more explanation to, and input from, the affected license holders than mailing a listing of the headings of sections with changes and posting the regulation changes to the Board website.

Amongst the comments from license holders at the ADS meeting:

- Why are the changes necessary?
- The costs for implementation and training have been grossly underestimated

- Excessive education requirements for moderate sedation permit
- Moderate sedation permit required for using minimal sedation on <12yo is excessive
- Does it make more sense to have oral moderate conscious sedation permit separate from parenteral sedation permit?
- Medical consult required for stable ASA III patient can limit access to care
- Single dose for minimal sedation clause should be removed because dentist may elect to give the maximum dose up front, instead of using the lowest possible dose for the therapeutic effect (Halcion used as example)
- ADA, AAPD, and AAP have guidelines already made, why is the board making changes or recommendations that are not in the guidelines?

Many other comments were made regarding points of change and clarification. Rather than belabor the issue the ADS suggests to the Board that implementation of changes to regulations regarding sedation under 12AAC28 be tabled and a work group formed with a representative group of board members and affected license holders. The ADS would suggest having members consisting of general dentists with and without parenteral sedation permits and dental specialists with and without parenteral sedation permits. The ADS would be willing to put forward names to meet whatever criteria the Board feels is appropriate.

The workgroup could meet during the summer – much of the work could be done by email – with recommendations presented to the Board at the September meeting. The Board could review those changes, incorporate recommendations from the ADA if approved at the 2016 ADA House of Delegates in October and returned to the drafter after the December meeting.

A measured approach such as this will allow affected license holders the opportunity for comment and produce a better end result to insure sedation dentistry in Alaska is both safe and affordable.

Zimmerman, Marilyn A (CED)

From: m fullerdds <mfullerdds@gmail.com>
Sent: Friday, April 29, 2016 12:45 PM
To: Zimmerman, Marilyn A (CED)
Subject: Comments on proposed changes to regulation of dental sedation
Attachments: Board of Dentistry Proposed Sedation Requirements. 2016.docx

Please see attached. Thank you. M Fuller, DDS, FICOI

4-27-16

The Alaska State Board of Dental Examiners:

My recommendation to the Board is to table the current proposals to change regulation of dental sedation, then identify the problem and substantiate the rationale behind any proposed changes with facts and sound, scientific evidence. As currently written, the inconsistencies, contradictions and areas of vague narrative are numerous and at best misleading. Proposals to allow nitrous oxide sedation as "minimal sedation" in one section (page 1, 12 AAC 28.005. General provisions. (2)) and then disallow its use in another section of the proposals (page 13, 12 AAC 28.015. Permit requirements for moderate sedation. (a) "Additionally, no dentist may administer sedation to a pediatric patient 12 years of age and under unless a permit for moderate sedation has been issued by the board.") is confusing and contradictory.

Is limiting access to care an intended result of these change? Research tells us that approximately forty percent of the population in the United States does not seek regular dental care because of significant levels of anxiety. Therefore, together with increased restrictions on sedation, there will be several dental procedures that will no longer be accomplished by general dentists, and therefore, availability of those procedures will become restricted, limiting access to care for a large portion of the population. Are the specialists who benefit from these proposed changes going to be willing to take care of all the patients needing operative, prosthetic, minor gingival surgery, and dental hygiene procedures when those patients need sedation for care? As written, if the proposals pass, general dentists won't be able to treat these patients unless they acquire a parenteral sedation certificate and I can comfortably predict the great majority of general dentists will not. Restricting free trade, limiting access to care, increased costs of care (won't most businesses pass increased costs on to patients), disincentives to grow the professional knowledge base: all negative effects of these broad reaching proposals.

The following are specific effects that will occur if the Board of Dentistry passes the current proposed changes regarding dental sedation:

1. No dentist may administer nitrous oxide/oxygen sedation without the equivalency of a parenteral moderate sedation certificate. (ref: Proposed Regulation Changes revised draft 4/5/16: page 13, 12AAC 28.015. sentence (a) "Additionally, no dentist may administer minimal sedation to a pediatric patient 12 years of age and under unless a permit for moderate sedation has been issued by the board"). And, as moderate sedation is defined in the Sedation Chart Matrix of Proposed AK and existing ID, MT, OR, WA. AK, proposed. "Moderate sedation: Moderate sedation and all sedation 12yo and younger".
2. Board certified pediatric dentists may not administer either nitrous oxide/oxygen or enteral sedation to patients under twelve years old unless they have the equivalency of a parenteral moderate sedation certificate. Many are out of residency more than five years and do not possess a parenteral certificate at present. (ref: Proposed Regulation Changes revised draft 4/5/16: page 2, (b) "...may be granted a permit to administer moderate sedation", if, (1) initial training or education in the permit category for which the applicant is applying has been completed no more than three years immediately prior to application")

3. More probable higher rates of over-sedation. Dentists who do not have a parenteral sedation certificate may administer one dose equivalent to the Federal Drug Administration's maximum daily dosage of a particular sedative drug for minimal sedation. This will be allowed, but giving a smaller dosage, with possibly one additional dose if necessary, the total not to exceed the same recommended maximum daily dosage, will not be. This one and only allowed technique is much more likely to result in over-sedation than taking a safer, partial dose route of administration. (ref: Proposed Regulation Changes revised draft 4/5/16: page 1, 12 AAC 28.005, (a), (3) "the administration of a single dose oral medication to achieve minimal sedation…")
4. No dentist in the State of Alaska will be able to moderately sedate patients under the age of twelve. The requirements set by the Board for the continuing education needed to apply for certification are impossible to achieve: there are no programs in the United States available that meet these requirements. None! (ref: Proposed Regulation Changes revised draft 4/5/16: page 15, (f),(2), "The course shall consist of 60 hours of didactic instruction plus management of at least 20 pediatric patients 12 years of age and under per participant… The course content shall be consistent with the guidelines published by the American Dental Association, Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry") Furthermore, these ADA Guidelines are not appropriate, nor do they apply to pediatric patients.
5. Greatly increased cost to dentists, patients and State agencies will occur, despite the claim by the State's own literature that claims there will be no increased costs involved. As written, increased costs to dentists and patients to administer nitrous oxide/oxygen sedation to patients 12 years old and younger will exist for required education and equipment. Costs to State agencies are anticipated for onsite inspections. How are these to be conducted at no additional cost? (ref: Notice of Proposed Changes. Page 4. 7. Estimated annual cost to comply…TABLE)
6. If implemented immediately, dentists without current certification will not be able to offer care involving sedation until required education courses can be attended and applications are approved for certification: conservatively taking twelve months to attend courses, then apply to the Board and wait for certification.

Establishing standards of care to improve public safety is admirable and is the top priority in our profession, but what warrants the sweeping proposed regulation changes to provide sedation of dental patients in Alaska? Are we harming patients in dentistry at an alarming or increasing rate? The answer is NO! There is zero evidence of any increase in incidence or risk to dental patients both here in Alaska, and Nationally. We can thank the media for sensationalizing the news and making us more aware that untoward events do occur, but the CNA insurance group dropped its additional premium for dental sedation, across the United States, some fifteen years ago because there was no justified reason to charge for an increased liability that didn't, and still doesn't exist. Here in Alaska, the CNA malpractice insurance company has had no claim of malpractice relating to dental sedation for at least twenty-seven years. So why the changes when there has not been a problem identified? Why the confusing and contradictory language? I hope a more succinct and better reasoned approach is taken to make any changes. Additionally, future changes to sedation regulation would best serve both the public and the profession if they were made according to evidence and science, not anecdote, and if those changes were made with forethought as to their implementation.

Most Sincerely,

Michael Fuller, DDS, FICOI

Zimmerman, Marilyn A (CED)

From: Chris Logan <chrisloganrn@hotmail.com>
Sent: Saturday, April 30, 2016 10:55 AM
To: Zimmerman, Marilyn A (CED); Maiquis, Jun C (CED)
Cc: Sheila Jensen
Subject: Dental board proposed regulations-CRNA input
Attachments: Dental Board public comments.docx

Hello Ms. Zimmerman,
Here is the input from the Alaska Association of Nurse Anesthetists (CRNAs) regarding the dental board sedation regulations. It is short and sweet, and simply corrects a certification body title.

Thank you for your attention,
If you have any questions or concerns please contact me

Chris Logan, CRNA
907-982-0513
chrisloganrn@hotmail.com

From: Alaska Association of Nurse Anesthetists (CRNA)

Re: Public comments for proposed dental board sedation regulations.

Dear Ms. Zimmerman and Mr. Maiquis,

Here are the comments for the CRNA section of the proposed regulations. We suggest including the current name of the credentialing body. Suggested blue highlighted text should be substituted for yellow highlighted text. We are in agreement with all other sections of the proposed regulations that specifically name CRNAs.

Thank you for your time,

Kind regards,

Wendy Monrad, CRNA, APRN
President, Alaska Association of Nurse Anesthetists

Chris Logan, CRNA, APRN
Past president, Alaska Association of Nurse Anesthetists
Past Co-Chair, APRN Alliance (Advanced Practice Registered Nurse)

12 AAC 28.030. Other than permit holders. (a) In addition to a dentist holding a valid

permit **under 12 AAC 28.010 and 12 AAC 28.015** for the administration of **moderate sedation, deep sedation, or** [AN ANESTHETIC AGENT OR AGENTS FOR THE PURPOSE OF INDUCING] general anesthesia, [AS PROVIDED IN 12 AAC 28.010, THE FOLLOWING PERSONS MAY ADMINISTER AN ANESTHETIC AGENT:] **a certified registered nurse anesthetist (CRNA) or physician anesthesiologist may provide those services in a dental office or facility upon meeting the following requirements under this section:**

(1) **the** [A] registered nurse **is** certified by the Association of Nurse Anesthetists **(CRNA) and maintains a current license in Alaska** [WHO WHILE IN A DENTAL OFFICE ADMINISTERS THE ANESTHETIC AGENT UNDER THE DIRECT SUPERVISION OF A DENTIST HOLDING A VALID PERMIT UNDER 12 AAC 28.010];

The text highlighted in yellow should be revised to read:

(1) the certified registered nurse anesthetist (CRNA) holds current certification by the American Association of Nurse Anesthetists and maintains a current license in Alaska.

Zimmerman, Marilyn A (CED)

From: Chris Logan <chrisloganrn@hotmail.com>
Sent: Saturday, April 30, 2016 10:55 AM
To: Zimmerman, Marilyn A (CED); Maiquis, Jun C (CED)
Cc: Sheila Jensen
Subject: Dental board proposed regulations-CRNA input
Attachments: Dental Board public comments.docx

Hello Ms. Zimmerman,
Here is the input from the Alaska Association of Nurse Anesthetists (CRNAs) regarding the dental board sedation regulations. It is short and sweet, and simply corrects a certification body title.

Thank you for your attention,
If you have any questions or concerns please contact me

Chris Logan, CRNA
907-982-0513
chrisloganrn@hotmail.com

From: Alaska Association of Nurse Anesthetists (CRNA)

Re: Public comments for proposed dental board sedation regulations.

Dear Ms. Zimmerman and Mr. Maiquis,

Here are the comments for the CRNA section of the proposed regulations. We suggest including the current name of the credentialing body. Suggested blue highlighted text should be substituted for yellow highlighted text. We are in agreement with all other sections of the proposed regulations that specifically name CRNAs.

Thank you for your time,

Kind regards,

Wendy Monrad, CRNA, APRN
President, Alaska Association of Nurse Anesthetists

Chris Logan, CRNA, APRN
Past president, Alaska Association of Nurse Anesthetists
Past Co-Chair, APRN Alliance (Advanced Practice Registered Nurse)

12 AAC 28.030. Other than permit holders. (a) In addition to a dentist holding a valid

permit **under 12 AAC 28.010 and 12 AAC 28.015** for the administration of **moderate sedation, deep sedation, or** [AN ANESTHETIC AGENT OR AGENTS FOR THE PURPOSE OF INDUCING] general anesthesia, [AS PROVIDED IN 12 AAC 28.010, THE FOLLOWING PERSONS MAY ADMINISTER AN ANESTHETIC AGENT:] **a certified registered nurse anesthetist (CRNA) or physician anesthesiologist may provide those services in a dental office or facility upon meeting the following requirements under this section:**

(1) **the** [A] registered nurse **is** certified by the Association of Nurse Anesthetists **(CRNA) and maintains a current license in Alaska** [WHO WHILE IN A DENTAL OFFICE ADMINISTERS THE ANESTHETIC AGENT UNDER THE DIRECT SUPERVISION OF A DENTIST HOLDING A VALID PERMIT UNDER 12 AAC 28.010];

The text highlighted in yellow should be revised to read:

(1) the certified registered nurse anesthetist (CRNA) holds current certification by the American Association of Nurse Anesthetists and maintains a current license in Alaska.

Zimmerman, Marilyn A (CED)

From: davebackus <davebackus@bex.net>
Sent: Monday, May 02, 2016 6:32 AM
To: Zimmerman, Marilyn A (CED)
Subject: Alaska rules review
Attachments: ALASKA BOARD rules review .pdf

Dear Marilyn,
Please forward these comments from my review of the proposals.
I had been forwarded a copy from others and offer these comments.
Thank you,
Respectfully,
David R. Backus

David R. Backus B.S. Pharm, D.D.S, R.Ph.
Anesthesiologist for Dentistry
Alaska License DEND 1549
Alaska GA permit 47

TO: Marilyn Zimmerman
marilyn.zimmerman@alaska.gov
SUBJECT: Dental Board regulation changes
DATE: 1MAY 2016

Please forward these reflections on the proposed changes to the Board for me.

Page 3
(2) only provide patients in ASA risk category Class III moderate sedation, deep sedation, or general anesthesia if
(A) he or she has documented a consultation with their primary care physician or other medical specialist regarding potential risks and special monitoring requirements that may be necessary; or
(B) he or she is an oral and maxillofacial surgeon or dental anesthesiologist and has performed an evaluation and documented the ASA risk assessment category of the patient and any special monitoring requirements that may be necessary;
It is my opinion that "medical consultations" for information reflecting a patients' "optimization" prior to any care, no matter what it be should be left up to the provider and not selected out according to provider licensure.
All providers are trained in Dental School to understand when further medical information is proper and preferred prior to care and that is a basis for a "standard of care" not a certificate relative to sedation or anesthesia provision.

Page 4
Please be more specific about what the statement "while returning the patient to the intended level of sedation" means.
Monitoring ANY patient in any manner to insure safety OF THE PATIENT is the most important concept to understand here.
Long before there were "monitors" Doctors or ancillary help "monitored" patients to insure safety of the patient while either sedated/anesthetized or recovering.
Proper monitoring relative to patient safety is a continuum and not something that is "periodically" monitored.

Page 5

(m) In a proceeding of the board at which the board must determine the degree of sedation or level of consciousness of a patient, the board will base its findings on
(1) the type and dosage of medication that was administered or is proposed for administration to a patient of that physical and psychological status; and
(2) the degree of sedation or level of consciousness that should reasonably be expected to

result from that type and dosage of medication.

Any provider who practices sedation/anesthesia is keenly aware that ALL patients are individually unique and "amounts" of medications vary.
The more important consideration is to abide by the guidelines set by the ADA sedation/anesthesia guidelines relative to the certificate and training of the provider.
Providers should be responsible to their patients/themselves based on their certificated training and experience and then accountable for their actions for care.
Having anyone not in the presence of "care" of the patient is only leading to "arm chair quarterbacking" and inappropriate.

