Original: 2233

James A. Coll D.M.D., M.S.
1600 East Market Street
York, Pennsylvania 17403
(717) 846-2900

January 27, 2002

Independent Regulatory Review Commission
Re: State Board of Dentistry Anesthesia Regulations

Dear Sirs:

I wish to submit comments on the proposed rulemaking by the State Board of Dentistry concerning the administration of general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia.

My background is I am a practicing pediatric dentist and have been since 1994 in York, Pennsylvania. I am a Clinical Professor in Pediatric Dentistry at the University of Maryland Dental School where I have been teaching part-time since 1976. I supervise the teaching and administration of conscious sedation to children by pediatric dental residents. I was also on the Pennsylvania State Dental Board from 1993 till I resigned in 1998 over the Dental Board's decision in the Dr. Mazula case concerning the death of Jonathan Walski.

My first comment concerns section 33.338, "Expiration and renewal of permits." As the Board outlined in their background and purpose sections, they eliminated the "grandfathering" requirements for dentists to obtain an unrestricted, restricted I, and restricted II anesthesia permit. I agree with their elimination of the "grandfathering," but this creates a potential problem in 33.338 if a dentist wishes to renew their permit but shift to a lower category. For example, a dentist may have an unrestricted permit and retires. He or she no longer performs general anesthesia or conscious sedation, but has a volunteer license and uses nitrous oxide/oxygen analgesia regularly. At renewal this dentist wishes to renew his anesthesia permit but ask for a restricted permit II because he can't attest to section 33.338 (b) (4) that he conducted general anesthesia during the preceding biennial period. This dentist may have been "grandfathered" for an unrestricted permit or no longer has the documentation he presented for an unrestricted permit. To obtain a restricted permit II, he would have to satisfy the 20 hours of courses outlined in 33.337 (a) (1). I do not think the Board considered how to allow permit holders to move to a lower permit classification.

I would propose the following in 33.338 (1): A dentist who has an unrestricted permit can renew their permit as a restricted permit I if they satisfy the requirements in 33.338 (b) relating to conscious sedation. A dentist who has an unrestricted permit or a restricted permit I can renew their permit as a restricted permit II if they satisfy the requirements in 33.338 (b) relating to nitrous oxide/oxygen.

My second comment is that the proposed rulemaking eliminated section 33.339 "Fees for issuance of permits". I don't see the five asterisks after 33.338 and before 33.340 to indicate 33.339 remains. I would assume this was an oversight.

My third comment applies equally to sections 33.340 (xvii) (xviii), 33.340a (xvii) (xviii), and 33,340b (xi) (xii) pertaining to the duties of the permit holder. All these sections were added or updated to address the "appropriate monitoring equipment" problems noted in *Watkins v. State Board of Dentistry*. These new sections I sighted pertain to "results of patient history and physical evaluation" plus the "signed patient consent." In these proposed regulations, section 33.340 (2), 33.340a (2), and 33.340b (2) requires the dental office in which the permit holder administers the anesthesia to contain equipment, systems, or areas but also the patient consent, history and physical evaluation. I feel the Board made an error since the patient consent and results of the history and physical evaluation must be part of the patient's record as stated in section 33.209 (7). The following example highlights the problem. A non-permit holder treats his patient under general anesthesia at a permit holder's office. The permit holder' dental office would be required to retain the signed consent and physical evaluation and history and not the non-permit holder's patient record. This seems to be a Catch 22 problem.

I would propose changing sections 33.340 (a) (1), 33.340a (a) (1), and 33.340 b (a) (1) to correct this problem. Add the following sentence after the end of the paragraph in the above sections: " The original or duplicated signed patient consent must be obtained and made part of the patient's record together with the results of the patient's history and physical evaluation for any permit holder or non-permit holder." Remove these same sections from the dental office requirements.

My fourth comment concerns section 33.340a (3) (iv). I feel the Board made an error in requiring dental assistants who assist the dentist when the dentist is administering conscious sedation to be currently certified in ACLS. In my opinion, the dentist and any nurse anesthetist should be currently certified in ACLS or Pediatric Advanced Life Support (PALS) for children 10 and younger. A dental assistant may hand the dentist a vial of local anesthesia or go to the locked drug box to get the oral sedation that the dentist dispenses. The assistant may place the pulse oximeter finger clip to get preoperative vital signs. I do not feel this assistant needs ACLS certification for the patient's safety to accomplish these duties and I feel it is over regulation. The current American Academy of Pediatric Dentistry's guidelines for deep sedation I think could be used as an outline for Pennsylvania's regulations concerning auxiliary personnel who assist the permit holder to administer conscious sedation. The AAPD guidelines state, "The techniques of deep sedation (level 4) require the following three individuals: (1) the treating practitioner who may direct the sedation: (2) a qualified individual to assist with observation and monitoring of the patient who may administer the drugs if appropriately licensed; (3) other personnel to assist the operator as necessary. Of the three individuals, one shall be currently certified in Advanced Cardiac Life Support or Pediatric Advanced Life Support and the other two shall be currently certified in basic life support." In essence the restricted permit I holder would need current certification in ACLS and or

PALS for children 10 and younger, but the treating dentist and his assistant need CPR certification.

I would recommend changing section 33.340a (3) (iv) to state the following: "Are currently certified in cardiopulmonary resuscitation (CPR)."

My fifth comment is in this same area where the regulations only allow ACLS certification in section 33.336 (b) and 33.338 (b) (3) for restricted permit I holders to exhibit they are competent to handle emergencies when administering conscious sedation to children age 10 and younger. At the University of Maryland where I teach conscious sedation, I feel PALS is more appropriate certification for dentists who perform conscious sedation on children. As I stated in my fourth comment, the AAPD recommends ACLS or PALS for deep sedation while here we are discussing conscious sedation in these regulations. I would recommend the Board to allow those restricted permit I holders doing conscious sedation on children age 10 and younger to have ACLS and or PALS certification. I propose they change the areas in 33.336(b) and 33.338 (b) (3) to allow for this.

My sixth comment concerns section 33.340a (a) (8) where I feel the Board made an error about the monitoring equipment having to "contain a fail-safe system." If you look at the same area under unrestricted permit, 33.340 (a) (8), that phrase is no present. Monitoring equipment does not possess fail-safe systems. The gas delivery system has a fail-safe control as is noted in 33.340a (a) (2) (v). I would propose eliminating "contain a fail-safe system from 33.340a (a) (8).

My seventh comment concerns section 33.344 which the Board did not address in this proposed rulemaking. This section was added in 1989, approximately 1 ½ years after the original regulations on the anesthesia permits became effective. The board gave dentists guidance as to when a restricted permit I was needed when nonparental medications were dispensed. Many dentists give a preoperative tranquilizer to ally a patient's apprehension. I feel this section needs updated by the present Board in the area of what constitutes conscious sedation in children so that dentists can tell when a restricted permit I is needed after referring to section 33.344 (d) (1). The AAPD revised its guidelines for conscious sedation, deep sedation, and general anesthesia in children in 1998. I feel the Board should revise 33.344 to give dentists better guidance about when a restricted permit I is needed when a dentist prescribes an oral (nonparenteral) sedative or a tranquilizer to a child to relieve anxiety. In my opinion, the Board can utilize the newest AAPD guidelines concerning conscious sedation for section 33.344 (d) (1). I have enclosed a copy of Appendix I of the AAPD guidelines about this area for you to review. If no further guidance is given to dentists in 33.344, I feel dentists who do not have a restricted permit I will withhold prescribing mild tranquilizers in anxious children. This will not be to the child's benefit.

I would recommend for children, the Board add better guidance in 33.344 (d) (1) by referring to the AAPD guidelines. I feel after the last sentence in the above section the following could be added: "In children, nonparenteral medications that produce a level

of sedation defined by the AAPD guidelines on the use of conscious sedation, deep sedation, and general anesthesia whereby the medication decreases or eliminates anxiety but promotes interaction and the patient responds appropriately at all times while maintaining their own airway without assistance docs not require a restricted I permit if all AAPD recommended monitoring is followed." I feel this would allow all dentists who treat anxious children and prescribe mild tranquilizers to do so no matter what permit they had or did not have. It would most importantly insure the patient's safety.

I apologize for not sending my comments any earlier. I was away on vacation and just discovered that IRRC had solicited public comment. I hope you will consider my suggestions.

Sincerely,

James A. Coll D.M.D., M. S.

Appendix I

Template of Definitions And Characteristics For Levels Of Sedation And General Anesthesia.