RE: ACLS/PALS
Page 7

.....such as courses in Advanced Cardiac Life Support (ACLS) for Health Professionals or Pediatric Advanced Life Support (PALS) for Health Professionals
Only if a practice limits their administration of anesthesia to patients 12 years or younger, should they only be certified in PALS. For example, if a Pediatric Dentistry practice sees teenagers or handicapped adults, they must also be certified in ACLS.
baseline vital signs shall be taken and recorded prior to administration of any controlled drug at the facility and prior to discharge;

A "requirement" for ACLS/PALS training is a "noble" consideration.
If this training is "mandated" then ACLS should be the considered BASELINE care provision.
If you are going to mandate PALS for "children" 12 or under, then add this to the requirement.
Please remember, children are NOT just "little adults" for many physiologic reasons. Size relative to age should NOT determine "adult status".
Baseline vitals are NOT always possible PRIOR to initiation of ANESTHESIA care.
I ask you, have any of you tried to obtain baseline vitals on a 2 year old prior to full mouth rehab due to bottle mouth caries, abscess or a variety of considerations? (they present like this for most times an obvious reason) Some mentally handicapped/spastic children/adults prior to administration of medications to accomplish base line vitals?
Even in a hospital setting, and even at a "pre operative" testing appointment at the pediatricians'/PCP's office is it most difficult if not next to impossible.
SEDATION levels of care should be considered/selected as possible prior to care OR, in my opinion, the patient may NOT be a candidate for a "sedation" level of care.

With respect to Monitoring again:
Page 8

(2) patients shall have continual monitoring of their heart rate, blood pressure, and respiration. In doing so, the permittee must utilize electrocardiographic monitoring, pulse oximetry, and end-tidal carbon dioxide monitoring;
You must include a manual or automatic blood pressure monitor.

(4) a patient may not be left alone in a room and must be monitored by the sedation provider or a staff member capable of handling procedures, complications, and emergency incidents related to deep sedation and general anesthesia;

I understand your "intent" BUT please understand that the ADA guidelines DO NOT mandate EKG monitoring on patients that are sedated v. under GA.
Not all Sedation courses as I understand it (going on past conversations) offer as a requirement for certification ACLS training. If a provider has no training in EKG reading and understanding and is NOT ACLS certified yet qualifies by certificate for sedation, how can EKG reading and evaluation be properly considered as a monitoring aid?
Other monitoring aids listed such as EtCO2 are again relative to the type/level of sedation as well as where in the continuum of sedation/anesthesia/recovery of the patient.
I prefer the EtCO2 monitoring but are the ADA guidelines specific on mandating it ALWAYS?

Page 9
(B) endotracheal tubes and appropriate connectors, laryngeal mask airway (LMA) and other appropriate equipment necessary to do an intubation;
The teachings these days in ACLS and other airway management courses are suggesting that supra glottic devices are safer, more convenient and overall " simplier " to aid in rescue airway management than are "intubation" measures. The word "OR" might be recommended here.
If out of practice intubating, more damage than harm and wasted/lost time may insue.
I do believe that "practice" at supra glottis devices be practiced "periodically" to keep the practitioner confident as well as competent.
Urgencies/Emergencies will happen over time.

Page 12

.....provide confirmation of completed coursework and 8 hours of clinical airway management review within the two years prior to
submitting the renewal application from one or more of the following:
(A) ACLS from the American Heart Association; or
(B) PALS in a practice treating pediatric patients 12 years of age and under;

It would be my opinion that sedation providers should NOT be able to treat children under 12 without advanced training and management. PALS may be considered a baseline credential.
Children ARE NOT "little adults" no matter what the body looks like. The AGE standard of 12 is set by people who have had many committees and discussions over time as a safety age and not arbitrarily picked.
The ASA and ADA have guidelines with this age according to my recollection.
ACLS should be the baseline if mandated and PALS should be an add on as according to the providers' patient care.

Page 20
(3) provide confirmation of completed coursework within the two years prior to submitting the renewal application from one or more of the following:
(A) ACLS from the American Heart Association; or
(B) PALS in a practice treating pediatric patients 12 years of age and under;
Why do you require this training when an EKG is not a required monitor?

(5) complete at least 10 moderate sedation cases per calendar year.

A requirement to complete a minimum case load or "else"..... is a statement that needs to be removed.
What is a remedy if this "requirement" is not obtained please?
If a provider obtains ALL of the didactic requirements yet has no patient load that requests certificated level of care, what is going to "happen" then in order for the provider to obtain the ability to treat patients if they request care?

Page 24-26

The discussion about having "other" non Dental providers enter into a Dental providers' office needs some consideration.
Providers in a DENTAL office provide care of sedation/anesthesia based on training and certification to patients. These Doctors are regulated by "THE BOARD" and must adhere to specific regulations and reviews.
When you then ALLOW non Dental providers to enter a DENTAL office, what scrutiny by "THE BOARD" do you provide? There should be NO FREE PASS on ANY non dental provider.
EXAMPLE: Dentists in their offices are the primary responsible providers of patient care.
A CRNA technically is, in a hospital setting unable to provide care without an MD anesthesiologist present. Why then is a CRNA able to enter into a Dentists' office, who has no training in sedation/anesthesia, and then be able to provide care WITHOUT submission to the same scrutiny by "THE BOARD" prior to care?
Why would any "DENTAL BOARD" allow an MD anesthesiologist without any scrutiny be allowed to provide care in a Dental office?
Do you think that any Dental provider would have privileges to practice in a medical setting without scrutiny? I don't think so!
I ask why then would this reverse be granted without scrutiny?
I believe that a DENTIST who requests a NON DENTAL DEGREE provider to practice in their office should be qualified to the level of requested sedation/anesthesia AND that this NON DENTAL DEGREE provider be held to the same considerations, licensure and degrees as Dental providers practicing sedation/anesthesia.
Anything less than this offers opportunity for lack of proper control and review of standards set by the ADA guidelines for sedation/anesthesia care in a Dental office.
Personally, it is my feeling and belief that any NON dental provider should NOT be able to provide care in a DENTAL office period.

Dentistry educates, regulates and provides education as well as residency training where the students are training at the same levels as medical students if not more due to scrutiny. Dentistry should be proud of and welcome a limited provider criteria because of our strict, policed and regimented standards within our organization.
We should NOT be so willing to just give up selectivity of providers no matter what the circumstance. IF we need more providers to match care.....then "we" should provide an environment that encourages providers proper access as well as reimbursement for rendering services.
Dentistry has great sedation and anesthesia courses and residencies.
WE should be proud of them, utilize them and support them from within our own organization and not "sell ourselves" out short.

Page 34
The definition, (9) "moderate sedation" means a drug-induced depression of consciousness, during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained;

Various levels of "sedation" still having patients able to respond yet slightly obstructed as a result of a proper amount of sedation coupled with good local anesthesia and a calm or quiet environment is very common. It is NOT necessarily a negative consideration to have a "snoring" patient who is simply responsive when verbally challenged or simply recoverable. A slight chin lift or side movement of the head may be all that is needed to correct such a consideration as well. If monitoring aids are appropriate for patient safety as well as for certificate qualifications then I have no difficulty with the above.
Finally, above all else, a provider needs to do an appropriate pre surgical evaluation and if necessary testing and consultation prior to any decision making to follow through with sedation/anesthesia care. Patient safety is tantamount. Vigilance during care is primary.
A provider must ALWAYS know where the patient IS during sedation/anesthesia care.

Zimmerman, Marilyn A (CED)

From: davebackus@bex.net
Sent: Monday, May 02, 2016 9:19 AM
To: Zimmerman, Marilyn A (CED)
Subject: Re: Alaska rules review

Hi
Thx
Hope another perspective helps.
Let me know if I can be of any further help.
Respectfully,

David R. Backus B.S. Pharm., D.D.S., R.Ph.
Dentist Anesthesiologist
Great Lakes Anesthesia for Dentistry
4720 Jackman Rd.
Toledo, Ohio 43612-2030
419-469-0540 cell
419-476-1484 office
419-476-6914 fax

On May 2, 2016, at 12:42, Zimmerman, Marilyn A (CED) <marilyn.zimmerman@alaska.gov> wrote:

> Dear Dr. Backus:
>
> I am in receipt of your email and letter with your comments regarding the Alaska Board of Dental Examiners' proposed regulation changes. Thank you for taking the time to review the proposed changes and for your comments. I will forward your comments on for review and consideration.
>
> Best regards,
>
> Marilyn Zimmerman
> Paralegal I
> Division of Corporations, Business and Professional Licensing
>
> marilyn.zimmerman@alaska.gov
> (907) 465-2532 desk

(907) 465-2974 fax (Please note: I do not have a direct fax line. Emailing documents will bring them to my attention sooner.)

Mailing address:
Marilyn Zimmerman
c/o Dept. of Commerce, Community and Economic Development
Div. of Corporations, Business and Professional Licensing
P.O. Box 110806
Juneau, AK 99811-0806

Visit www.professionallicense.alaska.gov to see if your problem can be resolved online.

From: davebackus [mailto:davebackus@bex.net]
Sent: Monday, May 02, 2016 6:32 AM
To: Zimmerman, Marilyn A (CED)
Subject: Alaska rules review

Dear Marilyn,
Please forward these comments from my review of the proposals.
I had been forwarded a copy from others and offer these comments.
Thank you,
Respectfully,
David R. Backus

Zimmerman, Marilyn A (CED)

From: Kent Newell <knewellak@gmail.com>
Sent: Tuesday, May 03, 2016 1:38 PM
To: Zimmerman, Marilyn A (CED)
Subject: Purposed Changes to Sedation Permits

May 3, 2016

Alaska Board of Dental Examiners

PO 110806

Juneau, Ak. 99811

Alaska Board of Dental Examiners

Recently I received an email with proposed changes to the Parenteral sedation permit. I have been a parenteral sedation permit holder since 2008. I have safely performed hundreds of sedation's without incident over the years. This has allowed me to serve a group of patients whom otherwise may not have been able to receive the dental care that they needed. I have been able to treat many mentally challenged patients providing care that otherwise would not have been possible without sedation.

I believe that the safety of the patient should be our number one objective, and I am not opposed to regulations that would help to minimize the risk to patients. I also believe that by heavily regulating the licensure process it will create an access to care issue. Many patients who need care will not be able to get it if the process is regulated to the point that very few people can obtain licensure.

I'm unsure what has brought about the need for a change. There has never been an explanation sent out as to the reasons why a proposed change is necessary. As I read through the proposed changes I find them to be confusing and with contradictory statements.

I feel that these new regulations are trying to be pushed through very quickly without giving the public a chance for input. There has also not been a forum where a licensed dentist could give input. It is my understanding that the board is not receiving public testimony at the next quarterly meeting this May. How could the board purpose such broad and sweeping changes to licensure without providing time for public input.

I believe that dentists and the public for which we care would be better served for a more measured approach allowing license holders time to comment about the purposed changes.

Kent Newell DMD

O: 907-562-2820 M: 907-441-2514

Zimmerman, Marilyn A (CED)

From: David Logan <dlogan@akdental.org>
Sent: Wednesday, May 04, 2016 2:54 PM
To: Zimmerman, Marilyn A (CED)
Cc: Erkenbrack, Stacia L (CED)
Subject: ADS commnets on proposed changes to the sedation regulations
Attachments: 5.4.16 ADS Board response.pdf

Marilyn
Please find the enclosed comments on the AK BODE proposed changes to the sedation regulations.

Dave Logan, DDS
Executive Director, Alaska Dental Society
P:(907) 563-3003 C:(907) 723-2884
Email: dlogan@akdental.org
Website: akdental.org

"Committed to enhancing the dental profession and the health of all Alaskans"

Alaska
DENTAL SOCIETY

May 2, 2016

Alaska Board of Dental Examiners
POB 110806
Juneau, AK 99811

Alaska Board of Dental Examiners,

The Alaska Dental Society (ADS), representing 365 dental license holders, held a meeting of its members on April 25th to discuss the proposed changes to sedation regulations.

Opinions varied amongst our members on the overall effect of the proposed changes but there was one universal point all attendees agreed on: there has been both limited time for public comment and no forum to allow license holders or public members to speak directly to the Alaska Board of Dental Examiners (Board) regarding the changes.

The proposed changes to the regulations span 35 pages, are very complex and would introduce new permitting and regulatory components. A change of this magnitude is deserving of more explanation to, and input from, the affected license holders than mailing a listing of the headings of sections with changes and posting the regulation changes to the Board website.

Amongst the comments from license holders at the ADS meeting:

- Why are the changes necessary?
- The costs for implementation and training have been grossly underestimated
- Excessive education requirements for moderate sedation permit
- Moderate sedation permit required for using minimal sedation on <12yo is excessive
- Does it make more sense to have oral moderate conscious sedation permit separate from parenteral sedation permit?
- Medical consult required for stable ASA III patient can limit access to care
- Single dose for minimal sedation clause should be removed because dentist may elect to give the maximum dose up front, instead of using the lowest possible dose for the therapeutic effect (Halcion used as example)
- ADA, AAPD, and AAP have guidelines already made, why is the board making changes or recommendations that are not in the guidelines?

9170 Jewel Lake Rd. Ste. 100 Anchorage, AK 99502
Phone: (907) 563-3003 • Fax: (907) 563-3009 • Website: akdental.org • E-mail: info@akdental.org

Many other comments were made regarding points of change and clarification. Rather than belabor the issue the ADS suggests to the Board that implementation of changes to regulations regarding sedation under 12AAC28 be tabled and a work group formed with a representative group of board members and affected license holders. The ADS would suggest having members consisting of general dentists with and without parenteral sedation permits and dental specialists with and without parenteral sedation permits. The ADS would be willing to put forward names to meet whatever criteria the Board feels is appropriate.

The workgroup could meet during the summer – much of the work could be done by email – with recommendations presented to the Board at the September meeting. The Board could review those changes, incorporate recommendations from the ADA if approved at the 2016 ADA House of Delegates in October and returned to the drafter after the December meeting.
A measured approach such as this will allow affected license holders the opportunity for comment and produce a better end result to insure sedation dentistry in Alaska is both safe and affordable.

Jesse G. Hronkin, DMD
President, Alaska Dental Society

Zimmerman, Marilyn A (CED)

From: David Logan <Davelogandds@outlook.com>
Sent: Wednesday, May 04, 2016 3:15 PM
To: Zimmerman, Marilyn A (CED)
Subject: Commnets of dental sedation regulation changes

AK BODE
I appreciate the time and effort the BODE has made towards changing and improving the regulations governing dental sedation in AK.
I would suggest, however, a more measured approach fully involving license holders. The issues regarding sedation are complex and all affected license holders should be able to have a chance to express their views before the Board sets the final regulations.
The primary concern appears to be, and should be, public safety. No matter how the Board chooses to set the final education and training requirements for dentists administering sedation it will still not be an assurance of the desired outcome.
I would suggest a change of direction from the Board's proposal. Rather then stipulate additional educational and training requirements for lessor sedation's, develop 3 classes of permits: Mild, moderate and deep/GA. Move the restrictions on mild to about 1/2 way between mild and moderate as currently proposed. Training requirements would simply be a dental education. With this, however, would come mandatory reporting requirements for adverse outcomes (not just death) for all classes of permits. Failure to report would automatically revoke license. Give the Board a little discretion, one bad outcome in 2 years, Board discretion for action if any, 2 additional education or permit revoked, 3 permit revoked.
This will identify the problem practitioners while allowing dentists who are practicing sedation carefully to continue their current practices.

David Logan, DDS
AK DD 698

Zimmerman, Marilyn A (CED)

From: Dustin Slunaker <dustin@mintdentalalaska.com>
Sent: Thursday, May 05, 2016 10:24 AM
To: Zimmerman, Marilyn A (CED)
Subject: Dental Statutes

To Marilyn Zimmerman,

I am writing to you regarding the recently proposed changes to the Alaska dental statutes on sedation. There is no denying that there have been deaths in the dental office involving sedation and we should evaluate what has happened, so that it does not happen here in the great state of Alaska. This does not however mean that the board of dentistry should start passing poorly written and poorly thought out regulations. This seems like a deliberate attempt to limit the general dentist's ability to serve their patients. Alaska is an enormous state with very diverse needs and I believe you need to reconsider these regulations. I would propose an open and fair dialogue to create reasonable rules that won't create an access to care issue.

Thanks for your consideration,

Dustin Slunaker DMD

Zimmerman, Marilyn A (CED)

From: Renee Robertson <renee_robertson@hotmail.com>
Sent: Thursday, May 05, 2016 11:17 AM
To: Zimmerman, Marilyn A (CED)
Subject: Sedation Changes

May, 5th, 2016

Alaska Board of Dental Examiners,

I am writing to urge the Board to slow the process of sedation regulation changes and involve the affected license holders. I can say with confidence that all sedation permit holders are in agreement that safe and effective sedation for our patients is the ultimate goal. The proposed changes need further review and input from the permit holders. This state has significant access to care issues, and the proposed regulation changes will make access much more difficult for patients. Safety is the goal, but fixing one problem to create another is not the answer and serves no one.

Thank you,

Renee Robertson DMD

Zimmerman, Marilyn A (CED)

From: Christine Roalofs <croalofs@gmail.com>
Sent: Friday, May 06, 2016 2:22 PM
To: Zimmerman, Marilyn A (CED)
Subject: Alaska Pediatric Dental Society response to proposed sedation regulations
Attachments: Sedation regs Peds.docx

Hi Marilyn,

I've attached a letter from the Alaska Pediatric Dental Society with our comments and requests related to the proposed sedation regulations.

Please contact me if there are any questions.

Thank you for your attention.

Christine Roalofs
President, APDS

TO: the Alaska Board of Dental Examiners

RE: Proposed sedation regulations

FROM: The Alaska Pediatric Dental Society

We are in support of the intent of the new regulations, but would like to offer our suggestions in regards to several points of the proposed regulations.

As pediatric specialists that have completed 2-3 years of additional training with sedating children in an accredited program, we should be considered the most qualified to treat and sedate children under age 12. Completion of a residency program should be sufficient qualification for obtaining the necessary moderate sedation permits.

Pediatric Dentists have advanced training in patient selection, assessing all treatment options, and can consider all mitigating factors, thus offering multiple options to the families, allowing for safe and effective treatment.

Placing restrictions on the utilization of moderate sedation by Pediatric Dentists could potentially impact the special needs and young children populations.

As Pediatric Dentists, we see only children and special needs patients, but we can't provide care for every child. We appreciate help from general dentists and understand many of them offer sedation services. We feel that they should have requirements specific to sedating young children if they are going to provide that service. PALS certification should certainly be required of all dentists sedating children. If a dentist has not completed a pediatric residency program, sixty (60) hours of didactic courses exclusively related to sedating children and managing emergencies in the office should be required, in addition to twenty (20) hours of hands-on sedation cases under supervision of trained personnel.

We would like the Board to consider that moderate conscious sedation can take different forms, and perhaps having separate permits for enteral and parenteral sedation be appropriate to dentists providing care in Alaska. Many Pediatric Dentists use an oral drug in combination with nitrous oxide. According to the new proposals, this would require a permit for moderate sedation in the same league as dentists using an IV to provide sedation, and with it requirements for monitoring the patient at a level of sedation not normally achieved in our offices (such as EKG and capnography).

There are pediatric dentistry programs that are training residents with the use of the drugs that the Board attempting to exclude. The AAPD guidelines do not exclude drugs from our armamentarium, which highlights the sophistication of our specialty. The American Academy of Pediatric Dentistry has well established guidelines for sedating children. These guidelines are constantly reviewed and updated to reflect the most current research available. Pediatric Dentists are well versed in these guidelines and strive to uphold them in their offices. Further restrictions in the State of Alaska could hinder our efforts to treat the high rates of oral disease in our state.

In summary we would like the Board to consider the following;

Pediatric Dentists should be allowed to obtain a moderate conscious sedation permit without further education requirements.

Pediatric Dentists should not have limitations on types of drugs they have been trained to use.

PALS training should count toward the eight (8) hours of airway management training proposed for permit renewal.

There should NOT be a yearly requirement of cases completed to maintain a permit. Many of us spend considerable time in an operating room environment and select our in-office moderate sedation cases carefully.

General Dentists sedating children under age 12 must show adequate training as outlined above.

While capnography has been demonstrated to increase patient safety when used in an intubated patient, there is no evidence to support its use when the airway is not secured and protective reflexes remain intact. Therefore it should not be required for oral conscious sedations.

A method for self-reporting adverse sedation outcomes should be required as part of a sedation permit. Failure to report can lead to disciplinary action, including restriction of a sedation permit.

Thank you for your consideration of these items.

Alaska Pediatric Dental Society

Zimmerman, Marilyn A (CED)

From: William Bergeron <william.bergeron@oralsurgeryalaska.com>
Sent: Friday, May 06, 2016 2:54 PM
To: Zimmerman, Marilyn A (CED)
Subject: Comments on proposed sedation regulation changes
Attachments: Sedation reguataion change comments.docx

Attached please find some of my comments about the proposed sedation regulation changes.

William F. Bergeron, Jr., D.D.S.
Alaska license # 1103

The Alaska State Board of Dental Examiners recently proposed to update various regulations regarding 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. Though it is about time these regulations were examined the Board's proposed changes do not address areas I feel need attention and seem to place excessive requirements where they are not needed. None of their proposals require reporting of adverse incidents unless a patient death or hospitalization occurs. I feel any time a provider feels it necessary to contact 911 or sends a patient to the emergency room for care due to a sedation procedure this incident should be reported to the Board and subsequently investigated. If the provider's sedation technique is found to be the cause of the incident the provider should be sanctioned appropriately. Sanctioning of a provider for this kind of a warning incident might help prevent a death or hospitalization during future patient care.

As to changes the Board has suggested some do not appear to have been completely thought through as to the impact on access to care or allowing providers to practice skills they were trained to perform and utilize on a daily basis. The following are some of the new regulations I feel need to be reviewed and altered.

1. Requiring providers to acquire a moderate sedation permits to administer oral sedation is a good idea. However the training requirement timing to obtain a new moderate sedation permit would exclude providers who have been out of specialty training for more than five years. This would preclude many of the practicing pediatric dentists in the state from continuing to provide sedations to their customers as they have on a daily basis without completing a significant amount of continuing education.
2. The requirement for 8 hours of continuing education dealing with ACLS or PALS I believe requires taking a complete initial course and the recertification courses will not account for that many hours of continuing education.
3. The requirement for 12 hours of continuing education dealing with the seven listed topics seems excessive when only 32 hours of continuing education are required to maintain a dental license. If a provider is sedating patients daily these courses will not change their technique and will serve minimally as a refresher on esoteric topics. I believe 4 hours would be more than sufficient to keep providers current and safe in the administration of moderate sedation agents and potential complications.
4. The requirement to maintain PALS certification to treat patients with moderate sedation for children under 13 seems to be built on false idea. PALS only covers children to the age of eight. Therefore I feel your age break would be better set at treating children under 9 would require PALS certification.

Hopefully the Board will not pass these new regulations without considering changes to accommodate those dentists and specialists presently delivering safe and effective dental care to the patrons in our state. I believe the best way to proceed forward would be to form a working group consisting of general dentists and specialists to review these proposed new regulations, suggest any and all changes deemed necessary and then after the revised regulations are reviewed by the Alaska Dental Society the Board would vote on their passage and implementation. Thank you for considering this request to work toward changing our laws in a responsible manner.

Sincerely,
William F. Bergeron, Jr., D.D.S.
Alaska License #1103

Zimmerman, Marilyn A (CED)

From: Adam Jensen <adamgjensen@gmail.com>
Sent: Friday, May 06, 2016 6:57 PM
To: Zimmerman, Marilyn A (CED)
Subject: Proposed Sedation Regulation concerns

Marilyn,

Please pass this to the Alaska Board of Dental Examiners.

Thank you,
Adam Jensen

Alaska Board of Dental Examiners:

Thank you for taking the time to read comments regarding the proposed changes to the regulations regarding sedation.

I certainly agree, regulation in some respects is a good thing. I have to believe that all dentist in Alaska hold patient safety as their number one priority, however, as a practicing sedation dentist in Alaska, I have some concerns with the new proposed regulations.

My main question is why such a broadly impacting change in regulations? I am not opposed to change, but simply request the ability to collaborate as dental professionals as a whole before major regulation changes are made. It appears little to any input from the majority of dentist actually affected by the regulations has been considered.

I feel there are some regulations that would benefit being added that are not in the proposal, like mandatory reporting for adverse outcomes. And there are regulations that are in the proposal that appear excessive for no reason.

I am specifically concerned with the proposed mandate for a required med consult for stable ASA III patients. I fear most medical doctors may not have had enough training to understand dental treatment and sedation. I have no issues sending a truly medically compromised patient for a med consult first, or seeking help from a dental anesthesiologist, but stable ASA Class III are becoming an increasingly larger portion of the population, based on the literal interpretation of ASA III. Some of these patients are safer treated under moderate sedation to reduce risk of a cardiac incident than without sedation.

All throughout four years of dental school, the overriding message was to decrease barriers to help manage and restore oral health. Some of these regulations do the opposite and create barriers to treatment, where Alaska is a state with arguably the highest barriers to care due to the majority of people living in remote places, with the largest distance to travel to care, more so than any other state in the nation. Requiring a med consult for someone that does not truly need it, and only comes to a city once or twice a year where they can receive much needed dental treatment is one more expense and obstacle for the people with the least resources, in the most need.

Please reconsider passing these new regulations so quickly, and allow input and help formulating new regulation in a more democratic, evidence based method.

Thank you for your time,
Adam Jensen

Eagle Summit Dental Group
Sanders, Fuller, Land & Land
13015 Old Glenn Hwy, #200
Eagle River, AK 99577
(907)694-8234
Fax (907)694-8225
msdental@mtaonline.net

Date: 5-9-16 Time: 1:29p

To: Marilyn Zimmerman

Fax Number: 907 465 2974

Re: Alt BODE Proposed Changes

From: M. Sanders DMD

Total number of pages including cover sheet: 6

If you did not receive this entire transmission or it was not intended for you, please contact our office at once.

Thank you,

Eagle Summit Dental Group

May 9, 2016

Dear Board Members,

I am writing this letter in reference to the recent proposed changes in Title 12, Chapter 28 of the Alaska Administrative Code. I am a licensed, practicing dentist in Alaska with a moderate parenteral sedation permit and although I applaud the Board's attempts to update these guidelines, I have several concerns to the proposed changes, as outlined below. I will address my concerns as they were presented to the dentists for review, starting with the section on Estimated Annual Costs.

Estimated annual cost to comply with the proposed actions:

Mild sedation to a child 12 yrs or younger = cost of training and equipment to obtain moderate sedation certificate: costs of training and equipment to obtain moderate sedation permit

At this time, there are no restrictions on dentists using oral mild sedation for kids. Personally, I think this is wrong and I encourage the board to continue their attempts to change this. However, it seems only fair to make it very clear that the cost of obtaining a moderate sedation permit as is outlined in the new proposals is not menial. One of the best courses and a course previously recognized by the Board costs, with airfare, room, board and tuition included, over $30,000 and up to two weeks out of the office over a period of 2-5 months. Is this inhibitory? I'm sure that it is. Will this decrease access to care? Absolutely. I applaud the board for addressing this issue with the unregulated sedation of pediatric patients; however the costs of obtaining the proposed permit cannot be overlooked.

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

This statement is inflammatory and not based on any current ADA guidelines. This statement shows the obvious disconnect between the board and the existing Standard of Care for the administration of moderate sedation. Capnography is NOT the standard of care unless a patient is intubated. The 2012 ADA guidelines state *"The dentist must monitor ventilation. This can be accomplished by auscultation of breath sounds, monitoring end-tital CO2 or by verbal communication with the patient"*. Et-CO2 is an option, not a standard. In the 2016 Proposed Revisions for the Guidelines, Et-CO2 MUST be monitored, but it needs to be emphasized that this is one of the reasons that these proposed changes were NOT adopted. There is much debate and confusion on this topic and many of the leaders in the field are on record as stating that ET-CO2 is useless with moderate sedation, unlike deep sedation or GA, within which it is a necessary safety precaution. This subject will be addressed below but since the Standard of Care is mentioned in the costs section, it needed mentioning here as well.

Although capnography equipment is listed in the costs category, ECG equipment is not. However according to the revised regulations, ECG monitoring would be required and therefore equipment and training should be added as an expense. I will address the use of ECG monitoring below.

Another cost that is not listed is the increased expense of additional CE that is required under these regulations. Since the proposed regulations would require CE that is not available in Alaska (and in some

instances require CE that does not exist!), this will likely require several thousands of dollars in tuition and travel fees.

My last comment on costs is more of a question: Where will the money come from for office inspections? From what I understand, the board has a very restrictive budget. To emphasize this fact, according to the Board's bylaws, an annual report is supposed to be sent to the dental community. I have never received one. I don't know anybody who has received one. The reason given for this is that they do not have money to produce this report. Perhaps this is one of the reasons that these proposed changes were sprung on the dentists at the last minute and that we were not made aware of the discussions that have taken place, but that is beside the point. Offices will need to be inspected all over the State – perhaps Barrow, Nome, Kenai, Fairbanks, etc. And nobody is going to volunteer to be an inspector for free. This sounds like a very expensive program and if there are means to pay for it, great. But if practitioner's fees will be going up because of it, let's be honest about it and put that in the costs that will be associated with the proposed regulations.

PROPOSED REGULATIONS:

I want to start out by stating that I agree on multiple items in the proposed changes. In my opinion, this new age of sedation dentistry is possibly getting out of control with the sedation of children with multiple different medications as well as the unregulated PO sedation of adults by dentists with questionable training. I repeat, this is MY opinion and I have nothing but hearsay to form these opinions. Although I agree on several aspects of the proposed regulations, there are multiple areas where the board is either ill-informed, using false information or, perhaps attempting to block a treatment modality that some would prefer to be reserved for a specialty group. Perhaps if the board would have communicated with current experts in the field or even practicing dentists throughout the State, more useful proposals could have been generated.

12 AAC 28.005. General Provisions

(e)(2)Care for ASA III patients. I cannot think of a case where I have sedated an ASA III patient; however I am concerned that the proposed guidelines mandate that I obtain medical clearance if I do. Of course this is my personal standard of care but we don't need a regulation to mandate it. In the ADA sedation guidelines, it states *...patients with significant medical considerations (ASA III, IV) MAY require consultation with their primary care physician....* If the ADA states they "may need" then why does the AK Board feel a requirement to state "must"? And on a side note, the Board states that this does not apply to oral surgeons, however the ADA guidelines have the exact same language for both groups. Also noted is that no changes to the word "MAY" are found in the proposed ADA guidelines that were NOT adopted in 2015. There is no reason that only an OMS or DA can evaluate ASA III patients. This requirement is unfair and without evidence.

12AAC 28.015. Moderate sedation permit required for mild sedation of pediatric patient.

I urge the board to better define this section as it relates to pediatric sedation. By definition, the use of N2O produces mild sedation. Is the board's intent that any dentist that uses N2O on a patient 12 years of age or younger be required to have a moderate sedation certificate? If this is the case, it would be a

dramatic change in regulations and one that would immediately cease the use of N2O with numerous implications on access to care and the safe and effective treatment of pediatric patients. In addition, I am confused by (f)(2) referencing a pediatric sedation course (such a training course does not exist) and the references to *Guidelines for Teaching the Comprehensive Control of Anxiety and Pain Control in Dentistry*. This publication does not address the topics of pediatric sedation nor the training required to perform sedation on pediatric dental patients. Therefore, the entire paragraph is unsupported. Additionally, an agency cannot write regulations that require a specific level of training where the training is impossible to obtain.

12 AAC28.015(f)(1) – Permit requirements

This section talks about course education requirements to obtain a moderate sedation permit. The board references the ADA's *Guidelines for teaching the comprehensive Control of Anxiety and Pain in Dentistry;* however they either did not read it or skipped a section. And of note, despite the board referencing the 2007 publication, the updated 2012 states the same thing. The ADA recognizes two ways to obtain moderate sedation: Enteral and Parenteral. The education requirements are much different for the two categories (24 hours and 10 cases for enteral and 60 hours and 20 patients for parenteral). The board ignores this and mandates the higher education requirements for both modes of sedation. The ADA, ASDA, ASA and multiple other organizations recognize enteral sedation as a safe, effective, cost-effective treatment option that increases access to care for a large segment of the population. Mandating that dentists that wish to practice enteral sedation obtain three times the education and treatment requirements that the ADA recommends will have very harsh consequences for the public. Dentists will likely eliminate this treatment option for their patients and those that don't will need to spend $30,000+ on training and equipment, likely over 6-8 months. This will dramatically decrease access to care, increase patient fees, and the benefit to patient safety is questionable, at best. It seems prudent that the board offer permits for moderate enteral sedation and moderate parenteral sedation, as is outlined in the ADA's educational guidelines as well as their treatment guidelines, and address educational requirements accordingly.