	Conscious Sedation			Deep Sedation	General Anesthesia
Functional Level of Sedation	Mild Sedation (Anxiolysis)	Interactive	Non-Interactive/Arousable With Mild/Moderate Stimulus	Non-Interactive/Non-Arousable Except With Intense Stimulus	General Anesthesia
Goal	(Level 1) Decrease anxiety; facilitate coping skills	(Level 2) Decrease or eliminate anxiety; facilitate coping skills	(Level 3) Decrease or eliminate anxiety; facilitate coping skills; promote non-interaction sleep	(Level 4) Eliminate anxiety; coping skills over-ridden	(Level 5) Eliminate cognitive, sensory and skeletal motor activity; some autonomic activity depressed
Responsiveness	Uninterrupted interactive ability; totally awake	Minimally depressed level of consciousness; eyes open or temporarily closed; responds appropriately to verbal commands	Moderately depressed level of consciousness; mimics physiologic sleep (vitals not different from that of sleep); eyes closed most of time; may or may not respond to verbal prompts alone; responds to mild /moderate stimuli (e.g., repeated trapezius pinching or needle insertion in oral tissues elicits reflex withdrawal and appropriate verbalization [complaint, moan, crying]); airway only occasionally may require re-adjustment via chin thrust.	Deeply depressed level of consciousness; sleep-like state, but vitals may be slightly depressed compared to physiologic sleep; eyes closed; does not respond to verbal prompts alone; reflex withdrawal with no verbalization when intense stimuli occurs (e.g., repeated, prolonged and intense pinching of the trapezius); airway expected to require constant monitoring; and frequent management	Unconscious and unresponsive to surgical stimuli. Partial or complete loss of protective reflexes including the airway; does not respond purposefully to physical and verbal command.
Personnel Monitoring Equipment	2 Clinical observation*	2 PO; precordial recommended*	2 PO, precordial, BP; capno desirable*	3 PO & Capno, ECG; precordial, BP, defibrillator desirable	3 PO, Capno, precordial, BP, ECG, temperature & defibrillator required
Monitoring Info	None	HR, RR, O_2, Pre-; During (q 15 min); Post, as needed	HR, RR, O_2, BP; [CO_2] if available Pre-; During (q 10 min); Post till stable/Discharge Criteria	HR, RR, O_2 & C [CO_2], BP, ECG Pre-; During (q 5 min); Post till stable/Discharge Criteria	HR, RR, O_2, CO_2, BP, EKG, Temperature Pre-; During (q 5 min minimum), post till stable/Discharge Criteria

Monitors: PO (Pulse Oximetry); Capno (Capnography); BP (Blood Pressure Cuff); ECG (Electrocardiogram)

* It should be noted that clinical observation should accompany any level of sedation and general anesthesia.

† "Recommended" and "Desirable" should be interpreted as not a necessity, but as an adjunct in assessing patient status.

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January 27, 2002

FAX TO: IRRC Attention Amy Lou Harris
Dental Board Anesthesia proposed regulations

FROM: James A. Coll

This fax contains 6 pages including the cover page.

Original: 2233

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January 2, 2002

Ms. Deborah B. Eskin
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State Board of Dentistry
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Reference No. 16A-4610
(Administration of General Anesthesia, Deep Sedation,
Conscious Sedation, and Nitrous Oxide/Oxygen Analgesia)

Dear Ms. Eskin:

I am writing to submit written comments as well as suggestions and objections regarding the proposed rulemaking on the administration of general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia.

First of all, I would like to let you know that I did not receive the original Pennsylvania Bulletin, which supposedly was issued on December 8th, 2001; thereby cutting short my available time for comment on this issue. However, there are a few things which I feel should be changed with regard to the proposed rulemaking on providing anesthesia in the State of Pennsylvania.

First of all, in section 33.340, *Duties of dentists who are unrestricted permit holders;* there are a few problems that I see. First of all, I feel it is unnecessary that all auxiliary personnel assisting unrestricted permit holders in the administration of general anesthesia, deep sedation or conscious sedation need be certified in ACLS. It is ridiculous to think that a Dental Assistant or Licensed Practical Nurse (LPN) has the training and background necessary to understand and become certified in ACLS. Even Registered Nurses (RN) without a critical care background find it difficult to learn and pass this difficult course. I would think it would be sufficient that the operator and the anesthetist both be certified in ACLS. I do not feel that it is necessary for any other auxiliary personnel to be ACLS certified. Rather, I would think that the current provision that they are CPR certified be sufficient.

Secondly, I have an objection with regard to administration of anesthesia to pediatric patients. First of all, I am not sure where the age of 10 was noted to set the limit between a pediatric and adult patient. Secondly, I feel that provisions should be made. It states that anyone administering anesthesia to patients aged 10 or under must comply to the standards outlined in the American Academy of Pediatric Dentistry Guidelines for the Elective Use of Conscious Sedation, Deep Sedation and General Anesthesia for Pediatric Patients. I feel that this provision should also consider the AAOMS Parameters and Pathways 2000: Clinical Practice, Guidelines for Oral and Maxillofacial Surgery, Anesthesia in Outpatient Facilities and the Office Anesthesia Evaluation Manual 6th Edition, published by the American Association of Oral and Maxillofacial Surgeons. These documents provide adequate training and adequate standards for providing anesthesia to pediatric patients in combination with the training of the anesthesia provider. There should be no delineation between Pediatric Dentists and Oral and Maxillofacial Surgeons and/or what guidelines they follow in providing anesthesia to pediatric patients.

Thirdly, I feel that it is unethical to charge a fee to have an office inspection. The American Association of Oral and Maxillofacial Surgeons inspects offices of its members without a fee imposed. I feel that this governing body should still continue with its office inspections for oral and maxillofacial surgeons. With regards to other specialties of dentistry, it is possible that the American Association of Oral and Maxillofacial Surgeons could also provide assistance and/or guidelines in inspecting those offices to provide for a consistent inspection. Non members of this association could be subject to a fee, however. It is already difficult enough to comply with all of the current anesthesia regulations, and any additional fees places a hardship on the anesthesia providers.

I would also like to point out, that throughout the proposed rule making, it states that certified registered nurse anesthetists work under supervision of the permit holder. Most nurse anesthetists would take great umbrage to this statement. According to the laws of the State of Pennsylvania, nurse anesthetists are allowed to practice independently of physician or dentist supervision. The American Association of Nurse Anesthetists is the governing body of these anesthesia providers and I would suggest that someone check with AANA regarding how nurse anesthetists should be treated under the Pennsylvania State Board of Dentistry. Most nurse anesthetists are not questioned when providing anesthesia care in a hospital or surgicenter setting. Why should this be any different in an office outpatient surgical setting?

In addition to my comments, I would suggest that the Pennsylvania State Board of Dentistry also take question and comments from the American Association of Oral and Maxillofacial Surgery, Pennsylvania Society of Oral and Maxillofacial Surgeons and American Board of Oral and Maxillofacial Surgery with regard to the proposed changes. There maybe a few things that I have missed which may be of great importance. I have had the minimal time to survey the proposed rule making as I have stated in the first portion of this letter, but I hope I have made some valid points.

If you have any questions, problems or concerns regarding my comments here today, please do not hesitate to contact me.

Sincerely,

Frank Falcone, Jr., DMD

FF: cas

Original: 2233

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December 23, 2001

Deborah B. Eskin, Counsel
State Board of Dentistry
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Dear Ms. Eskin:

This letter in reference to Document No. 16A-4610, *Administration of General Anesthesia, Deep Sedation, Conscious Sedation and Nitrous Oxide/Oxygen Analgesia.*

I have several questions, comments/advice regarding this proposed legislation.

First, the document requires that auxiliary personnel assisting unrestricted permit holder or permit one be ACLS certified. I agree that any CRNA or RN should be ACLS certified, but I believe that it is not legal to certify a dental assistant in ACLS. This course teaches a person to administer potent lifesaving or terminating drugs. Each person in ACLS is taught to "run a code". They are taught to perform as if they were in charge of the situation. I believe this is in direct violation of the dental practice act. Non-dentist or nonnurse training should be limited to BCLS.

Section 33.340(3)(i):

> *(3) Auxiliary personnel who assist the permit holder in the administration of general anesthesia, **deep sedation** or conscious sedation **[or nitrous oxide/oxygen analgesia]:***
>
> > *(i) Are trained to perform the duties that the permit holder delegates to them, if the duties do not require the professional judgment and skill of the permit holder and do not involve the administration of general anesthesia, **deep sedation** or conscious **sedation [or nitrous oxide/oxygen analgesia].***

Section 33.340a. (3) i-iv:

> *(3) Auxiliary personnel who assist the permit holder in the administration of conscious sedation:*

(i) Are trained to perform the duties that the permit holder delegates to them, if the duties do not require the professional judgment and skill of the permit holder and do not involve the administration of conscious sedation.

(ii) Perform their duties under the direct on-premises supervision of the permit holder, who shall assume full responsibility for the performance of the duties.

(iii) Do not render assistance in areas that are beyond the scope of the permit holder's authority.

(iv) Are currently certified in ACLS.

Second, equipment needs to be calibrated according to equipment manufacturer's guidelines and contain a failsafe. Many anesthesia machines used in dental offices use to be used in a hospital. When the manufacturer no longer certifies a machine it gets sold to alternate sites i.e. physician or dental office, etc. Do these regulations permit non-certified anesthesia machines to be used in a dental office? Do you address equipment that does not have a current manufacturer? Can a third party repair the equipment? What about equipment that has been modified against manufactures recommendation such as adding an anesthetic vaporizer to an analgesia machine

Third, when I renew my permit for the next renewal period, I have to state that I have been administering anesthesia in accordance with regulations that were not in effect during the previous period.

Section 33.338:

Expiration and renewal of permits. Under the proposal, renewal requirements have been amended to include proof of current certification in ACLS for unrestricted and restricted I permits, an attestation that the administration of general anesthesia, deep sedation and conscious sedation has been conducted ***(this should be changed to will be conducted)*** *during the preceding biennial period in accordance with the appropriate guidelines, and an attestation that equipment has been installed and calibrated according to the equipment manufacturer's guidelines and contains a failsafe system.*

Fourth, when will office inspections take place? Will there be a temporary permit issued until an inspection takes place?

Fifth, the new guidelines require an automatic external defibrillation (AED) device. This should read defibrillator. AED's are not recommended for children under eight. Most offices providing anesthesia have a manual defibrillator. Is this acceptable? Previous Dental Board rulings stated that as long as emergency drugs are available, a defibrillator is not needed. Is this statement still true?

Sixth, please explain what you mean by patient transport equipment.

Seventh, Permit II holders are not required to have a recovery area, patient transport equipment, oximeter, EKG, automatic BP, defibrillator or history. What is Required?

Section 33.340b.

> *Duties of dentists who are restricted permit II holders. This section is amended to require that patients be given a physical evaluation prior to the administration of nitrous oxide/oxygen analgesia. Equipment and operating room requirements are similar to those of restrictive permit I holders, with the exception that restricted permit II holders are not required to have a recovery area, patient transport equipment, an oximeter, an ECG, an automatic blood pressure monitoring device automatic defibrillation device and results of patient history.*

Eighth, It states that permits may not be issued unless the dental office has been inspected and meets the appropriate equipment and facility requirements. Does this mean that the facility will get a permit?

Section 33.341,

> *Duties of dentists who are not permit holders. This section would require that a permit may not be issued unless the dental office has been inspected and meets the appropriate equipment and facility requirements. Anyone administering general anesthesia, deep sedation or conscious sedation must possess current certification in ACLS. A non-permit holding dentist would be required to verify with the permit holder that monitoring equipment is present in the non-permit holder's office, is properly calibrated and in proper working condition, and is being used during the administration of general anesthesia. All equipment transported to a non-permit holder dentist's office would have to pass an inspection through the Board's authorized agents in accordance with the*

AAOMS Office Anesthesia Manual. The make, model and serial number of all equipment must be available and noted on the inspection report.

Also, Section 33.341, (stated above) states that non-permit holders should verify with permit holder that proper equipment is present and used for general anesthesia. Does this mean that deep sedation and conscious sedation are excluded? You should amend deep sedation and conscious sedation after General Anesthesia.

Ninth, I provide anesthesia services in multiple dental offices. Does each office require inspection? Inspecting each office would be a barrier to patient care. The mobile anesthesia provider should be inspected at one office location. He should then state that any other office he travels to will have services provided per guidelines.

Tenth, ACLS classes are not offered every month. In my area, the CEM offers classes twice a year. Is it acceptable to have a current ACLS card for renewal only? Do I have to stop practicing if my card is expired but will be renewed before the next license period?

Eleventh, in reference to 33.337(b), some manufacturers recommend that a nitrous oxide unit be sent to the factory every 2 years. Does the board have data that this is needed? I have never heard of anyone being injured with a nitrous oxide analgesia machine. When used as a sole agent it is very safe. When FedEx ships the nitrous unit back to you and bounces the unit around on an airplane, how do you know it has not lost calibration? I think that the board should inspect the unit and test its output. If it is not acceptable then the unit should be sent for re-calibration. In addition, every dentist calibrates the unit to each patient by slowly titrating the N_2O to patient response.

Twelfth, the description of Section 33.340b states that no patient history is required. In the actual wording of 33.340b it states you need a history. This section contradicts itself.

Thirteenth, regarding guidelines recommended in document, AAOMS Guidelines are developed for oral surgeons. If you are not an oral surgeon, then ADA or AAPD Guidelines should apply.

Fourteenth, please define failsafe. Section 33.340a mentions a failsafe or oxygen/gas delivery system and on monitors, what is a failsafe on a monitor?

Fifteenth, the wording "subsequent editions" should be changed to "current guidelines" due to the fact that the next subsequent edition could be used indefinitely without adhering to current guidelines. This would create the same situation that we are currently trying to correct.

Sixteen, I would add that a general anesthesia machine must have a functional oxygen analyzer in the circuit.

Very truly yours,

Thomas F. Cwalina DMD
Diplomat American Dental Board of Anesthesiology

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December 21, 2001

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RE: reference No. 16A-4610 (Administration of General Anesthesia, Deep Sedation, Conscious Sedation and Nitrous Oxide/Oxygen Analgesia) in Dental Offices

Dear Deborah B. Eskin:

In response to your call for interested parties to comment on the proposed Pennsylvania dental board rules changes regarding anesthesia in the dental office, I wish to respond as a full time practicing dentist anesthesiologist educator and clinician. Although I am a past president of the American Dental Society of Anesthesiology, Editor-in-Chief of "Anesthesia Progress", current president of the American Dental Board of Anesthesiology and the media spokesperson of the American Dental Association for anesthesia affairs, I write this letter to represent my own personal views and not that of any organization.

I commend those individuals in the state of Pennsylvania for attempting to modernize their dental office sedation and anesthesia standards. I however wish to point out a few areas that need some attention in order to better define your intent with alternative wording.

While the revisions allude to the anesthesia documents of the AAOMS, ADA and AAPD, the specifics in your revisions are quite different from those standards. I would suggest a much closer reading of these documents as they have been very carefully worded. For instance, the ADA's "Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry, Part II" (Guidelines Part II) were revised in 1993 to increase the general anesthesia training of general dentists to 2 full years instead of one year. While dentists who started their training before this change should be eligible for an unrestricted permit, a newly trained dentist with only a year of anesthesia training would be able to obtain an unrestricted permit in Pennsylvania with only half of the general anesthesia training that the ADA currently recommends. If the ADA recommends 2 years, why

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December 21, 20

would Pennsylvania accept half of that for recently trained dentists and those to be trained in the future?

The evidence of acceptable training for an unrestricted permit rightfully includes a Fellow of AAOMS or board eligible/certified Diplomate of the ABOMS. Oral surgeons with any of these three credentials have evidence of being trained in anesthesiology in ADA accredited specialty programs. Unfortunately your revision also includes newly-trained dentists with only 1 year of anesthesia training which commenced after 1993 who are still be eligible to become Fellows of the American Society of Dental Anesthesiology (sic), an organization that does not exist as worded. The correct term is the American Dental Society of Anesthesiology. It is inappropriate to list this group of ADSA Fellows since they are not officially an ADA-recognized certification, specialty or board. Rather, the criteria should be "or completion of a general anesthesia residency in accordance with the ADA's "Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry, Part II" which were in effect at the start of the training." This would then include those with one year prior to 1993 and those with two years who commenced training after 1993. That would of course include all ADSA Fellows trained before 1993 and some ADSA Fellows who may have had 2 years after 1993. Since most states include "Grandfathering of older practitioners", you might wish to include all ADSA Fellows, including those with only one year of training, until a specific date after these regulations go into effect. However, thereafter, any dentist with only one year should be excluded, whether or not he/she is an ADSA Fellow..

Without exception, only dentist anesthesiologists who were trained in accordance with the ADA Guidelines Part II which were in effect at the start of their training are eligible to be members of another group, the American Society of Dentist Anesthesiologists (ASDA). The qualifications for ASDA membership are therefore more rigorous than for the Fellowship of the ADSA. All ASDA members are either eligible or are currently Diplomates of the American Dental Board of Anesthesiology. Dentists trained since 1993 must have two full years of anesthesia training to qualify for ASDA and ADBA credentials. If Pennsylvania wishes to recognize organizations and credentials that are not officially recognized by the ADA, then at least membership in the ASDA and/or board certification by the ADBA should be included along with Fellowship in the ADSA. However, since anesthesia is not an ADA- recognized dental specialty and because

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the ADA's Commission of Dental Accreditation doesn't accredit any type of anesthesia residency, additional dentist anesthesia boards such as the NBA (2 year-trained dentists who frequently but not exclusively work in hospitals) and the NDBA (new board for ADSA members) are unfairly excluded in your revision, and this further confuses this issue. I therefore recommend including both credentialed oral surgeons as stated above or dentists trained according to the ADA Guidelines Part II which were in effect at the start of their training as the only criteria for an unrestricted permit. This is simple and clean and does not exclude any dentist who was properly trained in anesthesia according to the ADA. Alternatively, you could include any dentist who is an ADSA Fellow, or a diplomate of the ADBA, NBA or NDBA.