OF NOTE: This topic was addressed in the 2015 proposed changes to the ADA teaching guidelines. It was proposed that the enteral vs parenteral classifications be eliminated and that they were combined into one 'moderate sedation' classification with the increased education and patient treatment requirements. However this proposal was NOT adopted and this was one of the controversial topics. At this time, there is still a distinction between enteral and parenteral. If the ADA adopts changes to the current guidelines, I would expect the State to follow. However there is doubt that these changes will ever take effect.

(g)(2)

Et-CO2 and ECG monitoring is mandated with the proposed changes.

In the current ADA guidelines, it states: *A dentist must monitor ventilation. This can be accomplished by auscultation of breath sounds, monitoring end-tital CO2 or by verbal communication with the patient.* There is no confusion in this statement. Why would dentists in Alaska be mandated to use equipment that is only one of several accepted methods according to the ADA? In the proposed revisions to this document in 2015, Et-CO2 did become mandated and this was one of the reasons the ADA did NOT

adopt the revisions. On April 20, 2016, an open hearing testimony was held by the ADA on this very topic. There is significant controversy on et-CO2 usage for moderate sedation and for this very reason, Alaskan dentists should not be mandated to use controversial equipment that the leaders in the field feel offers no improved patient safety in moderate sedation cases. In addition, it is noted that in the 2012 ADA guidelines, even in deep or GA cases, et-CO2 is only required for an intubated patient. It is an optional piece of equipment for a deep/GA patient that is not intubated according to the most recent APPROVED guidelines.

In regards to ECG monitoring for moderate sedation cases, I challenge the board to provide evidence that this improves patient safety for every moderate sedation case. According to the ADA's 2012 guidelines, *Continuous ECG monitoring of patients with significant cardiovascular disease should be considered.* This wording does not change in the proposed revisions of 2015 that were NOT approved. So we have two ADA documents that refer to ECG monitoring in extreme cases, however Alaskan dentists under the Board's proposal would be required to use an ECG on every case. Those dentists that do not have this equipment would be further burdened by the added expense and training associated with obtaining this equipment.

(h)(10) – see above re. et-CO2

(i) – I cannot find a mandated drug list for moderate sedation posted by the ADA, ASDA, or other professional organizations. Several of these medications I see no reason to have for a moderate sedation case. It seems more prudent for a practicing dentist to have on hand those drugs which are required for the safe and effective treatment of his or her patients and an emergency kit adequate for rescuing patients when needed. A mandated kit will require frequent turnover of short shelf-life medications adding to unnecessary expense. If the ADA has a recommended list, it seems acceptable to list those specific medication types to have on hand.

(k) – CE requirements for renewal: 16 hours (8 airway) in addition to ACLS

I urge the board to provide specific references to mandated airway CE outside of ACLS training as it relates to patient safety. A common mantra of BLS and ACLS training is "airway, airway, airway" and the majority of training is directly related to advanced airway management. Is there documentation collected nationally or locally that points to a danger to patients resulting from a lack of "advanced airway" techniques? This does not include monitoring or manually repositioning the airway as this is a 'basic' technique. If there is either evidence or ADA guidelines pointing to such, I'll gladly accept it. However finding and attending an advanced airway management course as well as 8 other CE credits outside of ACLS on the topic seems redundant and a waste of resources.

12AAC 28.075 – on-site inspections

As referenced above, I question the practicality of on-site visits as well as the *"board member or its designated representative that has experience in the administration of the method of delivery of sedation or anesthesia used by the dentist or anesthesia provider being evaluated".* Is there a budget for this or will the costs of these visits be passed on to the practicing dentists even though this was not listed in the 'expected costs' section. Additionally, is there a list of dentists that will be doing the site-

visits? As far as I know, there are no parenteral moderate sedation permit holders on the board so as described, outside providers will be used. What is the qualification of these potential individuals and can the dentists be assured that these will be unbiased and fair visits?

In conclusion, I respect the board's position on attempting to ensure the public's safety as it relates to sedation techniques used in dentistry. I question the timing and range of the proposed changes as it seems prudent to follow the ADA guidelines and recommendations. These documents are currently under discussion at the ADA headquarters in Chicago. If the AK BODE approves the proposed local changes and they are inconsistent with national changes (or current un-changed documents), will the board again change the local requirements? Or will our Alaskan dentists be held to a different standard? If so, what is the justification for this? Is there evidenced-based decisions that are being made in Alaska that the ADA is not privy to? If not, then the process appears to be political in nature and this would be quite concerning.

I urge the board to either modify the existing proposals to fall in line with current nationally accepted standards or delay action until the ADA makes any updates to their 2012 publications. I further urge the board to give advanced notice of any implementation or approval dates as to prevent an interruption in sedation and anxiety management services provided by Alaskan dentists.

Thank you for your time in considering this letter.

Michael Sanders, DMD, DABOI
AK License 1086

Zimmerman, Marilyn A (CED)

From: David Stewart <davidmsstewart@hotmail.com>
Sent: Saturday, May 07, 2016 12:08 AM
To: Zimmerman, Marilyn A (CED)
Subject: Comments regarding newly proposed Moderate Sedation Guidelines

May 6, 2016

To whom it may concern within Alaska's Division of Corporations, Business and Professional Licensing Board of Dental Examiners;

I am a board certified pediatric dentist that has been practicing pediatric dentistry since 2000; and I have been practicing pediatric dentistry in Alaska since 2011. I would like to voice my opinion in regard to the newly proposed changes on anesthesia and sedation permits by dentists in Alaska. First I applaud the steps toward updating various regulations to improve patient safety during sedations performed in dental offices in Alaska. As a practicing board certified pediatric dentist performing sedations in the dental office, I recognize the benefits and risks of treating patients under sedation in order to perform necessary dental procedures.

I maintain current PALS and BLS training, and I attend continuing education to maintain the skills necessary to treat patients under moderate sedation. I attended a two year CODA accredited pediatric training program, and I have had the opportunity to be involved in hundreds of moderate sedation, deep sedation, and general anesthesia cases which were performed to allow dental restorative procedures to be performed for children and special needs patients.

Having had many years of experience sedating patients in the dental office utilizing enterally absorbed, orally administered medications in order to induce minimal to moderate sedation; I agree with the critical nature of monitoring and ongoing observation in order to keep patients safe. My concern with the newly proposed regulations in regards to moderate sedation in the dental office is that I feel that the requirements are excessive in regards to monitoring singlely dosed, weight based, orally administered, enterally absorbed sedation medicines with the goal of obtaining minimal to moderate sedation. Understanding that sedation is a continuum, I recognize that any orally induced sedation cannot be specifically defined as minimal or moderate sedation from a given weight based dose of orally administered medications; because absorption and individual response to the medicines can vary dramatically from individual to individual. My concern is that the proposed monitoring requirement of capnography and EKG monitoring for this type of moderate sedation in the dental office is excessive and beyond the guideline of the AAPD, ADA, and the American Society of Dental Anesthesiology as I interpret their guidelines.

For moderate sedation the ADA states:
"For children 12 years of age and under, the American Dental Association supports the use of the American Academy of Pediatrics/American Academy of Pediatric Dentistry
Guidelines for Monitoring and Management of Pediatric Patients During

and After Sedation for Diagnostic and Therapeutic Procedures"

.

The AAPD recommends in regards to all levels of sedation "Monitors: functioning pulse oximeter with size appropriate oximeter probes and other monitors as appropriate for the procedure (eg, noninvasive blood pressure, end-tidal carbon dioxide, ECG, stethescope)." The key phrase being "monitors as appropriate for the procedures." In regards to monitoring during moderate sedation the AAPD guidelines state: "There shall be continuous monitoring of oxygen saturation and heart rate and intermittent recording of respiratory rate and blood pressure; these should be recorded in a time-based record." No where do I find in the AAPD or the ADA guidelines that capnography and EKG monitoring are the standard of care for minimal to moderate sedation induced by enterally administered medications.

For "deep sedations" the AAPD recommendations state "A competent individual shall observe the patient continuously. The monitoring shall include all parameters described for moderate sedation. Vital signs, including oxygen saturation and heart rate, must be documented at least every five minutes in a time based record. The use of precordial stethoscope or capnograph for patients difficult to observe (eg, during MRI, in a darkened room) to aid in monitoring adequacy or ventilation is encouraged." There is a distinct difference in my mind and the guidelines between minimal to moderate enterally induced sedations and deep, parenterally medication induced sedations. Having been involved hundreds of times in both types of procedures, I am very aware of the nuances of both types of sedation and the intended sedation level of both. I personally utilize them as two different types of tools for two completely different types of patients. I always utilize a secondary anesthesia provider to deliver the sedation medications and continuous monitoring if "deep sedation" or "general anesthesia" is the goal.

I personally feel and would recommend that the requirements for moderate and deep sedation should be created distinctly and as stated in the AAPD guideline, with monitor requirements "as appropriate for the procedures." I see no significant issue requiring capnography and perhaps even EKG monitoring for deeply sedated patients who are deeply sedated and not likely to be bothered by the application of EKG wires, but I think this requirement is excessive and from experience distracting in regards to minimal and moderate sedations induced from orally administered medicines and nitrous oxide; where the pediatric patient is not deeply sedated and has to be interacted with and cajoled through the procedure. In these cases, I have found capnography and EKG wires at times to be very distracting to the case.

I have found that many times even the addition of a precordial stethoscope has become distracting to the procedure and had to be abandoned in order to complete the procedure. A blanket state for the use of capnography and EKG monitoring on all moderate and deep sedation cases (which in my opinion have different types of treatment objectives) would lead to the discontinuance of moderate sedation by orally induced means in my office; because I feel that I would not be able to complete many of the orally induced sedation cases due to equipment/monitoring distraction. The loss of this oral medicine induced minimal to moderate sedation tool in my treatment of pediatric patients would be significant in hindering patient care, and would force many more of my patients to be treated under deep sedation or general anesthesia by anesthesiologists. This change would increase the cost of the patient's care and lead to some patients not receiving treatment when this type of treatment becomes cost prohibitive to the parents of the child needing restorative dentistry.

Thank you for your time and consideration of this matter. I hope that my comments will lead to a more in-depth look into an appropriately balanced regulatory approach to these procedures which are very important tools to supplement compassionate dental care for children.

Respectfully,
David Stewart DDS
Board Certified Pediatric Dentist
Phone: 907-953-2544

P.S.--I also feel that the requirement as stated below in addition to a PALS and BLS renewal that has to occur every two years is excessive, because technology and procedures do not change quickly enough to warrant 20 hours of continuing education every two years in the areas stated below in order to perform orally induced minimal to moderate in office sedation.

" To maintain and renew a permit to administer moderate sedation under this chapter a dentist shall:
(1) participate in eight contact hours of continuing education every renewal period that relates specifically to advanced airway management. The course shall be a pediatric course if the permit holder is providing anesthesia for patients 12 years of age and under. In addition to airway management, the permit holder shall participate in 12 contact hours of continuing education every renewal period that focuses on one or more of the following:
(A) venipuncture;
(B) intravenous sedation;
(C) enteral sedation;
(D) physiology;
(E) pharmacology;
(F) nitrous oxide analgesia; or
(G) patient evaluation, patient monitoring or medical emergencies;
(2) maintain records that can be audited, including course titles, instructors, dates attended, sponsors, and number of hours for each course."

Maiquis, Jun C (CED)

From: Alaska Online Public Notices <noreply@state.ak.us>
Sent: Saturday, May 07, 2016 12:01 AM
To: Maiquis, Jun C (CED); Zimmerman, Marilyn A (CED); Zimmerman, Marilyn A (CED)
Subject: New Comment on NOTICE OF PROPOSED CHANGES ON ANESTHESIA AND SEDATION PERMITS BY DENTISTS, EXPIRATION AND RENEWAL OF PERMITS, SUSPENSION OR REVOCATION OF PERMIT, ON-SITE INSPECTIONS, LOCAL ANESTHESIA CERTIFICATION, NITROUS OXIDE SEDATION BY DENTAL HYGIE...

A new comment has been submitted on the public notice **NOTICE OF PROPOSED CHANGES ON ANESTHESIA AND SEDATION PERMITS BY DENTISTS, EXPIRATION AND RENEWAL OF PERMITS, SUSPENSION OR REVOCATION OF PERMIT, ON-SITE INSPECTIONS, LOCAL ANESTHESIA CERTIFICATION, NITROUS OXIDE SEDATION BY DENTAL HYGIENISTS, ETC.**.

Submitted:

5/7/2016 12:01:29 AM

David Stewart
davidmsstewart@hotmail.com

Unknown location
Anonymous User

Comment:

May 6,2016

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You can review all comments on this notice by clicking here.

Alaska Online Public Notices

Zimmerman, Marilyn A (CED)

From: Kenley Michaud <kenley.michaud.dds@gmail.com>
Sent: Sunday, May 08, 2016 8:39 PM
To: Erkenbrack, Stacia L (CED); Zimmerman, Marilyn A (CED)
Subject: Re: Right places for comments?
Attachments: Public Comment - Kenley Michaud.pdf

Marylin and Stacia,

Thank you both for helping the board move forward with regulation updates. I am unsure as to how this upcoming meeting will proceed, but I do hope it goes smoothly. I have attached my letter for the dental board. It consists of amendments I would recommend as well as support for specific sections of the proposed regulations. Please let me know if there is anything further I should do.

Kenley Michaud, DDS
Northern Lights Dental Anesthesia

May 4, 2016

The Alaska Board of Dental Examiners
550 West Seventh Avenue
Suite 1500
Anchorage, AK 99501-3567

Alaska Board of Dental Examiners,

I would like to reiterate my appreciation to the board for their dedication these last years as the board as a whole has strived to improve and publish Alaskan sedation regulations. I hope it is evident that I support the board in this endeavor, and am willing to help in any way the board requires.

The proposed regulations are a vast improvement upon current regulations. I believe they may further be improved with minor changes, clarification and amendments to the sections regarding:

- GA Permits for all anesthesia providers – No changes required in State Statues
- Enteral and Parenteral Moderate Sedation Permits
- Dental Staff handling procedures, complications, and emergency incidents
- Addressing Supplemental Dosing in Mild Sedation

There have been many questions regarding the following sections; however, I believe what the board currently has posted is appropriate and in line with current guidelines. Support for the following sections can be found in the attached pages:

- Clarification on drugs classified as General
- Moderate Sedation Permits for Minimal Sedation on Children
- Consulting a physician prior to sedating an ASA III patient
- Minimal Sedation as defined by ADA – Single dose within recommended FDA dose

If there are any questions please don't hesitate to ask. I have attached specifics to this letter to further explain and support proposed regulations and proposed amendments.