Whereas the ADA's "Guidelines Part III" accepts 60 hours of didactic hours and 20 clinical sedation intravenous sedation cases as evidence of proper training in IV conscious sedation, your revision of "80 hours of didactic and clinical training" for a Restricted Permit-I might allow for 70 hours of didactic education and only two clinical cases if each were 5 hours long or some other combination that would be educationally unacceptable. Why not use the ADA's language which provides for a proper balance of didactic hours and supervised clinical experience.

The same is true for nitrous oxide-oxygen conscious sedation. The ADA recommends "14 hours, including a clinical component during which competency in inhalation sedation technique is demonstrated". That phrase perfectly states exactly what is needed to train a dentist to use nitrous oxide safely. What evidence is available that 20 hours is needed when the experts in the ADA have agreed upon a reasonable national standard?

While it is clear that a permitted dentist working in his/her own office must be periodically inspected, it is not clear to me what the inspection requirements are for dentist anesthesiologists who practice in multiple locations. In order be document safe practice, to remain fair to these dentists and to not over-burden the inspectors with dozens of unnecessary duplication of inspections in every office where dentist anesthesiologists provide the service, the Ohio Board inspects the mobile dentist anesthesiologist in one office on the same schedule as other permit holders who work in a single office, provided that the dentist anesthesiologist informs the board of every office where the anesthesia is administered and provided that he/she swears to have all of the listed equipment, monitors,

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December 21, 20

drugs, etc that were used during the office inspection in every other office where anesthesia is administered according to the ADA Practice Guidelines. Otherwise the dentist anesthesiologist might have to be asked the same questions in 50 different offices, an unnecessary burden for the dentist and the inspection team.

In offices where an ECG is required for sedation and general anesthesia, an Automated Electronic Defibrillator (AED) is required. Please note the proper name is not Automatic External Defibrillator as is contained in your revision. These are nice devices for anyone not trained in electrocardiography such as policeman and airline personnel, but certainly dentist anesthesiologists are able to diagnose shockable rhythms and to use a manual defibrillator. The problem with most current AED's is that most are not designed for use in children. Personally, I need a manually operated defibrillator which would be able to be adjusted to resuscitate the small children (18 months and older who I regularly anesthetize) without killing a significant amount of heart muscle with an adult-sized overdose electrical shock produced by an adult-only AED. While some oral surgeons and other permit holders may be more comfortable with an AED, you must at least give the option of a manual or automated defibrillator, depending on the experience and training of the dentist.

Finally, it appears that your sedation rules do not permit light oral sedation, not even a single low-dose anxiolytic of relatively safe drug like 5 mg of oral Valium for a somewhat anxious adult. Although I have only seen those portions of your rules that are changed, it is regretable if light oral anxiolysis is lost for the average general dentist. The ADA has appropriate practice guidelines for the safe administration of oral conscious sedation and for a combination of oral conscious sedation with the addition of nitrous oxide. I would hope that you would allow oral anxiolytics to be prescribed to adults. In Ohio, oral sedation of children is limited to dentists with advanced training such as pediatric dentists and sedation/anesthesia permit holders, but any dentist may prescribe a single dose of an oral sedative to an adult. Titration of multiple oral doses at the same appointment however is not allowed for drugs like Halcion since oral absorption is often erratic and thus the margin in safety for oral sedation is reduced. Further, the term "Sleep Dentistry" is interpreted by the Ohio Dental Board as implying general anesthesia (Put you to sleep for the dental procedure) and is therefore either false and misleading if the dentist does

THE OHIO STATE UNIVERSITY
HEALTH SCIENCES CENTER

College of Dentistry

Postle Hall
305 West 12th Avenue
PO Box 182357
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December 21, 20

not have a general anesthesia permit or else the unlawful administration of oral deep sedation/general anesthesia by a non-GA permitted dentist.

I hope my investment in time to reply to you is judged with an open mind. The citizens, especially the small children of the State of Pennsylvania, are depending on you to make a reasonable and just revision.

Sincerely,

Joel M Weaver

Joel Weaver, DDS, PhD
Associate Professor
Director of Anesthesiology
Section of Oral and Maxillofacial Surgery
College of Dentistry
Associate Professor
Department of Anesthesiology
College of Medicine and Public Health
The Ohio State University

Original: 2233

Dr. James A. Parenti

GENERAL DENTIST

3811 WEST LAKE ROAD

ERIE, PA 16505

TELEPHONE (814) 833-8484

December 17, 2001

Deborah B. Eskin
Counsel, State Board of Dentistry
P.O. Box 2649
Harrisburg, Pa. 17105-2649

RE: 16A-4610 SPECIFICALLY CONSCIOUS SEDATION—**PUBLIC COMMENT**

Dear Ms. Eskin,

Revision of Anesthesia regulations has been under consideration for a long time. As a Restricted I permit holder no one has made me aware of the proposed changes. I found out by a fluke and have since worked with my local state legislator. It would have been nice as a permit holder to have been notified from the beginning and have been kept abreast of developments. You have contacted 138 dental schools, associations, and "interested individuals" **but not the permit holders directly.**

You will have trouble finding someone who has more hours of conscious sedation experience while performing general dentistry than myself over the last 22 years in all the 138 you have contacted.

The most important areas you have not addressed according to the latest Pa Bulletin I received are:

1. The fiscal impact to the permit holder—which will be tremendous
2. More importantly the fiscal impact to the patient.
3. The impact of lack of access by the patients to CONSCIOUS SEDATION for GENERAL DENTISTRY. (EX. RESTORATIONS, ROOT CANALS, ETC.)

The revisions lack practicality, common sense, and have no regard for cost containment with regard to conscious sedation.

I will use only one example for lack of space in a letter. The AAOMS is being used for most protocol information revisions. Now this was written for oral surgeons not the general dentist. So oral surgeons do general anesthesia or deep sedation and need an EKG. This is correct. So when writing the manual now they come to CONSCIOUS SEDATION and they indicate an EKG is needed. An EKG is not needed for conscious sedation. But the oral surgeon already has one so no big deal to

include it in the next protocol since it is in place already. But EKG monitoring is not needed for CONSCIOUS SEDATION of a healthy patient. Now a medically compromised patient would need it. But that patient should not receive any type of anesthesia in the office-outpatient setting. It should be done in a hospital setting. I will digress to the two morons/murders referred to in the Bulletin. Sedation of a 3 ½ year old in an office setting!?? A prudent practitioner would not even orally sedate a child of that age. They are too fragile. But because of these two idiots, regulations will be put in place that takes access away for everyone or makes it so costly that in essence it takes it away. Those practitioners should be punished not the prudent dentists and the patients. Just no common sense being used.

By the way I don't even see oral sedation being addressed. This is the most dangerous type of sedation. The practitioner has not control once the medication is swallowed. If oral sedation goes awry the patient is in deep trouble. IV lines have to be established, etc. Time is against this patient!

Passing of these amendments as I am reading them will have the same result it has had in other states with other dentists I know personally. **Conscious sedation for the purpose of general dentistry will not happen anymore.** Everyone I know in other states where these changes regarding anesthesia have been made, **STOPPED DOING THE PROCEDURE**. It simply was not cost effective.

So who gets hurt? Not the dentist. The patient has to have the treatment anyway. Obviously the patient. They either have to endure general dental care with extreme fear and anxiety OR they are sentenced to dentures because general dentistry has been taken from them under CONSCIOUS SEDATION. So they must opt for the extraction of savable teeth and be condemned to dentures. It is the latter that will prevail!

Please reconsider and talk with professionals like myself before these regulations are finalized. The State Board has done much research regarding these matters and I commend you, but you simply have not considered it thoroughly from a practical and cost standpoint at the point of delivery to the patient who we are trying to "protect".

Sincerely,

Dr. James A. Parenti

Original: 2233

DR. W. KEVIN MAHONEY, DMD,FADSA
GENERAL DENTISTRY & ANESTHESIOLOGY
3915 CAUGHEY ROAD
ERIE, PA 16506

Deborah B. Eskin, Counsel
State Board of Dentistry
P.O.Box 2649
Harrisburg, Pa 17105-2649
Refernce # 16A-4610

December 17, 2001

Dear Ms. Eskin,

I have carefully reviewed the proposed regulatory changes regarding the administration of anxiety and pain control modalities in the practice of dental medicine and surgery. As a practicing Dentist Anesthesiologist and an instructor in Advanced Cardiac Life Support, I understand the current political environment regarding anesthesia safety.

Subsequently, I have several points in the proposed draft that need clarification or further explanation. What are office inspections intended to do or prevent? Why six years duration? Also, the model and serial number of all equipment will be noted in the inspection report. Consequently, the next day all new or different equipment could be purchased and installed , leaving the days previous report an interesting collection of names and numbers. In addition, who will appoint the authorized agents for these inspections and who will be considered for authorized agents? Also, the proposal of having unrestricted permit holders pass a clinical evaluation as a component of a successful office inspection appears excessive. The American Society of Anesthesiologists does not require its members to demonstrate anesthesia technique for membership, nor residency program accreditation or facility accreditation.