Thank you,

Kenley Michaud DDS
Dentist Anesthesiologist
Diplomate of American Dental Board of Anesthesia and American Society of Dentist Anesthesiologists
Diplomate of American Society of Dental Anesthesia
Executive Member of Anchorage Dental Society
Member of Alaska Dental Association
Member of American Dental Association

Non-Dentist Anesthesia Providers in the Dental Office

Amendments to section 12AAC 28.030

When the public comment is finished and the board published the final sedation regulations the standard of care for sedation and anesthesia performed by dentists on dental patients will be raised. The proposed regulations however will not raise the standards for non-dental anesthesia providers to the same level required of a sedation dentist, dental anesthesiologist, or oral surgeon. Dentists and oral surgeons are required to disclose a denial, curtailment, revocation, or suspension of hospital privileges while non-dental anesthesia providers are not. Dentists are required to disclose denial of memberships and disciplinary actions by associated organizations while non-dental anesthesia providers are not. Dentists are required to disclose denial of licensure, licensure renewal or disciplinary action by a regulatory body while non-dental anesthesia providers are not. Dentists are required to have an Alaska DEA permit while a non-dental anesthesia provider is not. Dentists are required to be ACLS certified when treating patients over the age of 12 years old while non-dental anesthesia providers are not. Dentists are required to be PALS certified when treating patients age 12 and younger while non-dental anesthesia providers are not. Dentists are required to submit an application fee to the dental board while non-dental anesthesia providers are not. Dentists are required to take eight hours of continuing education to maintain a permit to practice in the dental office during each period that directly relates to advanced airway management while non-dental anesthesia providers are not. Each renewal period a dentist must participate in 12 contact hours of continuing education every renewal period while non-dental anesthesia providers are not. Anesthesia care provided in the dental office should be equally regulated and all providers should be treated the same in the eyes of the board. Every anesthesia provider should pay an application fee. Every provider should meet the continuing education requirements set by the board, and every provider should be required to disclose disciplinary action, license denials, and suspensions to the board.

It may seem petty to state that a dentist must submit an application fee when a non-dentist anesthesia provider does not; however, part of the budget for the board comes from fees for licensure and permits. There will come a time when the board is called on to investigate an outcome done by a non-dental anesthesia provider. These types of cases are far more frequent than one would expect. Information regarding a case in Austin, Texas is still limited but in March an MD anesthesiologist put a 14 month old under general anesthesia and then left the room. The dentist states that the anesthesiologist was not in the room when the child started to have trouble breathing. After struggling to breathe the baby went into cardiac arrest. Upon returning the MD anesthesiologist began CPR and the dentist called paramedics. The paramedics transferred the patient to a local hospital where the baby was pronounced brain dead. The AAPD sent a letter to their members stating that the Texas Dental Board learned of the incident from the media, not from the anesthesiologist. If a similar case occurred in Alaska, I would hope the dental board would use funds that partially arise from permit fees, which all anesthesia providers should be paying, to investigate the case further. When a 14 month old baby dies in the dental chair secondary to negligence of the anesthesia provider, it doesn't matter if the sedation regulations say the anesthesiologist should have been in the room. What will matter is the ability of the

board to stop it from happening again. The primary body that should be investigating and preventing such a case is the dental board.

Discussions with Ed Riefle, one of the Dental Boards investigators, and after reviewing the permitting process for CRNA's and physician anesthesiologists in California. Ed believes the following plan is a reasonable method of regulating who provides anesthesia in the dental office and no changes in state statues are required.

Line 6 is added to section 12 AAC 28.030 (c)

(c) The dentist employing or collaborating with the CRNA or physician anesthesiologist must...

(6) Ensure that the CRNA or physician have a received a current deep sedation/ general anesthesia permit as issued by the Alaska Dental Board;

The section 12 AAC 28.010. Permit requirements for deep sedation and general anesthesia, would need minor changes as well. There are 7 uses of the word dentist that would need to be replaced with permittee or anesthesia provider. Amending the proposed regulations will ensure that dental patients receive care from a sedation provider that has the same permitting process and continuing education requirements no matter what type of provider. It will allow the board to have direct insight into previous revocations and denials of all providers' licenses. It will provide the board with the knowledge of who has lost hospital privileges, received disciplinary action, or been suspended prior to issuing permit. Funds from permit applications will be increased when all providers are required to submit a permit fee. All providers will be required to maintain current training in ACLS and PALS (if treating children). All anesthesia providers will be required to practice at the level the board has set and as such the board will continue to protect the safety of dental patients.

With the concern of state statues out of the picture, the benefits of issuing a GA permit to all anesthesia providers far outweighs the drawbacks.

Enteral Moderate Sedation Permit and Parenteral Moderate Sedation Permit

Many pediatric dentists have voiced concern that the proposed regulations will not separate moderate sedation modalities. Although both methods reach the same level of sedation, competency in oral or enteral does not qualify a provider to perform parenteral sedation. However, the proposed regulations make no distinction between the two modalities. Any dentist that is certified to do oral moderate sedation is now also certified to do IV sedation. In Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students, the ADA separates Moderate Enteral Sedation from Moderate Parenteral Sedation and suggests the following educational requirements to treat healthy adults. The ADA emphasizes in bold that these courses and educational requirements are not designed for the management of children (aged 12 and under.) If the board acknowledges that it would be reasonable create a separate enteral and parenteral permit, the following educational guidelines set by the ADA for adult oral/enteral sedation are 24 hours of instruction and management of at least 10 adult cases.

When sedating children, it is reasonable to require more instruction than required for adults. CODA requirements for pediatric dental residents require that a resident be involved in at least 50 sedations, 25 of which the resident is performing the sedation and the dentistry. A requirement of performing 20 supervised sedation cases on a child twelve and under with 60 didactic hours does not approach the two years of study a pediatric dentist spends learning how to safely treat the pediatric patient. It does however, double the amount of cases required to treat an adult and just more than double the didactic requirements.

Coda Requirements Pediatrics:

http://www.ada.org/~/media/CODA/Files/ped.pdf?la=en

Clarification of Staff handling procedures, complications, and emergency incidents

Clarification or Amendment to section 12 AAC 28.015 (g4)

12 AAC 28.015 (g4) – a patient may not be left alone in a room and must be monitored by the sedation provider or a staff member capable of handling procedures, complication, and emergency incidents;

Currently OMFS has programs in place to train anesthesia assistants. There are currently no programs or certifications in Alaska to train a moderate sedation assistant. This clarification is specific to Moderate sedation permit holders. California has programs in place to train Dental Sedation Assistants. California has a permit process for dental sedation assistants and has specified specific duties. Under direct supervision of the dentist, a certified dental sedation assistant may place monitors and monitor a patient intraoperatively while evaluation of the condition of a sedated patient shall remain the responsibility of the dentist who shall be at the patient's chairside while conscious sedation is being administered. Placement of the IV and the initial dose of drug or medication are to be administered or performed by the supervising licensed dentist.

Currently in Alaska, a dental assistant must be certified to do coronal polishing, but no mention is made as to certification to perform functions like removal of intravenous lines, administering intravenous medications, monitoring patients, and managing emergencies. Placement of intra venous lines, administering intravenous medications, managing emergencies, managing sedation complications, or handling sedation procedures are not duties recognized by the Dental Assisting National Board. These duties are duties of the permit holder.

When patients receive care in the dental office. They assume the provider has training and certifications to perform the duties they are doing. This is also when patients are being sedated. They have the right to know that the individual placing their IV or administering medications is the dentist who has been trained and certified to so and is not an assistant without certification or formal training. No matter how seasoned a flight attendant is, one expects the pilot to be in the cockpit, not the flight attendant. The same goes for dental sedation. The pilot should stay in the cockpit until the planes lands safely and the permittee should remain with the patient until recovery is adequate to safely discharge the patient. Until such a time when a sedation assistant permit is available in Alaska, 12 AAC 28.015 (g4) should be clarified to something as follows:

12 AAC 28.015 (g4) – a patient may not be left alone in a room and must be monitored by the sedation provider ~~or a staff member capable of handling procedures, complication, and emergency incidents;~~ Placement of IV lines, administration of medications, patient assessment, and recovery are the responsibility of the sedation permit holder and not to be delegated to an assistant. Although the dental team is to aid in providing a safe sedation, ultimately it is the responsibility of the permittee to recognize, manage, and treat complications and emergency incidents.

http://www.dbc.ca.gov/formspubs/pub_table_of_duties_revised.20100101.pdf

http://www.aaoms.org/continuing-education/certification-program-daance

Mild Sedation and General Provisions – Supplemental Dosing

Amendment to 12 AAC 28.005 (a3B).

> 12 AAC 28.005 (a3B) – "The single dose of administered drug is within the Food and Drug Administration's (FDA) maximum recommended dose as printed in FDA approved labeling for unmonitored home use. Titration is not permitted unless a moderate sedation, deep sedation, or general anesthesia permit is obtained from the board."

The board has addressed titration, but has not addressed supplemental dosing. ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists defines supplemental dosing as follows,

> During minimal sedation, supplemental dosing is a single additional dose of the initial dose of the initial drug that may be necessary for prolonged procedures. The supplemental dose should not exceed one-half of the initial dose and should not be administered until the dentist has determined the clinical half-life of the initial dosing has passed. The total aggregate dose must not exceed 1.5x the MRD on the day of treatment.

It is suggested that that the previous definition follow section (B) in an additional bullet point.

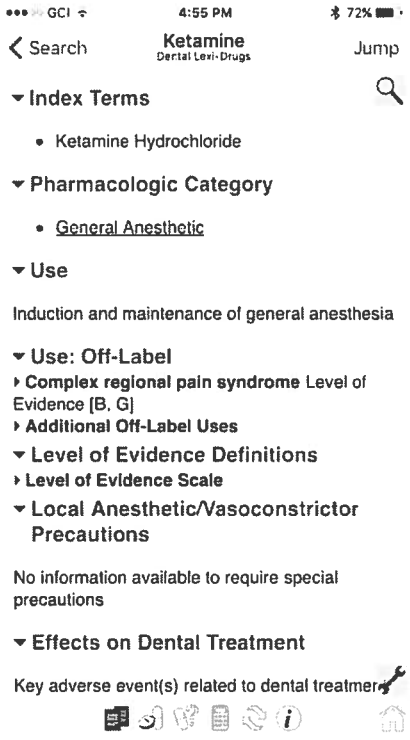
Moderate Sedation Permit holders and use of General Anesthetics

Support of section 12 AAC 28.015 (d).

> 12 AAC 28.015 (d) – "A dentist that holds a moderate sedation permit shall not administer or employ any agents or techniques which have a narrow margin for maintaining consciousness and are conclusively presumed to produce deep sedation or general anesthesia."

Regarding using general anesthetics like propofol or ketamine with a moderate sedation permit, I believe it's best to leave the regulations as they currently are. To start off with a quick summation, if a provider wants to use a general anesthetic, they should have a general anesthesia permit. The ADA 2012 guidelines regarding moderate sedation state,

> "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."



Let's define what propofol and ketamine are, general anesthetics. Just as Lidocaine is from the drug category of local anesthetics or aspirin is categorized as a non-steroidal anti-inflammatory drug. Propofol and Ketamine are categorized as general anesthetics. They do not carry a margin of safety wide enough to rend unintended loss of consciousness unlikely. They are designated as general anesthetics because of the propensity to cause a loss of consciousness. Lexicomp, one of the largest drug references, states the category and use of ketamine. Ketamine's pharmacologic category is general anesthetic, and its use, induction and maintenance of general anesthesia. Propofol is in the same pharmacologic category. Under propofol's use Lexicomp states, "Induction of anesthesia in patients >3 years of age; maintenance of anesthesia in patients > 2 months of age." In the same section regarding propofol's use it states concerning adults that the drug can be used ICU patients that are intubated and mechanically ventilated or for sedation under the direct eye of an anesthesiologist.

After conversations with the board and Dr. Wells, it was quite evident that the board has always been of the opinion that dentists performing moderate sedation should not be using drugs that have narrow window for maintaining consciousness, such as drugs designed to induce general anesthesia. Clarifying the board's opinion benefits both licensees and the public. Alaska is not the first state to clarify this with specific examples for their licensees.

Minimal Sedation on Children

Support of section 12 AAC 28.005 (a3A)

> 12 AAC 28.005 (a3A) – Before administering moderate sedation, deep sedation or general anesthesia by any means or method, a dentist licensed under AS 08.36 must possess a permit issued by the board. It does not apply to the administration of a single dose of oral medication to achieve minimal sedation if "the patient is 13 years of age and older;"

It is important to realize that children are not small adults. They have a physiology specific to pediatric patients. According to the Guideline for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures published by the American Academy of Pediatric dentistry and cited by the ADA guidelines, Studies have shown that it is common for children to pass from the intended level of sedation to a deeper, unintended level of sedation. They are more susceptible to becoming moderately sedated when only a minimal sedation is intended. As such, when sedating a population that is at risk for becoming moderately sedated, it is reasonable to require that providers administering minimal sedation be trained in moderate sedation. The ADA guidelines for the Use of Sedation and general Anesthesia by Dentists states the following regarding children aged 12 and under.

> The use of preoperative sedatives for children (aged 12 and under) prior to arrival in the dental office, except in extraordinary situations, must be avoided due to the risk of unobserved respiratory obstruction during transport by untrained individuals. Children (aged 12 and under) can become moderately sedated despite the intended level of minimal sedation; should this occur, the guidelines for moderate sedation apply.

The AAPD guidelines go further to discuss how the concept of rescue is essential to safe sedation. Providers of sedation need to have the skills to rescue the patient from a deeper level of sedation than the intended level. Quoting from the Guideline for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures, "For example, if the intended level of sedation is "minimal," practitioners must be able to rescue from "moderate sedation"."

Requiring Moderate sedation training to provide minimal sedation to children is in accordance with the guidelines set by AAPD and ADA.

Moderate Sedation on Complex Adults and Children

Support of Section 12 AAC 28.005 (e1-e2B)

12 AAC 28.005 (e1-2) – The dentist shall "provide sedation or anesthesia in a dental office or clinic for patient who are Class I and II as classified by the American Society of Anesthesiologists (ASA); only provide patients in ASA risk category Class III moderate sedation, deep sedation, or general anesthesia if he or she has documented a consultation with their primary care physician... or he or she is an oral and maxillofacial surgeon or dental anesthesiologist..."

Regarding the sedation training received by a general dentist the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students states,

> Typically, clinical experience will be provided in managing healthy adult patients. Additional supervised clinical experience is necessary to prepare participants to manage children (aged 12 and under) and medically compromised adults.

The definition of ASA III is a patient with severe systemic disease, also known as a medically compromised patient. The required 60 didactic hours and participation in 20 sedation cases do not prepare a dentist to medically evaluate a complex patient. Acknowledging that it is not the dentists responsibility nor expertise to draw medical conclusions, the board follows this section with the following wording in section 12 AAC 28.005 (g),

> The dentist is not required to make a medical examination of the patient and draw medical diagnostic conclusions; therefore, if the dentist suspects a problem and calls in a physician for an examination and evaluation, the dentist may then rely upon that conclusion and the diagnosis.

Specific dentists with extensive training are more prepared to evaluate a complex patient and decide when a consult with a physician is necessary. Two specific examples would be oral surgeons and dentist anesthesiologists. During residency both residents will function as internal medicine residents drawing medical conclusions and providing medical care to the medically compromised patients under the supervision of a physician specialized in the field of internal medicine. CODA requires that during residency an oral surgery resident is required to at least perform 300 general anesthesia/ deep sedation anesthetics. At least 150 of which must be ambulatory anesthetics and 50 must be under the age of 18 years old. During residency a dental anesthesia resident must perform at least 800 general anesthesia/ deep sedation anesthetics. At least 125 of these cases must be on a child age 7 and younger and 75 must be on patients with special needs. Quoting CODA requirements for dental anesthesia, a resident is to have "clinical experiences sufficient to meet the competency... in managing ambulatory patients, geriatric patients, patients with physical status ASA III or greater, and patients requiring moderate sedation." Both oral surgeons and dentist anesthesiologists will have a greater understanding of when and if it is appropriate to forgo a phone call to or consult with a patient's primary care physician. Whereas a phone call from a sedation dentist to a medically compromised patient's physician can only yield beneficial information that will aid in providing the safest possible sedation.

The most common complaint against this regulation is that it will create an access to care issue. The rhetoric is that it will require too much time to call a patients primary care physician and that the board

should place more trust in the sedation dentist allowing them to do what they have been trained to do. Interestingly enough, the argument to allow sedation dentists to do what they are trained to do only further clarifies the need to consult a physician. As according the ADA and the Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students, a moderate parenteral sedation course will train dentists where "clinical experience will be provided in managing healthy adult patients."