The American Heart Association guidelines for Advanced Cardiac Life Support are intended to address the patient suffering from cardiac disease and its emergent treatment. The proposal of requiring auxillary dental personnel in the dental anesthesia environment to complete the ACLS program in not vital. I also question the permit holder requirement for ACLS completion. There is no data that would suggest ACLS trained providers have better treatment outcomes than any other group. Moreover, the proposal of classifying appropriate monitoring by specific names has limitations for future advances in monitoring technology. The requirements for pulse oximetery should be stated that "a device that can measure arterial oxygen concentration and cardiac rate be used". The electrocardiograph, ECG, should be described as a device that can

measure the electromechanical energy and cardiac rythm. The automatic blood pressure monitoring device doesnt have to be automatic, any device that accurately determines BP should be adequate, a current example is an arterial line placement with BP transducer. The requirement for an automatic external defibrillator device-first, I am not convinced this is a requirement for a safe and successful anesthetic and second, why automatic, why not manual. The requirement might read , "any device that can develop and discharge an electrical shock capable of causing cardiac defibrillation".

The history of anesthesiology in medicine and dentistry is colorful and varied . The last forty years has seen numerous studies in anesthesia research and development which have translated into much better, highly trained anesthesia providers of today. Also, the advances in patient monitoring have been unparalled, the introduction of pulse oximetry, the pulmonary artery catheter, capnography, bispectral anaylsis and all the invasive and non-invasive critical care monitoring technology currently in use today can provide second by second patient evaluation.

Sadly, the one area where great change has not occurred in anesthesiology is in morbitity and mortality rates. Even with all the advances in pharmacology, anesthesia training and patient monitoring the number of anesthesia misadventures has remained about the same over the last forty years. The safe and successful practice of providing aneshtesia care is that of eternal vigilance, recognition and prepardness. All the training and monitoring equipment available can not replace a provider who lacks professionalism and a conscience. Safe anesthetics have been administered to patients for over one hundred years by providers who lacked our current sophisticated patient monitors and knowledge. It all comes down to the Doctor. Even in today's world, if monitoring equipment would fail during anesthetic administration, the vigilent, prepared doctor can usually navigate to a safe ending. Therefore, in the end, all the regulations and requirements cannot replace a caring , compassionate and vigilent Dentist.

Respectfully,

Kevin Mahoney

W. Kevin Mahoney, DMD, FADSA

Consider w/ ones. neg. comments

University of Pittsburgh

Original: 2233

School of Dental Medicine
Office of the Dean

Salk Hall
3501 Terrace Street
Pittsburgh, Pennsylvania 15261-1933
412-648-8880
Fax: 412-648-8219

November 20, 2001

RECEIVED
NOV 2 8 2001
DOS LEGAL COUNSEL

Norbert O. Gannon, D.D.S
Chairman State Board Of Dentistry
1028 S. Braddock Avenue
Pittsburgh, PA 15218

Dear Norb,

I would like to present the following comments after reviewing the information that was provided to us by Ms. Eskin regarding the status of the anesthesia regulations and the inquiry directed from Darrel Crimmins, Operations Officer for the Bureau of Enforcement and Investigation. While I must admit the process is relatively new to me, I find that there appear to be areas of confusion overlap and misunderstanding in regard to original intent of the regulations that were previously developed by the Board. First, I would like to address the comparison of House Bill 286 to the proposed regulations prepared by Ms. Eskin. I find these particularly helpful and an excellent reference. I believe in comparing House Bill 286 with the proposed regulations that have the attached legal commentary, House Bill 286 appears to be more in keeping with the intent of the original regulations as they were formed and more in keeping with established standards and practices nationwide.

After reviewing the memorandum from John Henderson to David J. DeVries, not dated, regarding Department of State Regulation Number 16A-4610, I would note the following. The American Academy of Pediatric Dentistry **Guidelines for the Elective Use of Conscious Sedation, Deep Sedation, and General Anesthesia in Pediatric Dental Patients** is referenced as well as the American Association of Oral and Maxillofacial Surgeons' **Office Anesthesia Manual**. Both are accurate but directed towards specific audiences. On the third page of that memo, the second paragraph is read as, "as to procedures and documentation, the guidelines provide that provision of general anesthesia to a pediatric patient requires the following three individuals: 1) a physician or dentist who has completed an advanced training program in Anesthesia or Oral and Maxillofacial Surgery in related subjects beyond the undergraduate medical or dental curriculum who is responsible for anesthesia and monitoring of the patient, 2) a treating dentist who is responsible for the provision of

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dental services, 3) other personnel who assist the operator as necessary." In specific reference to this item, I would note that the intent of the **Guidelines for Pediatric Dentistry** were for pediatric dentists who are not comprehensively anesthesia trained. Extrapolating those guidelines to practicing oral and maxillofacial surgeons who are comprehensively trained in general anesthesia delivery as well as the delivery of surgical care, I believe, is cumbersome, not necessary, and likely to limit access to care. Two licensed practitioners are not required for pediatric patients when the practitioner is an unrestricted permit holding oral and maxillofacial surgeon.

In regard to the memorandum from Darrel Crimmins, I would like to provide the following comments.

1. Both this memorandum and the regulations refer to a clinical evaluation. It is essentially impossible that an adequate clinical evaluation be provided by any non-professional who has not been trained and practices the area of anesthesia. This evaluation as outlined in the **Office Anesthesia Manual** was designed to be done by practicing oral and maxillofacial surgeons. A clinical evaluation portion, therefore, should be established in conjunction with a professional organization such as the Pennsylvania Society of Oral and Maxillofacial Surgeons, a voluntary professional group. The initial office examination, inspection, and clinical evaluation may be done in close conjunction with one another, although on repeated office inspections, which are noted at every six years, that may not be necessary.
2. It is my suggestion that non-permit holders who intend to have anesthesia administered in the office undergo inspection at the same interval as offices of permit holders. One inspection, therefore, would be good for six years.
3. Equipment being transferred to offices should be inspected at the same interval as equipment which resides within the office.
4. Inspections may be conducted with or without prior notice. It is my belief that office inspections which would, in my opinion, consist only of recognition of the equipment make, model, serial numbers, and a safety check should not significantly interfere with patient care or require a "clinical evaluation" and likely take one hour or less. Similarly, I do not believe medical record review need take place at the time of the office inspection, especially if that inspection is a surprise inspection. A request may be made that the records be available at one to two days

following the inspection to provide adequate time for the office staff to recognize this. It is unreasonable to essentially shut down an office for a day while inspectors are requesting records. Further, I think recognition of the new HPPA must be considered.

5. Inspectors can be educated at the University of Pittsburgh and conceivably at other institutions of the state that are familiar with this process. I would specifically recommend in addition to the University of Pittsburgh, the University of Pennsylvania.

Sincerely,

Thomas W. Braun, D.M.D., Ph.D.
Dean

cc: Commissioner Albert Masland
Ms. Deborah Eskin
Ms. Lisa Burns
Members of the State Dental Board

TWB\lt

Original: 2233

Dr. James A. Parenti

GENERAL DENTIST

3811 WEST LAKE ROAD

ERIE, PA 16505

TELEPHONE (814) 833-8484

May 31, 2001

Mr. Robert E. Nice
Executive Director
Independent Regulatory Review Commission
333 Market Street
14th Floor
Harrisburg, PA 17101

RE: STATE BOARD OF DENTISTRY'S PROPOSED ANESTHESIA REGULATIONS DRAFT #10B DATED: MARCH 26, 2001 - RESTRICTED PERMIT I HOLDERS.

Dear Mr. Nice

I have been performing conscious sedation safely, professionally, and without mishap on over a thousand patients for 21 years! Patients who have ended up losing their teeth in our non-fluorinated community and sentenced to dentures forever instead of having their own teeth as we as professional have been trained to perform. Performing it prior to the 80-credit requirement and prior to this new proposed regulation. I am going to only address only a couple of items from a practical and cost standpoint.

A. **CERTIFICATION OF THE PERMIT HOLDER IN ACLS:**

While on the surface this sounds very noble on paper it is impractical. ACLS would familiarize the permit holder with intubation support of the airway and borderline informal training in identifying abnormal cardiograms, medications, and electronic cardioversion – This is the basic difference between CPR and BLS and ACLS.

It is impractical because like any other procedure such as Root Canal, you can study it every 2 years. But if you do not perform it on a regular basis you are not qualified from a practical end to perform it. In fact, if a practitioner of any type would try to perform these procedures rarely, the practitioner could cause more injury to the patient than good. Any dentist who doesn't regularly intubate patients or perform "emergency codes" is as foolish and detrimental to the patient and the one who is performing outpatient conscious sedation on medically compromised patients which they have no business doing.