Requiring a consult with a physician for patients with severe systemic diseases ASA III, may require more time for the dentist and staff that want to sedate complex patients. It will however further patients safety as sedation dentist and physicians work together to provide a complex patient with the safest possible sedation.

CODA Requirements OMFS and Dental Anesthesia:

http://www.ada.org/~/media/CODA/Files/oms.pdf?la=en

http://www.ada.org/~/media/CODA/Files/anes.pdf?la=en

Zimmerman, Marilyn A (CED)

From: Ernest Sorensen <ernest.sorensen@gmail.com>
Sent: Sunday, May 08, 2016 9:12 PM
To: Zimmerman, Marilyn A (CED)
Subject: Sedation revision

My name is Ernest Sorensen I hold a current dental license(1496) and practice in Fairbanks.
I have concerns about many aspects of the potential revisions in sedation permitting.
Other than the fact that there has been very limited time for public comment on the matter, I feel that the proposed changes are not needed.
I currently sedate using oral conscious protocols both adults and pediatric patients regularly. I have attended DOCS education seminars for both and am very competent.
Under the new proposed guidelines where does that leave me?
By changing the current rules you only create access to care issues and belittle competent practitioners.
I feel these changes are a knee jerk reaction to problems that have occurred in other states.
Please consider the extreme consequences for both patients and practitioners as you deliberate this revision.

A few questions for you...

How many oral conscious sedation problems have arisen in the state of Alaska because of general dentists vs. dental specialties?

How will changing existing regulations make sedation safer than the proven algorithms that I use from DOCS?

How do my patients get treatment if you create an enormous access to care issue?

WHO really benefits from this change?

Thanks for your time,

Ernie
8013699308

Please call or email with any questions

Sent from my iPhone

Zimmerman, Marilyn A (CED)

From: Justin Coffman <jcoffman21@gmail.com>
Sent: Sunday, May 08, 2016 9:43 PM
To: Zimmerman, Marilyn A (CED)
Subject: Concerns over proposal 12AAC28
Attachments: Concerns on 12AAC28; Concerns on 12AAC28.pdf

> Alaska Board of Dental Examiners:
>
> Please see the attached letter detailing my concerns over the proposed regulations on 12AAC28.
>
> Thank you,
>
> Justin Coffman DDS
> Wasilla Dental Center

May 8, 2016

Alaska Board of Dental Examiners
POB 110806
Juneau, Ak 99811

Alaska Board of Dental Examiners

The proposed regulation changes to dental sedation under 12AAC28 are the reason for my letter to the board. I am not concerned with sedation being regulated, but with the haste in which these changes are being brought forth. Without sufficient time being allotted for us as affected license holders to seek explanations and voice our issues, we are left at a loss for understanding the reasons behind these proposed changes.

The strong language in the proposal leads me to the assumption that there is a rise in Emergency Room patients being seen with dental sedation related complications. I would expect to see the data supporting this assumption if these changes are pushed through. If the board has this data and is willing to explain the origin of the proposal then as a practitioner I am able to understand the logic behind the changes. However, the data is not being communicated from the board to us as license holders.

If there is supporting data showing our current sedation methods are harming patients then I will be in support of making changes as needed. Until such time that the board conveys the necessary means to support changes of this magnitude I am requesting that we are given more time to research and voice our concerns. It is my fear that these changes will create an access to care issue for our dental phobic and/or anxious patients.

I very strongly urge the board to table the regulation changes regarding sedation under 12AAC28 and allow for a committee of board members and affected license holders to be formed and to work together on these proposed changes.

Justin Coffman, DDS
Wasilla Dental Center

Zimmerman, Marilyn A (CED)

From: Terry Preece <mesialdrifter@hotmail.com>
Sent: Sunday, May 08, 2016 11:20 PM
To: Zimmerman, Marilyn A (CED)
Subject: Comments on proposed sedation rule changes

Alaska Board of Dental Examiners ,

I am concerned about the proposed changes to the sedation rules in the dental practice act. The changes appear to be very complex and I question the science behind some of the changes. I, like you, am concerned that we need to protect our patients and I feel some changes may be needed. I have safely practiced oral conscious dental sedation for many years without any adverse incidents. **I would ask that you please allow more time for discussion and input from the dental community before implementing any proposed changes.** I would also like some explanation regarding the background of the need for these changes. Couldn't we use the ADA recommended guidelines? Thank you for your consideration in this matter.

Sincerely,

Terry J. Preece DDS
license # 1274

FAX

Date:	05/09/2016
Pages including cover sheet:	5

To:	+19074652974
Phone	
Fax Number	*+19074652974*

From:	Jack Hamilton
	Soldotna Dental Arts
	35657 Kenai Spur Hwy
	Soldotna
	AK 99669
Phone	*19074203938*
Fax Number	*(888) 788-4617*

NOTE:

Proposed Regulation Changes Response

Soldotna Dental Arts

May 9, 2016

Marilyn Zimmerman, Paralegal
Division of Corporations, Business and Professional Licensing
PO Box 110806
Juneau, AK 99811-0806

Dear Marilyn Zimmerman,

My name is Jack Hamilton, DDS. I recently received notification of the proposed changes to the dental regulations by the board for sedation. I have several specific areas of concern that I have listed below, but my initial and overall impression is simply that the proposed regulations have an excess volume of regulation and detail that is unnecessary and cumbersome. I sincerely question if all of the proposed regulations are truly necessary. Previous regulations for all areas specific to dentistry, including sedation, are currently about 35 pages with cover page and table of contents. The proposed new regulations alone are about 35 pages without a cover page or index. This is a substantial break on the part of the board from past regulations that is neither reasonable nor warranted. It seems that most of the areas could be addressed in a simple, and less detailed paragraph rather than pages of minutia. The regulations are so minutely particular as to indicate that I need to have a tourniquet to start an IV, tape is required to secure the IV and how bright the lighting has to be. Who starts IVs without a tourniquet, doesn't tape the IV line to secure it or works in a room without good lighting? It specifics I even need to use sterile needles. Who in their right mind would use dirty needles? This level of specificity is present throughout the proposed changes and is unnecessary. The proposed changes, while generally sound, are written as if those to be bound by them lack any common sense whatsoever. The style of the proposed regulations is completely different than those of the existing regulations which are generally concise but comprehensive. The proposed regulations could be written in the same manner as the current regulations without the inordinate superfluous detail and achieve a much less odious document. My recommendation is that the entire set of proposed regulations be re-written with an eye for succinctness and in the same manner the current regulations are written.

Specific concerns:

1. 12 AAC 28.005 (a)(3). Proposed regulations allow only one dose of oral sedative up to the "maximum normal home dose" for use in mild sedation. This provision will tend to make sedation less safe as any normal dentist would lean toward the larger dose to ensure mild sedation rather than hazarding a rescheduled appointment. Repeated dosage of an oral sedative up to the "maximum normal home dose" would be far more prudent on the part of the board and promote safer sedation generally. This provision should be rewritten to allow multiple doses up to the "maximum normal home dose".
2. 12 AAC 28.005 (a)(3)(B). This section refers to repeated dosing of an oral sedative as "titration." Repeated dosing of an oral sedative is not titration and use of such language is not only unscientific but only promotes the unsafe practices I assume you are trying to restrict. This wording should be replaced with language indicating repeated doses.

35657 Kenai Spur Hwy Soldotna, AK 99669
(907)420-3938 info@soldotnadentalarts.com

3. 12 AAC 28.005 (a)(4). The premise on which these regulations are submitted to us is the safety of the public. The only logical reason this provision is in place is to allow the designated entities to practice below what is the proposed standard of care in the regulations. Logically, if you believe the proposed regulations are necessary to protect public safety inclusion of this provision is a breach of your role as the guardian of the public as the board is not protecting the safety of the public that seeks care in those locations. Are those who seek care provided by those practitioners at the listed facilities not worthy of the same standard of care you feel is so necessary of all other providers? This section should be deleted in its entirety.
4. 12 AAC 28.005 (m). This section I find exceedingly execrable as it is inherently unscientific and an affront to justice. The diagnosis of level of sedation is a clinical diagnosis. Anyone who does sedation can tell you patients respond along a classic bell curve with some being hyper-responsive and some being hypo-responsive and the rest falling anywhere between, most in a standard range. What is required for one patient to obtain minimal sedation may provide deep sedation in another. Simply take for example Midazolam, which is well documented in the literature to take from less than 1mg to well over 40mg to achieve moderate sedation. The "degree of sedation or level of consciousness that should be reasonably expected" from 5-10 mg of Midazolam could be anywhere from nothing to deep sedation, but the same could be true for either 40mg or 1mg of Midazolam in some patients. Similarly, nitrous oxide can cause general anesthesia in a small percentage of patients and the "degree of sedation or level of consciousness that should be reasonably expected" from a 75% concentration of nitrous oxide can be nothing up to general anesthesia. I agree large doses should be taken into consideration as possibly contributing to complications, but to arbitrarily state the board can determine level of sedation without seeing the patient is absolutely absurd and can only lead to incorrect conclusions thus resulting injustice to a practitioner if discipline is administered based on such a grossly unscientific and preposterously illogical provision.

   This provision also in practice mandates that those on the board make a diagnosis of the level of sedation without ever seeing the patient. Additionally, if there are any non-dentist members of the board this provision would be mandating practicing without a proper license as they are required to make a diagnosis for which they do not hold a license. Mandating such actions on the part of the board would be causing them to commit illegal acts as this regulation would cause violation of multiple other statutes and regulations in this area. I would recommend you consult with legal counsel concerning this. This section should be deleted in its entirety. Another section could be written that simply states what appears to be the intent of this provision: that if high doses of sedatives or anesthetics are administered this would be taken into account in the investigation process. This however, would be common sense and does not require lengthy explanation in the regulation, if at all.
5. 12 AAC 28.015 (g)(2). End tidal carbon dioxide monitoring should be optional if a pre-tracheal stethoscope is used. Use of end tidal CO2 is construed as standard of care when it is, and has been, highly debated and is again before the ADA for review in their guidelines. Many sedation providers realize that working in an open system as we do with moderate sedation end tidal CO2 can have substantial limitations in value of the data obtained and that a pre-tracheal stethoscope is of equal or greater value. I have been doing sedation roughly 9 years and have always used <u>both</u> a pre-tracheal stethoscope and CO2 monitor for <u>every</u> case of parenteral sedation. In my experience the pre-tracheal stethoscope gives a better idea of quality of breathing that may or may not be visible with end tidal CO2 due to mouth breathing or a myriad of other reasons that cause variation in the CO2 monitor in an open system. This section should be re-written to include an either or choice of end tidal CO2 or a pre-tracheal stethoscope.
6. 12 AAC 28.015 (i). This section should be re-written to have generic categories as the deep sedation/general sedation guidelines read. Drug shortages and changes to emergency drug recommendations routinely occur and this could cause a hardship for the practitioner if specific drugs are delineated rather than general categories.

35657 Kenai Spur Hwy Soldotna, AK 99669
(907)420-3938 info@soldotnadentalarts.com

7. 12 AAC 28.015 (k)(1).There is a CE requirement of 8 hours that "specifically relates to airway management." Is there even a course that offers this? I could not find such a course in my searching. There is no mandate or provision in the regulations for such a course to be offered by the state or another organization. This must be remedied. The least that should be required of the Board is an annual listing of courses that would meet the regulations requirements. There are many good classes that relate to managing complications, the primary complication being airway complications. If the intent is to require a hands-on type class that deals with complications it should be reworded to read "specifically related to managing complications and include hands-on simulations."
8. 12 AAC 28.015 (k)(5). This makes no provision for those practitioners who would obtain the permit to provide only mild oral pediatric sedation who are required to have a moderate sedation permit. How would one who wished only to provide mild oral pediatric sedation meet this requirement? This should be addressed.
9. Regulatory Question 6. I find the answers to this question disingenuous and misleading for the following reasons.
    a. Increased regulation always translates to increased costs simply to ensure regulatory compliance.
    b. CE costs are easily $1,000.00 a day and oftentimes more for many sedation CE classes. With travel expenses this would total at least $4,000.00 every two years in costs.
    c. The value of lost production for three days for CE for most practitioners would normally range from six thousand to over thirty thousand dollars depending on the size of their office.
    d. Assuming a small office and a practitioner who did only the minimum required 10 cases a year costs would be at least ten thousand dollars in direct expenses and lost production divided between 20 cases for a renewal period. That would be $500.00 per patient in costs to the provider.
    e. Costs for initial pediatric and adult sedation classes are from about fifteen to twenty thousand dollars in addition to the two weeks of lost production and travel costs which would amount to forty thousand dollars or more in costs and lost production to the practitioner.
    f. Glaringly absent from this table is the practitioner who currently and legally provides adult moderate oral sedation without a parenteral sedation permit. The cost to attend a parenteral sedation course as noted above would substantially increase their costs. This absence gives the appearance of purposeful omission.
    g. A standalone end tidal CO2 monitor is roughly $2,500.00 also increasing the cost per patient to the provider.
    h. These increases in cost will very likely reduce the number of practitioners providing such services thus decreasing supply and thus according to the law of supply and demand an increase in cost to the patient is certain.
    i. For all the above reasons costs will increase to the both the practitioner and consumer and it is false to imply otherwise.

    This questions and response should be re-written to include realistic expectations in increase of costs to the practitioner and public as the chart listed is incomplete and grossly misstated. To state that there is no expected increase in cost to the public is at best naïve and at worst a gross falsehood as substantial increases in cost should be expected to both practitioner and the public.
10. Regulatory Question 7. I support the limitation of use of certain agents for use in mild and moderate sedation and the proposed changes in 12 AAC 28.015(d) are worded more appropriately. This question however has multiple interpretations of the proposed changes that are grossly incorrect and misleading. Those agents listed in 12 AAC 28.015(d) are not general anesthetic agents. Quoting from Patel PM, et al. Goodman & Gilman's 2011 "General anesthesia

is a collection of "component" changes in behavior or perception. The components of the anesthetic state include amnesia, immobility in response to noxious stimulation, attenuation of autonomic responses to noxious stimulation, analgesia, and unconsciousness." Also from Katzung BG, Trevor AJ. Basic & Clinical Pharmacology, 13th ed. 2015. "The neurophysiologic state produced by general anesthetics is characterized by five primary effects: unconsciousness, amnesia, analgesia, inhibition of autonomic reflexes, and skeletal muscle relaxation." The only general anesthetic mild and moderate sedation providers are using is nitrous oxide. Most of what we use in mild and moderate sedation are simply sedatives that can cause deep sedation, not general anesthesia as they do not meet the above definitions. This question clearly implies that general anesthetic agents should not be used by mild or moderate sedation providers yet the board allows even hygienists to administer the most common of all general anesthetics, nitrous oxide. This response is at best uneducated, very poorly written and misleading while at worst it gives the appearance of purposeful misconstrual. This question should be re-written to be scientifically accurate and honest.

Sincerely,

Jack Hamilton, DDS

35657 Kenai Spur Hwy Soldotna, AK 99669
(907)420-3938 info@soldotnadentalarts.com

Alaska Pediatric Dental Society

CONFIDENTIAL

Fax Transmittial Form

To: Division of Coporations, Business, and Licensing

Fax: 907-465-2974

From: Alaska Pediatric Dental Society

Date Sent: 5/9/16

Number of Pages: 3

Message:

RECEIVED
Juneau
MAY 09 2016
CBPL

TO: the Alaska Board of Dental Examiners

RE: Proposed sedation regulations

FROM: The Alaska Pediatric Dental Society

We are in support of the intent of the new regulations, but would like to offer our suggestions in regards to several points of the proposed regulations.

As pediatric specialists that have completed 2-3 years of additional training with sedating children in an accredited program, we should be considered the most qualified to treat and sedate children under age 12. Completion of a residency program should be sufficient qualification for obtaining the necessary moderate sedation permits.

Pediatric Dentists have advanced training in patient selection, assessing all treatment options, and can consider all mitigating factors, thus offering multiple options to the families, allowing for safe and effective treatment.

Placing restrictions on the utilization of moderate sedation by Pediatric Dentists could potentially impact the special needs and young children populations.