BASIC LIFE SUPPORT, MAINTENANCE OF THE PATIENT AIRWAY AND CARDIO-PULMONARY RESUSCITATION IS ALL THE PERMIT HOLDER NEEDS TO PRACTICALLY PERFORM CONSCIOUS SEDATION. SUPPORT THE PATIENT UNTIL **EXPERIENCED** AND **ACTIVELY DAILY PERFORMERS OF ADVANCED LIFE SUPPORT** ARRIVE. Yes training in emergency medication or anaphylactic reactions and reversal of medications, etc. I would say yes and indeed in the 80 credit hours this was covered.

Hospitals have special teams in this area, not every doctor who performs a procedure performs emergency medical treatment that may occur with regard to that procedure. Examples and facts can support this. One week ago I referred a patient to the oral surgeon for removal and biopsy of an oral lesion. The patient had a delayed hypersensitivity reaction and the oral surgeon performed basic life support and called the ambulance and the patient was hospitalized and the ENT department took over and intubated the patient and did the "advanced" emergency medical treatment. I refer to intelligent and PRACTICAL specialist, wouldn't you agree? Couldn't you just see this highly trained oral surgeon who hasn't intubated a patient since his residency but "knows how" perforating the pharynx or esophagus! How foolish he would have been. But he could say the state required they insisted be trained every 2 years and made it standard of care. It won't fly. IT IS IMPRACTICAL AND DANGEROUS.

AUXILIARY PERSONNEL WHO ASSIST CONSCIOUS SEDATION HAVE ACLS

The average dental assistant in the dental office does not have the academic background in pharmacology, anatomy, physiology, etc. to even grasp the information contained in ACLS **let alone perform it a rare emergency situation**. They can however perform basic CPR proficiently until experienced and advanced emergency medical personnel arrive.

Therefore, if this ACLS is required, it will require a third party other than the present dental assistant to assist the dentist-permit holder to perform conscious sedation resulting in higher costs to the patient and very difficult logistics in the arrangement of the procedure (since the third party will only be in the dental office for the sedation and must interview and obtain consent from the patient) as well as the dental treatment in the office out-patient situation.

Ideally the dentistry and the sedation should be performed in the hospital. I have pursued this avenue but the local hospitals will not arrange a dental suite where **general dentistry** can be performed on a regular basis. The reason – **they can't make money at it.** It is not cost effective in the dental office as an outpatient under proposed regulations.

But if these and other regulations are introduced it can only result in the following:

1. Extreme and non effective costs to the practitioner regularly performing in office conscious sedation. Resulting in termination of the procedure in the office setting.

2. Purchase of costly "overkill" equipment, which significantly raises the cost to the patient putting in out of their reach.

3. Absolute need for a second trained professional to be creating the same scenario as point #2.

BOTTOM LINE:

1. In most cases those performing conscious sedation cautiously, ethically, professionally, and safely will be forced to stop offering the needed service. It happened in New York State to fellow colleagues of mine.

2. It will reduce availability of conscious sedation to the patient and where it is available the cost will be significantly increased to the patient and thus in many cases disqualify them from obtaining regular dental care because of their extreme fears and anxiety – FORCING THEM TO THE OLD REGIME OF DENTURES and EXTRACTIONS INSTEAD OF MAKING AVAILABLE TO THEM ALL THE MODALITIES OF MODERN DENTISTRY WITH THE USE OF CONSCIOUS SEDATION AND PRESERVING THEIR NATURAL TEETH.

In closing, all the regulations in the world will not protect the dental patient from the unscrupulous, unethical, neglectful, and dangerous practitioner. That can only be done by prosecuting those practitioners, who are proven neglectful, not imposing impractical and extremely costly regulations on those of us who are responsible and providing needed and comprehensive dental care to the public.

So what is the goal of these new regulations? Higher quality and safer care. You will accomplish this but not the way you think. It will be safer because a lot fewer patients will be able to access conscious sedation on an outpatient basis for the purpose of general dental care. But it will not be for the reasons I know you are trying to accomplish.

Thank you for this opportunity for input. I could write for hours and am willing if necessary to write more or testify in person before the State Dental Board in order to have them look practically at this situation and act accordingly and prevent this detrimental over-regulation.

Dr. James A. Parenti
3811 West Lake Road
Erie, PA 16505
(814) 833-8484

Original: 2233

2964 Sequoia Drive
Macungie, PA. 18062

TO: State Board of Dentistry
From: Mary J. Baker
RE: Regulations – Administration of Nitrous Oxide

I am writing to protest the new, severe Regulations for Nitrous oxide Administration.

For the past thirty-five years, I have not had a dental procedure without Nitrous. The regulations you have imposed will drive Nitrous Fees beyond the financial means of most people, myself included.

These regulations are thrusting us back to the dark Ages, and are unfair to all the patients who will not go to the dentist without this analgesia.

Mary J Baker

Week of:

November 18, 2001

OriginalL: 2233

PENNSYLVANIA SOCIETY of ORAL & MAXILLOFACIAL SURGEONS

Lathe L. Bowen, D.M.D. — *President, PSOMS*
425 Heights Drive
Gibsonia, PA 15044-6032
Phone: 412-648-8605
Fax: 412-648-3600

March 16, 2001

VIA FACSIMILE AND U.S. MAIL

Commissioner Al Masland
Bureau of Professional and Occupational Affairs
Department of State
124 Pine Street
P.O. Box 2649
Harrisburg, PA 17105

Chairman Norbert Gannon
State Board of Dentistry
Department of State
124 Pine Street
P.O. Box 2649
Harrisburg, PA 17105

Re: Proposed Regulations of the State Board of Dentistry: Anesthesia

Dear Commissioner Masland and Chairman Gannon:

I am writing on behalf of the Pennsylvania Society of Oral and Maxillofacial Surgeons (PSOMS), a non-profit organization with more than 350 members. PSOMS is also a component society of the American Association of Oral and Maxillofacial Surgeons (AAOMS), which presently has over 6,000 members.

PSOMS has been actively monitoring the progress of the development of the State Board of Dentistry's (Board) draft regulations on anesthesia. In May 2000, we submitted pre-draft input on draft #5 and we thank the Board for its revision regarding section 33.340(a)(8) in subsequent versions of these draft regulations. A copy of our pre-draft #5 comments is enclosed for your review. The pre-draft input was requested under a very short response time and therefore, we focused our comments on our primary area of concern, section 33.340(a)(8).

However, following subsequent reviews of the draft regulations, and the public discussion among Board members at the last Board meeting regarding these regulations, PSOMS offers additional comments. PSOMS is concerned that the phrase "authorized agents" in sections 33.335, 33.336 and 33.342 is not clearly defined. It is unclear as to who will qualify as an "authorized agent" of the

Board tasked with the responsibility of performing office inspections for unrestricted permit and restricted permit I holders. We request that the Board clarify "authorized agents" to mean unrestricted permit holders and restricted permit I holders with at least 5 years experience in the administration of dental anesthesia and conscious sedation, respectively.

It is essential that competent and experienced dental professionals be the inspectors. The administration of dental anesthesia and conscious sedation are complicated and sophisticated processes that cannot be adequately observed or evaluated by someone unfamiliar with their intricacies. PSOMS has developed specific recommendations for changes to the language in draft #9 that we believe clarify the qualifications of an "authorized agent." The recommendations are enclosed for your review. Please adopt these proposed language changes prior to the Board's final approval of the draft regulations.

If you have any questions regarding this proposal, please feel free to contact me (412-648-8604) or our public affairs consultants, Jay Layman and Beth Zampogna at Capital Associates, Inc. (717-234-5350).

Sincerely,

Lathe Bowen, DMD

Lathe Bowen, D.M.D.
President
Pennsylvania Society of Oral and Maxillofacial Surgeons

Enclosures

cc: Thomas W. Braun, D.M.D.
Deborah B. Eskin, Counsel, State Board of Dentistry
PSOMS Executive Committee
Carol O'Brien, American Association of Oral and Maxillofacial Surgeons
Melissa DiSanto Simmons, Pennsylvania Dental Association

Language change suggested for State Board of Dentistry regulations Draft #9:
Drafted 3.16.01

§33.335. Requirements for unrestricted permit
(d) To determine whether the applicant is equipped to administer general anesthesia, deep sedation and conscious sedation in a dental office as prescribed in §33.340(a)(2) (relating to duties of dentists who are permit holders), an office inspection will be conducted by the Board through its authorized agents in accordance with the *American Association of Oral andMaxillofacial Surgeons' Office Anesthesia Evaluation Manual* and the *American Dental Association's Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia for Dentists.* "Authorized agents" under this section shall be unrestricted permit holders with at least 5 years experience in the administration of dental general anesthesia.

§33.336. Requirements for restricted permit I.
(d) To determine whether the applicant is equipped to administer general anesthesia, deep sedation and conscious sedation in a dental office as prescribed in §33.340(a)(2) (relating to duties of dentists who are permit holders), an office inspection will be conducted by the Board through its authorized agents in accordance with the *American Association of Oral andMaxillofacial Surgeons' Office Anesthesia Evaluation Manual* and the *American Dental Association's Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia for Dentists.* "Authorized agents" under this section shall be restricted permit I holders with at least 5 years experience in the administration of dental conscious sedation.

§33.342. Inspection of dental offices.
(a) *Routine inspections.* No more than once a year during regular business hours, the Board, through its authorized agents as defined in §§ 33.335(d) and 33.336(d), may conduct a routine inspection of a dental office with or without prior notice, for the purpose of determining whether the office is in compliance with the equipment and facility requirements prescribed in §§ 33.340(a)(2), 33.340a(a)(2) or 33.340b(a)(2).

(b) *Special inspections.* In addition to the routine inspections authorized by subsection (a), the Board, through its authorized agents as defined in §§ 33.335(d) and 33.336(d), may conduct a special inspection of a dental office:

Original: 2233

Pennsylvania Society of Oral and Maxillofacial Surgeons

John J. Ciabattoni, DDS – President
1075 Berkshire Boulevard
Suite 800
Wyomissing, PA 19610-2034
Phone: 610-374-4093
Fax: 610-374-6454

Established 1964

May 26, 2000

Deborah B. Eskin, Counsel
State Board of Dentistry
Department of State
124 Pine Street
P.O. Box 2649
Harrisburg, PA 17105

Re: Pre-Draft Input: Regulations of the State Board of Dentistry 16A-4610: Anesthesia

Dear Ms. Eskin:

I am writing on behalf of the Pennsylvania Society of Oral and Maxillofacial Surgeons (PSOMS), a non-profit organization with more than 350 members. PSOMS is also a component society of the American Association of Oral and Maxillofacial Surgeons (AAOMS), which presently has over 6,000 members.

Your letter dated May 12th requesting pre-draft input on the proposed State Board of Dentistry (Board) regulations pertaining to the administration of anesthesia was forwarded to me by Dr. Anthony Lewandowski on Friday, May 19th (it is not clear in what capacity Dr. Lewandowski received this letter). PSOMS has significant concerns with not only the substance of these draft regulations, but also the manner in which public input was sought on this important matter.

I do not understand why PSOMS did not receive the letter directly – the oral and maxillofacial surgeons and patients that we are privileged to treat are the two groups most likely to be affected by any changes in the regulations. General anesthesia, administered by and in the office of oral and maxillofacial surgeons, has been an integral part of the practice of our specialty for over fifty years. Tens of millions of patients in the Commonwealth have benefited from these services, and we take great pride in the record of safety that has been established.

Likewise, a request for responses to this important proposal within such a limited timeframe is inappropriate given the complex and technical issues under consideration. Our response today is, therefore, limited due to this timeframe and we reserve the right to comment further as the Board reviews this issue. We request that future requests be handled in a different manner. Until further notice, please send such requests to our public affairs consultants as follows: PSOMS, c/o Capital Associates, Inc., P.O. Box 1085, Harrisburg, PA 17108-1085.

A principal concern of PSOMS with these draft regulations is the new proposal in section 33.340(a)(8) requiring two licensed practitioners when anesthesia or conscious sedation is

administered as part of a dental procedure. Oral and maxillofacial surgeons have a long history of providing safe and cost effective anesthesia services to the citizens of the Commonwealth as single practitioners and as part of an anesthesia team – dental anesthesia has been practiced in the operator/anesthetist model for over 150 years.

In fact, in 1845, Drs. Horace Wells and William Morton demonstrated the use of nitrous oxide to medical students at Massachusetts General Hospital on a patient having a tooth removed. In 1864, after successful administrations, the American Dental Association and the American Medical Association declared Dr. Morton the discoverer of practical anesthesia. This discovery was monumental and led the profession of dentistry into being the leaders in ambulatory anesthesia.

The safety record for this form of outpatient anesthesia is exemplary. According to a recent AAOMS national study of insurance claims of oral and maxillofacial surgeons, 12.3 million anesthetics were administered between 1988 and 1998 with extraordinarily low mortality and morbidity rates resulting from our practitioners adhering to the exceptional standards of care developed by the profession.

AAOMS and PSOMS have been leaders in the development and safe use of anesthesia for decades. As you are aware, the AAOMS Committee on Anesthesia published its first edition of the *Office Anesthesia Evaluation Manual* in 1975. This publication has been updated approximately every five years with the seventh edition to be published by January 2001. PSOMS has advocated the use of this manual to its membership since the early 1970s. This manual is a nationally recognized resource for dental outpatient anesthesia and the Board justifiably references it and the American Dental Association Guidelines for Anesthesia as the standard for care in these regulations. The publications describe and enumerate the necessary education, facilities, equipment and personnel required for the safe and effective delivery of anesthesia. They do not, however, require two licensed practitioners to be present when anesthesia is administered.

PSOMS has strong reservations about any changes to the current regulations. If changes are to be made, PSOMS requests that our organization be involved with their development. I look forward to hearing from you to discuss these issues. If you have any questions in the meantime, please feel free to contact me or our public affairs consultants, Jay Layman and Beth Zampogna at Capital Associates, Inc. (717-234-5350).

Sincerely,

John Ciabattoni, D.D.S.
President
Pennsylvania Society of Oral and Maxillofacial Surgeons

cc: Carol O'Brien, American Association of Oral and Maxillofacial Surgeons
PSOMS Executive Committee
Marisa Fenice, Pennsylvania Dental Association

Original: 2233

James A. Coll D.M.D., M.S.
1600 East Market Street
York, Pennsylvania 17403
(717) 846-2900

January 27, 2002

FAX TO: IRRC Attention Amy Lou Harris
Dental Board Anesthesia proposed regulations

FROM: James A. Coll

This fax contains 6 pages including the cover page.

James A. Coll D.M.D., M.S.
1600 East Market Street
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January 27, 2002

Independent Regulatory Review Commission
Re: State Board of Dentistry Anesthesia Regulations

Dear Sirs:

I wish to submit comments on the proposed rulemaking by the State Board of Dentistry concerning the administration of general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia.

My background is I am a practicing pediatric dentist and have been since 1994 in York, Pennsylvania. I am a Clinical Professor in Pediatric Dentistry at the University of Maryland Dental School where I have been teaching part-time since 1976. I supervise the teaching and administration of conscious sedation to children by pediatric dental residents. I was also on the Pennsylvania State Dental Board from 1993 till I resigned in 1998 over the Dental Board's decision in the Dr. Mazula case concerning the death of Jonathan Walski.

My first comment concerns section 33.338, "Expiration and renewal of permits." As the Board outlined in their background and purpose sections, they eliminated the "grandfathering" requirements for dentists to obtain an unrestricted, restricted I, and restricted II anesthesia permit. I agree with their elimination of the "grandfathering," but this creates a potential problem in 33.338 if a dentist wishes to renew their permit but shift to a lower category. For example, a dentist may have an unrestricted permit and retires. He or she no longer performs general anesthesia or conscious sedation, but has a volunteer license and uses nitrous oxide/oxygen analgesia regularly. At renewal this dentist wishes to renew his anesthesia permit but ask for a restricted permit II because he can't attest to section 33.338 (b) (4) that he conducted general anesthesia during the preceding biennial period. This dentist may have been "grandfathered" for an unrestricted permit or no longer has the documentation he presented for an unrestricted permit. To obtain a restricted permit II, he would have to satisfy the 20 hours of courses outlined in 33.337 (a) (1). I do not think the Board considered how to allow permit holders to move to a lower permit classification.

I would propose the following in 33.338 (1): A dentist who has an unrestricted permit can renew their permit as a restricted permit I if they satisfy the requirements in 33.338 (b) relating to conscious sedation. A dentist who has an unrestricted permit or a restricted permit I can renew their permit as a restricted permit II if they satisfy the requirements in 33.338 (b) relating to nitrous oxide/oxygen.

My second comment is that the proposed rulemaking eliminated section 33.339 "Fees for issuance of permits". I don't see the five asterisks after 33.338 and before 33.340 to indicate 33.339 remains. I would assume this was an oversight.

My third comment applies equally to sections 33.340 (xvii) (xviii), 33.340a (xvii) (xviii), and 33,340b (xi) (xii) pertaining to the duties of the permit holder. All these sections were added or updated to address the "appropriate monitoring equipment" problems noted in *Watkins v. State Board of Dentistry*. These new sections I sighted pertain to "results of patient history and physical evaluation" plus the "signed patient consent." In these proposed regulations, section 33.340 (2), 33.340a (2), and 33.340b (2) requires the dental office in which the permit holder administers the anesthesia to contain equipment, systems, or areas but also the patient consent, history and physical evaluation. I feel the Board made an error since the patient consent and results of the history and physical evaluation must be part of the patient's record as stated in section 33.209 (7). The following example highlights the problem. A non-permit holder treats his patient under general anesthesia at a permit holder's office. The permit holder' dental office would be required to retain the signed consent and physical evaluation and history and not the non-permit holder's patient record. This seems to be a Catch 22 problem.