As Pediatric Dentists, we see only children and special needs patients, but we can't provide care for every child. We appreciate help from general dentists and understand many of them offer sedation services. We feel that they should have requirements specific to sedating young children if they are going to provide that service. PALS certification should certainly be required of all dentists sedating children. If a dentist has not completed a pediatric residency program, sixty (60) hours of didactic courses exclusively related to sedating children and managing emergencies in the office should be required, in addition to twenty (20) hours of hands-on sedation cases under supervision of trained personnel.

We would like the Board to consider that moderate conscious sedation can take different forms, and perhaps having separate permits for enteral and parenteral sedation be appropriate to dentists providing care in Alaska. Many Pediatric Dentists use an oral drug in combination with nitrous oxide. According to the new proposals, this would require a permit for moderate sedation in the same league as dentists using an IV to provide sedation, and with it requirements for monitoring the patient at a level of sedation not normally achieved in our offices (such as EKG and capnography).

There are pediatric dentistry programs that are training residents with the use of the drugs that the Board attempting to exclude. The AAPD guidelines do not exclude drugs from our armamentarium, which highlights the sophistication of our specialty. The American Academy of Pediatric Dentistry has well established guidelines for sedating children. These guidelines are constantly reviewed and updated to reflect the most current research available. Pediatric Dentists are well versed in these guidelines and strive to uphold them in their offices. Further restrictions in the State of Alaska could hinder our efforts to treat the high rates of oral disease in our state.

In summary we would like the Board to consider the following;

Pediatric Dentists should be allowed to obtain a moderate conscious sedation permit without further education requirements.

Pediatric Dentists should not have limitations on types of drugs they have been trained to use.

PALS training should count toward the eight (8) hours of airway management training proposed for permit renewal.

There should NOT be a yearly requirement of cases completed to maintain a permit. Many of us spend considerable time in an operating room environment and select our in-office moderate sedation cases carefully.

General Dentists sedating children under age 12 must show adequate training as outlined above.

While capnography has been demonstrated to increase patient safety when used in an intubated patient, there is no evidence to support its use when the airway is not secured and protective reflexes remain intact. Therefore it should not be required for oral conscious sedations.

A method for self-reporting adverse sedation outcomes should be required as part of a sedation permit. Failure to report can lead to disciplinary action, including restriction of a sedation permit.

Thank you for your consideration of these items.

Alaska Pediatric Dental Society

Zimmerman, Marilyn A (CED)

From: Craig Lowrie <craigrlowrie@gmail.com>
Sent: Monday, May 09, 2016 1:57 PM
To: Zimmerman, Marilyn A (CED)
Subject: Sedation proposal

To whom it may concern,

Myself, Dr. Craig Lowrie, and the owner of our dental practice Dr. Stephen Christensen are against the proposed changes to sedation regulation.
The regulation as written are confusing, conflicting and difficult to read due to all the contradictions. One section says no moderate sedation in kids under 12 years of age and no nitrous, and yet another says nitrous is considered minimal sedation.
Some of the cited ADA material was actually not passed as it states in the bill. It seems that these 70 some pages of regulations were not read thoroughly enough to put this forth to the members and needs some more work.
Furthermore, the regulations would provide a serious access to care issue in our state. There is no clear path to obtaining these hours of training without taking a IV sedation course. It would put a lot of dentists out of business and rates for insurance would sky rocket as we would need to have coverage for IV sedation due to the structure of the wording in these regulations.
We at Advanced Family Dentistry strongly urge you to reconsider and drop these proposed regulations.

Thank you,

Dr. Craig R. Lowrie, DMD
Advanced Family Dentistry
Wasilla, AK

TO: the Alaska Board of Dental Examiners

RE: Proposed sedation regulations

FROM: The Alaska Pediatric Dental Society

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A method for self-reporting adverse sedation outcomes should be required as part of a sedation permit. Failure to report can lead to disciplinary action, including restriction of a sedation permit.

Thank you for your consideration of these items.

Alaska Pediatric Dental Society

Zimmerman, Marilyn A (CED)

From: Brian Kelleher <bakdds@yahoo.com>
Sent: Monday, May 09, 2016 2:08 PM
To: Zimmerman, Marilyn A (CED)
Subject: Sedation comment

Dear Board,

Solely for informational purposes, and maybe to offer some perspective on what our dental colleagues need to do to in order to practice oral conscious sedation in other states: In California, dental practitioners--including pediatric dentists--must take an initial extensive CE course and pay a permit fee in order to perform this service. And then more CE courses and fees every two years to continue the practice. Then there are the extensive and cumbersome doctor and staff monitoring regulations (BP cuffs, capno, pulse oximeters, recording all this, and more, every 5 minutes, etc) which are subject to audit in order to stay in compliance.

All that in the name of safety for the benefit of California pediatric patients. Hard to argue with safety.
Yet there continues to be oral conscious sedation morbidity and mortality, in California, and country wide, despite these and other regulatory efforts. How do/will Alaskan regulations compare today? Tomorrow? Do they do any good now? Will they in the future?

Just goes to show common sense, and good clinical judgement and ability can't (maybe shouldn't?) be regulated, as any Alaskan might very well agree.

Brian

Zimmerman, Marilyn A (CED)

From: Four Corners <fourcornersdental@yahoo.com>
Sent: Monday, May 09, 2016 2:30 PM
To: Zimmerman, Marilyn A (CED)
Subject: Sedation changes dental

I am against any proposed changes and recommend a discovery time period where the board will utilize its resources to come up with an agreeable solution. AK dental license 1262.

Thanks,

Shane Rhoton

Zimmerman, Marilyn A (CED)

From: Hans Nordstrom <hpnordstrom@hotmail.com>
Sent: Monday, May 09, 2016 2:37 PM
To: Zimmerman, Marilyn A (CED)
Subject: Sedation

To whom it may concern,

I am a dentist who has worked in Alaska the last 12 yrs. I understand the concern that the board has in relation to sedation in the dental field. Far too many dentists are administering sedation that they do not have adequate training for. The proposed rules go too far though in trying to curb this. The inclusion of nitrous in this is a little concerning to me. It appears that the board would consider antianxiety medication with nitrous as a moderate form of sedation even if sedation isn't intended or doesn't occur. The board needs to find a way to balance reasonable regulations to coincide with safety. It also appears that there are certain individuals that are pushing for this who may potentially gain financially. The area of "dental anesthesiology" needs to be looked at carefully. These are individuals who do not have the training of an anesthesiologist or crna, but would have you believe they do. It is not a recognized specialty, and therefore the individuals should be treated the same as a general dentist that has taken appropriate CE for sedation.

Thank you,
Hans Nordstrom DDS

Zimmerman, Marilyn A (CED)

From: Katie <Katie@SoldotnaDentalArts.com>
Sent: Monday, May 09, 2016 2:40 PM
To: Zimmerman, Marilyn A (CED)
Subject: Proposed Regulation Changes Response
Attachments: 2016_05_09_10_45_25.jpg; 2016_05_09_10_45_27.jpg; 2016_05_09_10_45_29.jpg; 2016_05_09_10_45_31.jpg

Good Afternoon,

Attached is the response letter from Jack Hamilton, DDS regarding the proposed regulation changes. Please do not hesitate to contact me if you have any questions or have difficulty viewing any of the attachments. Thank you for your consideration.

Best Regards,
Katie

Soldotna Dental Arts
35657 Kenai Spur Hwy
Soldotna, AK 99669
(907)420-3938
www.SoldotnaDentalArts.com

Soldotna
Dental Arts

May 9, 2016

Marilyn Zimmerman, Paralegal
Division of Corporations, Business and Professional Licensing
PO Box 110806
Juneau, AK 99811-0806

Dear Marilyn Zimmerman,

My name is Jack Hamilton, DDS. I recently received notification of the proposed changes to the dental regulations by the board for sedation. I have several specific areas of concern that I have listed below, but my initial and overall impression is simply that the proposed regulations have an excess volume of regulation and detail that is unnecessary and cumbersome. I sincerely question if all of the proposed regulations are truly necessary. Previous regulations for all areas specific to dentistry, including sedation, are currently about 35 pages with cover page and table of contents. The proposed new regulations alone are about 35 pages without a cover page or index. This is a substantial break on the part of the board from past regulations that is neither reasonable nor warranted. It seems that most of the areas could be addressed in a simple, and less detailed paragraph rather than pages of minutia. The regulations are so minutely particular as to indicate that I need to have a tourniquet to start an IV, tape is required to secure the IV and how bright the lighting has to be. Who starts IVs without a tourniquet, doesn't tape the IV line to secure it or works in a room without good lighting? It specifies I even need to use sterile needles. Who in their right mind would use dirty needles? This level of specificity is present throughout the proposed changes and is unnecessary. The proposed changes, while generally sound, are written as if those to be bound by them lack any common sense whatsoever. The style of the proposed regulations is completely different than those of the existing regulations which are generally concise but comprehensive. The proposed regulations could be written in the same manner as the current regulations without the inordinate superfluous detail and achieve a much less odious document. My recommendation is that the entire set of proposed regulations be re-written with an eye for succinctness and in the same manner the current regulations are written.

Specific concerns:

1. 12 AAC 28.005 (a)(3). Proposed regulations allow only one dose of oral sedative up to the "maximum normal home dose" for use in mild sedation. This provision will tend to make sedation less safe as any normal dentist would lean toward the larger dose to ensure mild sedation rather than hazarding a rescheduled appointment. Repeated dosage of an oral sedative up to the "maximum normal home dose" would be far more prudent on the part of the board and promote safer sedation generally. This provision should be rewritten to allow multiple doses up to the "maximum normal home dose".
2. 12 AAC 28.005 (a)(3)(B). This section refers to repeated dosing of an oral sedative as "titration." Repeated dosing of an oral sedative is not titration and use of such language is not only unscientific but only promotes the unsafe practices I assume you are trying to restrict. This wording should be replaced with language indicating repeated doses.

35657 Kenai Spur Hwy Soldotna, AK 99669
(907)420-3938 info@soldotnadentalarts.com

3. 12 AAC 28.005 (a)(4). The premise on which these regulations are submitted to us is the safety of the public. The only logical reason this provision is in place is to allow the designated entities to practice below what is the proposed standard of care in the regulations. Logically, if you believe the proposed regulations are necessary to protect public safety inclusion of this provision is a breach of your role as the guardian of the public as the board is not protecting the safety of the public that seeks care in those locations. Are those who seek care provided by those practitioners at the listed facilities not worthy of the same standard of care you feel is so necessary of all other providers? This section should be deleted in its entirety.
4. 12 AAC 28.005 (m). This section I find exceedingly execrable as it is inherently unscientific and an affront to justice. The diagnosis of level of sedation is a clinical diagnosis. Anyone who does sedation can tell you patients respond along a classic bell curve with some being hyper-responsive and some being hypo-responsive and the rest falling anywhere between, most in a standard range. What is required for one patient to obtain minimal sedation may provide deep sedation in another. Simply take for example Midazolam, which is well documented in the literature to take from less than 1mg to well over 40mg to achieve moderate sedation. The "degree of sedation or level of consciousness that should be reasonably expected" from 5-10 mg of Midazolam could be anywhere from nothing to deep sedation, but the same could be true for either 40mg or 1mg of Midazolam in some patients. Similarly, nitrous oxide can cause general anesthesia in a small percentage of patients and the "degree of sedation or level of consciousness that should be reasonably expected" from a 75% concentration of nitrous oxide can be nothing up to general anesthesia. I agree large doses should be taken into consideration as possibly contributing to complications, but to arbitrarily state the board can determine level of sedation without seeing the patient is absolutely absurd and can only lead to incorrect conclusions thus resulting injustice to a practitioner if discipline is administered based on such a grossly unscientific and preposterously illogical provision.

   This provision also in practice mandates that those on the board make a diagnosis of the level of sedation without ever seeing the patient. Additionally, if there are any non-dentist members of the board this provision would be mandating practicing without a proper license as they are required to make a diagnosis for which they do not hold a license. Mandating such actions on the part of the board would be causing them to commit illegal acts as this regulation would cause violation of multiple other statutes and regulations in this area. I would recommend you consult with legal counsel concerning this. This section should be deleted in its entirety. Another section could be written that simply states what appears to be the intent of this provision: that if high doses of sedatives or anesthetics are administered this would be taken into account in the investigation process. This however, would be common sense and does not require lengthy explanation in the regulation, if at all.
5. 12 AAC 28.015 (g)(2). End tidal carbon dioxide monitoring should be optional if a pre-tracheal stethoscope is used. Use of end tidal CO2 is construed as standard of care when it is, and has been, highly debated and is again before the ADA for review in their guidelines. Many sedation providers realize that working in an open system as we do with moderate sedation end tidal CO2 can have substantial limitations in value of the data obtained and that a pre-tracheal stethoscope is of equal or greater value. I have been doing sedation roughly 9 years and have always used <u>both</u> a pre-tracheal stethoscope and CO2 monitor for <u>every</u> case of parenteral sedation. In my experience the pre-tracheal stethoscope gives a better idea of quality of breathing that may or may not be visible with end tidal CO2 due to mouth breathing or a myriad of other reasons that cause variation in the CO2 monitor in an open system. This section should be re-written to include an either or choice of end tidal CO2 or a pre-tracheal stethoscope.
6. 12 AAC 28.015 (i). This section should be re-written to have generic categories as the deep sedation/general sedation guidelines read. Drug shortages and changes to emergency drug recommendations routinely occur and this could cause a hardship for the practitioner if specific drugs are delineated rather than general categories.

35657 Kenai Spur Hwy Soldotna, AK 99669
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7. 12 AAC 28.015 (k)(1).There is a CE requirement of 8 hours that "specifically relates to airway management." Is there even a course that offers this? I could not find such a course in my searching. There is no mandate or provision in the regulations for such a course to be offered by the state or another organization. This must be remedied. The least that should be required of the Board is an annual listing of courses that would meet the regulations requirements. There are many good classes that relate to managing complications, the primary complication being airway complications. If the intent is to require a hands-on type class that deals with complications it should be reworded to read "specifically related to managing complications and include hands-on simulations."
8. 12 AAC 28.015 (k)(5). This makes no provision for those practitioners who would obtain the permit to provide only mild oral pediatric sedation who are required to have a moderate sedation permit. How would one who wished only to provide mild oral pediatric sedation meet this requirement? This should be addressed.
9. Regulatory Question 6. I find the answers to this question disingenuous and misleading for the following reasons.
    a. Increased regulation always translates to increased costs simply to ensure regulatory compliance.
    b. CE costs are easily $1,000.00 a day and oftentimes more for many sedation CE classes. With travel expenses this would total at least $4,000.00 every two years in costs.
    c. The value of lost production for three days for CE for most practitioners would normally range from six thousand to over thirty thousand dollars depending on the size of their office.
    d. Assuming a small office and a practitioner who did only the minimum required 10 cases a year costs would be at least ten thousand dollars in direct expenses and lost production divided between 20 cases for a renewal period. That would be $500.00 per patient in costs to the provider.
    e. Costs for initial pediatric and adult sedation classes are from about fifteen to twenty thousand dollars in addition to the two weeks of lost production and travel costs which would amount to forty thousand dollars or more in costs and lost production to the practitioner.
    f. Glaringly absent from this table is the practitioner who currently and legally provides adult moderate oral sedation without a parenteral sedation permit. The cost to attend a parenteral sedation course as noted above would substantially increase their costs. This absence gives the appearance of purposeful omission.
    g. A standalone end tidal CO2 monitor is roughly $2,500.00 also increasing the cost per patient to the provider.
    h. These increases in cost will very likely reduce the number of practitioners providing such services thus decreasing supply and thus according to the law of supply and demand an increase in cost to the patient is certain.
    i. For all the above reasons costs will increase to the both the practitioner and consumer and it is false to imply otherwise.

    This questions and response should be re-written to include realistic expectations in increase of costs to the practitioner and public as the chart listed is incomplete and grossly misstated. To state that there is no expected increase in cost to the public is at best naïve and at worst a gross falsehood as substantial increases in cost should be expected to both practitioner and the public.
10. Regulatory Question 7. I support the limitation of use of certain agents for use in mild and moderate sedation and the proposed changes in 12 AAC 28.015(d) are worded more appropriately. This question however has multiple interpretations of the proposed changes that are grossly incorrect and misleading. Those agents listed in 12 AAC 28.015(d) are not general anesthetic agents. Quoting from Patel PM, et al. Goodman & Gilman's 2011 "General anesthesia

is a collection of "component" changes in behavior or perception. The components of the anesthetic state include amnesia, immobility in response to noxious stimulation, attenuation of autonomic responses to noxious stimulation, analgesia, and unconsciousness." Also from Katzung BG, Trevor AJ. Basic & Clinical Pharmacology, 13th ed. 2015. "The neurophysiologic state produced by general anesthetics is characterized by five primary effects: unconsciousness, amnesia, analgesia, inhibition of autonomic reflexes, and skeletal muscle relaxation." The only general anesthetic mild and moderate sedation providers are using is nitrous oxide. Most of what we use in mild and moderate sedation are simply sedatives that can cause deep sedation, not general anesthesia as they do not meet the above definitions. This question clearly implies that general anesthetic agents should not be used by mild or moderate sedation providers yet the board allows even hygienists to administer the most common of all general anesthetics, nitrous oxide. This response is at best uneducated, very poorly written and misleading while at worst it gives the appearance of purposeful misconstrual. This question should be re-written to be scientifically accurate and honest.

Sincerely,

Jack Hamilton, DDS

35657 Kenai Spur Hwy Soldotna, AK 99669
(907)420-3938 info@soldotnadentalarts.com

Zimmerman, Marilyn A (CED)

From: lothar479 . <btpollo7@gmail.com>
Sent: Monday, May 09, 2016 2:47 PM
To: Zimmerman, Marilyn A (CED)
Subject: Proposed Sedation Comment to Board of Examiners
Attachments: sedation.docx

Marilyn Zimmerman,

I have attached my comments regarding the proposed sedation changes.

Thank You,

Blair J Tudor DMD

Date: May 1, 2016

To: Alaska Board of Dental Examiners

Re: Proposed Changes on Anesthesia and Sedation

I am writing you due to the recently proposed changes to the Alaska dental statutes on sedation. While there is no denying there have been deaths nationally in the dental office involving/not involving sedation, I think it is important to evaluate regulations in an objective evidence based matter. The passing of poorly written and poorly thought out regulations, severely limits the dentists ability to serve their patients. Rather than limiting the people of Alaska access of care, I would propose an open and fair dialogue to discuss the issues at hand. In order to provide adequate dental care to the diverse and enormous state of Alaska these regulations should be reconsidered.

Thank you for your consideration,

Blair J Tudor III DMD

Zimmerman, Marilyn A (CED)

From: Clinic <clinic@wasilladentalcenter.com>
Sent: Monday, May 09, 2016 3:21 PM
To: Zimmerman, Marilyn A (CED)
Subject: Letter on Conscious sedation
Attachments: Scan_20160509_151722.pdf

Robert Cassell DDS
Wasilla Dental Center

WASILLA
Dental Center

(907) 376-5315
www.wasilladentalcenter.com

WASILLA
Dental Center

Robert Cassell DDS
Justin Coffman DDS
Brian Wight DDS

May 9, 2016

Alaska Board of Dental Examiners
P O Box 110806
Juneau, AK 99811

I adamantly oppose the recent regulation changes for dental sedation under 12 AAL 28 and request in writing from the Alaska Board of Dental Examiners why these regulations are indicated. In your response please inform who on the Alaska Board of Dental Examiners proposed these regulations.

I use conscious oral sedation in my practice to facilitate treating phobic dental patients who otherwise would not receive needed dental treatment. When I made the decision to offer conscious sedation during dental treatment I voluntarily completed 24 hours of training and seek regular CDE updates to stay current. If the board enacted these regulations as proposed I would not seek further training and stop offering these service giving the business to the oral surgeons who would then profit by removing teeth, I could have saved.

Respectfully,

Robert Cassell DDS

376-5315
351 W Swanson Avenue, Suite 1, Wasilla, Alaska 99654
clinic@wasilladentalcenter.com
Fax 376-7855

QUALITY CARE waltherdental.com

WALTHER DENTAL CENTER

FOR FAMILIES AND CHILDREN

Dr. Brian Hutchings
Walther Dental Center
1700 E. Bogard Rd. Ste. B204
Wasilla, AK 99645
(907) 376-9449

Alaska Board of Dental Examiners
POB 110806
Juneau, AK 99811
Fax: (907) 465-2974
Email: marilyn.zimmerman@alaska.gov

RE: Proposed Changes on Anesthesia and Sedation Permits by Dentists

To the Alaska Board of Dental Examiners,

Upon reviewing the proposed changes to sedation in the state of Alaska, I am concerned about the negative effect this wide-reaching legislation would have on access to dental care for Alaskan residents. Moderate enteral conscious sedation by Alaskan general dentists allows those with extreme dental phobia, an often under-served and vulnerable part of our population, to receive preventive and restorative dental care. It is estimated that approximately 15% of Americans avoid receiving routine dental care due to extreme dental anxiety (see PMID 6579095).

If this legislation is passed, it will effectively remove the ability of general dentists in the state of Alaska to administer safe and effective conscious sedation. It will leave those with dental phobia only able to see dental specialists who currently carry a parenteral sedation permit, a group which is chiefly composed of oral surgeons. This will further increase the number of teeth that are extracted that could otherwise have been saved by intervention from a general dentist.

While I do not oppose increase regulation, the very short comment period given did not allow sufficient time for this sweeping, complex legislation to be fully vetted. Also, no input was received from those who this legislation will ultimately effect the most – general dentists. Please do not approve these sweeping changes to sedation dentistry. If the board feels new legislation is absolutely necessary, then please involve Alaskan general dentists who provide conscious sedation in that process.

Sincerely,

Brian Hutchings, D.D.S.

Zimmerman, Marilyn A (CED)

From: Seth Lookhart <seth.lookhart@gmail.com>
Sent: Monday, May 09, 2016 4:21 PM
To: Zimmerman, Marilyn A (CED)
Subject: Dental Changes
Attachments: dental letter.docx

Attached is my letter regarding the proposed sedation regulation changes.

Respectfully,

Dr. Seth Lookhart

Thank you for allowing me the opportunity to present my concerns to you on the proposed changes to sedation regulations. My name is Seth Lookhart D.M.D., I have been performing IV sedation to patients of Alaska for well over 500 cases.

Let me first begin by asking what value the dental license hanging on our office walls has. Of course, it's a physical sign of our accomplishment, a trophy of sorts. But it also clearly shows to us (as well as our staff and patients) the confidence that you the Alaska Dental Board has placed in us myself and others to correctly apply the principles and practices we've been taught.

Why does this carry so much weight? It is because we view the State Dental Board as a governing body. They are the end-all, the final say. It is for this reason the license on your wall is no small thing. In effect, it says loud and clear: "You have been properly trained. You can make decisions. We trust you." The same holds true for the parental sedation permit. This also holds true with the DEA permit you keep carefully guarded. It would be disastrous for this permit to fall into unqualified hands; the decision to grant you these rights was not taken lightly. Again, "You have been properly trained. You can make decisions. We trust you."

Also, for those who have gone on to specialize, it is significant that the ADA has declared you a specialist. There's that trust again. They view you as qualified to set the standard of care that everyone must practice by. Using this lens, let's look closer at some of the proposed changes.

12 AAC 28.005. General provisions (point e)

This proposed revision stands in contrast to the ADA's clear statement that all specialists set the standard for care. To lump them into the same category as general dentists, requiring them to obtain a medical consult, disregards the ADA's classification of their unique qualifications. To then denote that a dental anesthesiologist, however, does not need to abide by this same regulation is counterintuitive. It makes no sense to exclude specialists, like Pediatric dentists, and include a practitioner who the ADA has clearly determined to NOT recognize as a specialist. The demarcation of the expected standard of care is completely lost because this revision infers that the ADA must be mistaken in what type of practitioner truly is qualified to set that standard. It is a contradiction to the governing body's decision. One must also take into consideration that the state of Alaska has had zero dental sedation related fatalities since the 1960's, and incidentally, this occurred under the care of an oral surgeon, the only other practitioner distinguished as qualified in this revision. The pointed exclusion of other specialists does not seem sound. There are currently 60 active parenteral licenses in the state; **sixty** qualified practitioners who have seen zero fatalities with their use sedation.

12 AAC 28.015. Permit requirements for moderate sedation (point d)

A second area of concern is the proposed revision to deny administration of certain agents currently deemed appropriate for dental sedation. Again, this proposal stands in stark contrast to the trust the DEA has placed in dentists by granting them a permit. Why do we think that the DEA does not know what they are doing? If they have given license to prescribe these agents, why can we not use them?

Furthermore, specialists like Pediatric dentists are trained during their residency to administer ketamine this included those who train right here in Anchorage. Does this not qualify them to be considered able to administer it in their own practice?

Additionally, to rule out the use of agents, such as propofol, simply because they may be used for general anesthesia blatantly ignores the fact that they may also be safely used for other levels of sedation. Included in the package insert for propofol are step by step instructions, with dosages, of how to perform MAC as well. It is not the particular agents that ought to be the issue. If we truly are concerned about patient safety, we would not target medications that have been safely and effectively used for years. Any agent administered incorrectly is potentially harmful; does this mean we refuse the use of *all* medications? Being trained in administering correct dosages, understanding patient response, and identifying warning signs associated with various levels of sedation; these are steps a responsible practitioner takes. How do we know they're responsible? The DEA has deemed them to be. The Dental Board has deemed them to be by granting approval of the training received. It is my fear that by listing specific drugs by name or class, we are limiting the unforeseeable future. As science progresses new pharmaceuticals are being developed, we can not say what their effects will be or how they can help us. It would be a very sad day if we prevented our profession from giving adequate care because of exclusion that are being proposed currently, especially given that the states tract record has been with out fatality for near half a century

In this age of unending regulations, when every matter seems to need approval by the governing body, why are changes being proposed that laugh in the face of that body's authority? Does it mean nothing that the DEA has given their approval to administer these agents? Does it mean nothing that the ADA has determined Pediatric dentists to be specialists, and then by default qualified to practice procedures beyond that which a dental anesthesiologist can? What stock do we put in these documents hanging from our walls and all that they represent? Please carefully consider the implications of what adopting these revisions would scream in the face of our governing bodies. Do we really know better/more than they do?

It is clear by resolution 77 that the ADA has not made a stance or defined where its position is in regard to sedation. I side with the ADA and ask that the Alaska State Dental board give the active license holders and those providing the service more time for input, IF any changes are needed at all.

Respectfully,

Seth Lookhart D.M.D.

Zimmerman, Marilyn A (CED)

From: Jesse Hronkin <jhronkin@hotmail.com>
Sent: Monday, May 09, 2016 4:26 PM
To: Zimmerman, Marilyn A (CED)
Subject: Sedation Regulations
Attachments: Alaska Board of Dental Examiners.doc

Please find my letter of comment attached.

Jesse G. Hronkin DMD

May 9, 2016

Alaska Board of Dental Examiners,

I have reviewed the proposed sedation regulation changes and am concerned that if they are approved and implemented as written, they may very well have an unintended adverse effect on many patients and dentists alike. I am sure those who drafted them have good intentions, and as a general dentist who has safely used oral conscious sedation on my patients safely for the past 12 years, I understand the need for further regulation in this arena but only if is based on solid evidence. We all hate to see the few unfortunate cases of sedation related deaths which have made national headlines recently. However, over the years, these have almost always been on pediatric patients and in offices of specialists, many of whom practiced in states that already have stringent sedation regulations on the books. That being the case, no new regulation could have prevented these tragic outcomes.

A call to any liability insurance carrier will reveal that there are many more claims paid on harm done to patients from use of local anesthetic than from oral conscious sedation. Why, then if the use of anesthetic puts patients at greater risk of adverse effect does the board zero in on these burdensome sedation regulations in the name of safety alone? We all want the best for our patients. I know I treat mine like family, and would do anything necessary to ensure their safe and successful treatment. Safe oral conscious sedation has allowed countless numbers of patients to receive care that they would not otherwise get. If these regulations are approved in their current form there will surely be a negative effect on access to care for many. Another potential risk is posed from a dentist who would no longer be able to prescribe oral medication to be titrated via multiple doses to reach the desired level of sedation, but instead chooses to prescribe the maximum single dose in one bolus. If this occurs surely there will be more adverse outcomes.

It is surprising that given the extent of changes proposed, we were only given several weeks to review the draft regulations. Unless one attended the regular board meetings or read their minutes there was no real way to know that these drastic changes were being considered until the mailing was sent out just weeks ago. I also feel that a complex issue such as this deserves more dialogue than can be expressed in a written submission only. Surely extending the comment period would not place anyone at risk and the opportunity for oral testimony would help resolve the many questions that these proposals give rise to. Also, creating a workgroup of Alaskan dentists that practice safe oral conscious sedation daily to help refine the proposed regulations would ultimately lead to the best solution for the health, safety and access to care for our patients.

Respectfully submitted,

Jesse G. Hronkin DMD
Alaska Dental License #1123

Zimmerman, Marilyn A (CED)

From: Kathleen Sage <sagealaska@gmail.com>
Sent: Monday, May 09, 2016 4:29 PM
To: Zimmerman, Marilyn A (CED)
Subject: Fwd: 12 AAC28.005 sedation

---------- Forwarded message ----------
From: **Kathleen Sage** <sagealaska@gmail.com>
Date: Mon, May 9, 2016 at 4:27 PM
Subject: 12 AAC28.005 sedation
To: marilyn.zimmer@alaska.gov

Dear Alaska State Board Dental Members,

I have been very safely providing IV sedation in a private dental office setting for 18+ years. My father had been providing very safe IV sedation in his private practice setting for 40 years. Properly trained dentists who have completed a post doctoral residency in AEGD or GPR or other such training where rotations in medical, OMFS, anesthesia experience and who have successfully completed an ADA/AGD nationally recognized Stanely Malamed (USC) type educational training program, should be allowed to continue providing this much needed and appreciated service to patients.

I personally have provided in office sedation to hundreds of developmentally disabled adults as well as those with Parkinson's Disease whom otherwise would not have been able to have had their dental needs addressed. This type of patient may otherwise leave their dental caries and infection needs unattended until they see an oral surgeon to then provide extractions and dentures. IV sedation provided by a properly trained general dentist is safe and increases safety, not to mention comfort to medically delicate elderly patients. An older, nervous, anxious patient that may have congestive heart failure, hypertension, atherosclerosis type medical issues (ASA 3, 4 and 5 type patient) will be less likely to have a cardiac related episode while in the dental chair if that patient is treated while under IV sedation.

I am certain the vast majority of the dental deaths and emergency incidents are not related or caused by dentist's providing IV sedation. Rather these types of deaths and emergencies are caused by dentists providing oral sedation and who have never completed a residency, have no OR experience and have never completed an accredited IV sedation training course.

I do not agree with 12 AAC28.005 e 3 that sedation of ASA 4 and 5 patients not be provided in a dental office. This will severely limit patient access care. Also, sedating these patients is going to relax them making them more safe and less likely to have an emergency cardiac or stroke type episode.

Yours Truly, Sincerely,

Charles M. Sage Jr. DDS, FAGD

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	**What will these proposed regulation changes do?**
Answer: 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	**What is the public need or purpose for these proposed regulation changes?**
Answer: 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	**What is the *positive* impact on the public or to a private person, business, or organization as a result of these proposed regulation changes?**
Answer: 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	**What *negative* impact will result from these proposed regulation changes on the public or to a private person, business, or organization?**
Answer: 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	**Why does the public need for this change outweigh any negative impact?**

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

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

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

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

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	**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?**
Answer: Training in moderate sedation needs to be current. 12 AAC 28.005(b) outlines training requirements.	
13 4/22/2016	**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?**

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;
> …