I would propose changing sections 33.340 (a) (1), 33.340a (a) (1), and 33.340 b (a) (1) to correct this problem. Add the following sentence after the end of the paragraph in the above sections: " The original or duplicated signed patient consent must be obtained and made part of the patient's record together with the results of the patient's history and physical evaluation for any permit holder or non-permit holder." Remove these same sections from the dental office requirements.

My fourth comment concerns section 33.340a (3) (iv). I feel the Board made an error in requiring dental assistants who assist the dentist when the dentist is administering conscious sedation to be currently certified in ACLS. In my opinion, the dentist and any nurse anesthetist should be currently certified in ACLS or Pediatric Advanced Life Support (PALS) for children 10 and younger. A dental assistant may hand the dentist a vial of local anesthesia or go to the locked drug box to get the oral sedation that the dentist dispenses. The assistant may place the pulse oximeter finger clip to get preoperative vital signs. I do not feel this assistant needs ACLS certification for the patient's safety to accomplish these duties and I feel it is over regulation. The current American Academy of Pediatric Dentistry's guidelines for deep sedation I think could be used as an outline for Pennsylvania's regulations concerning auxiliary personnel who assist the permit holder to administer conscious sedation. The AAPD guidelines state, "The techniques of deep sedation (level 4) require the following three individuals: (1) the treating practitioner who may direct the sedation: (2) a qualified individual to assist with observation and monitoring of the patient who may administer the drugs if appropriately licensed; (3) other personnel to assist the operator as necessary. Of the three individuals, one shall be currently certified in Advanced Cardiac Life Support or Pediatric Advanced Life Support and the other two shall be currently certified in basic life support." In essence the restricted permit I holder would need current certification in ACLS and or

PALS for children 10 and younger, but the treating dentist and his assistant need CPR certification.

I would recommend changing section 33.340a (3) (iv) to state the following: "Are currently certified in cardiopulmonary resuscitation (CPR)."

My fifth comment is in this same area where the regulations only allow ACLS certification in section 33.336 (b) and 33.338 (b) (3) for restricted permit I holders to exhibit they are competent to handle emergencies when administering conscious sedation to children age 10 and younger. At the University of Maryland where I teach conscious sedation, I feel PALS is more appropriate certification for dentists who perform conscious sedation on children. As I stated in my fourth comment, the AAPD recommends ACLS or PALS for deep sedation while here we are discussing conscious sedation in these regulations. I would recommend the Board to allow those restricted permit I holders doing conscious sedation on children age 10 and younger to have ACLS and or PALS certification. I propose they change the areas in 33.336(b) and 33.338 (b) (3) to allow for this.

My sixth comment concerns section 33.340a (a) (8) where I feel the Board made an error about the monitoring equipment having to "contain a fail-safe system." If you look at the same area under unrestricted permit, 33.340 (a) (8), that phrase is no present. Monitoring equipment does not possess fail-safe systems. The gas delivery system has a fail-safe control as is noted in 33.340a (a) (2) (v). I would propose eliminating "contain a fail-safe system from 33.340a (a) (8).

My seventh comment concerns section 33.344 which the Board did not address in this proposed rulemaking. This section was added in 1989, approximately 1 ½ years after the original regulations on the anesthesia permits became effective. The board gave dentists guidance as to when a restricted permit I was needed when nonparental medications were dispensed. Many dentists give a preoperative tranquilizer to ally a patient's apprehension. I feel this section needs updated by the present Board in the area of what constitutes conscious sedation in children so that dentists can tell when a restricted permit I is needed after referring to section 33.344 (d) (1). The AAPD revised its guidelines for conscious sedation, deep sedation, and general anesthesia in children in 1998. I feel the Board should revise 33.344 to give dentists better guidance about when a restricted permit I is needed when a dentist prescribes an oral (nonparenteral) sedative or a tranquilizer to a child to relieve anxiety. In my opinion, the Board can utilize the newest AAPD guidelines concerning conscious sedation for section 33.344 (d) (1). I have enclosed a copy of Appendix I of the AAPD guidelines about this area for you to review. If no further guidance is given to dentists in 33.344, I feel dentists who do not have a restricted permit I will withhold prescribing mild tranquilizers in anxious children. This will not be to the child's benefit.

I would recommend for children, the Board add better guidance in 33.344 (d) (1) by referring to the AAPD guidelines. I feel after the last sentence in the above section the following could be added: "In children, nonparenteral medications that produce a level

of sedation defined by the AAPD guidelines on the use of conscious sedation, deep sedation, and general anesthesia whereby the medication decreases or eliminates anxiety but promotes interaction and the patient responds appropriately at all times while maintaining their own airway without assistance docs not require a restricted I permit if all AAPD recommended monitoring is followed." I feel this would allow all dentists who treat anxious children and prescribe mild tranquilizers to do so no matter what permit they had or did not have. It would most importantly insure the patient's safety.

I apologize for not sending my comments any earlier. I was away on vacation and just discovered that IRRC had solicited public comment. I hope you will consider my suggestions.

Sincerely,

James A. Coll D.M.D., M. S.

Appendix I

Template of Definitions And Characteristics For Levels Of Sedation And General Anesthesia.

	Conscious Sedation			Deep Sedation	General Anesthesia
Functional Level of Sedation	Mild Sedation (Anxiolysis)	Interactive	Non-Interactive/Arousable With Mild/Moderate Stimulus	Non-Interactive/Non-Arousable Except With Intense Stimulus	General Anesthesia
Goal	(Level 1) Decrease anxiety; facilitate coping skills	(Level 2) Decrease or eliminate anxiety; facilitate coping skills	(Level 3) Decrease or eliminate anxiety; facilitate coping skills; promote non-interaction sleep	(Level 4) Eliminate anxiety; coping skills over-ridden	(Level 5) Eliminate cognitive, sensory and skeletal motor activity; some autonomic activity depressed
Responsiveness	Uninterrupted interactive ability; totally awake	Minimally depressed level of consciousness; eyes open or temporarily closed; responds appropriately to verbal commands	Moderately depressed level of consciousness; mimics physiologic sleep (vitals not different from that of sleep); eyes closed most of time; may or may not respond to verbal prompts alone; responds to mild /moderate stimuli (e.g., repeated trapezius pinching or needle insertion in oral tissues elicits reflex withdrawal and appropriate verbalization [complaint, moan, crying]), airway only occasionally may require re-adjustment via chin thrust.	Deeply depressed level of consciousness; sleep-like state, but vitals may be slightly depressed compared to physiologic sleep; eyes closed; does not respond to verbal prompts alone; reflex withdrawal with no verbalization when intense stimuli occurse (e.g., repeated, prolonged and intense pinching of the trapezius); airway expected to require constant monitoring; and frequent management	Unconscious and unresponsive to surgical stimuli. Partial or complete loss of protective reflexes including the airway; does not respond purposefully to physical and verbal command.
Personnel Monitoring Equipment	2 Clinical observation*	2 PO; precordial recommended†	2 PO, precordial, BP; capno desirable†	3 PO & Capno, ECG; precordial, BP, defibrillator desirable	3 PO, Capno, precordial, BP, ECG, temperature & defibrillator required
Monitoring Info	None	HR, RR, O_2; Pre-; During (q 15 min); Post, as needed	HR, RR, O_2, BP; [CO_2] if available Pre-; During (q 10 min); Post till stable/Discharge Criteria	HR, RR, O_2 & C [CO_2], BP, ECG Pre-; During (q 5 min); Post till stable/Discharge Criteria	HR, RR, O_2, CO_2, BP, EKG, Temperature Pre-; During (q 5 min minimum); post till stable/Discharge Criteria

Monitors: PO (Pulse Oximetry); Capno (Capnography); BP (Blood Pressure Cuff); ECG (Electrocardiogram)

* It should be noted that clinical observation should accompany any level of sedation and general anesthesia.

† "Recommended" and "Desirable" should be interpreted as not a necessity, but as an adjunct in assessing patient status.

Original: 2233

Consider w/ ones reg. comments

Eskin, Deborah

From: WTSpruill@aol.com

Sent: Sunday, January 13, 2002 6:17 PM

To: liburns@state.pa.us;

Subject: Clarification please

Dear Ms. Eskin:
Draft 10B dated March 26, 2001 that you sent to me upon request back in October as an attached file simply lists 33.340b.(a)(2)(iv)Suction equipment. That's it.

The PaBulletin copy of the proposed rulemaking page 6698 lists 33.340b.(a)(2)(iv)Suction equipment with appropriate oropharyngeal suction.
and lists (xi)Results of patient history and physical evaluation,
the same as Restricted Permit I. Is this an error in the PaBulletin?

And in the preamble to the proposed rulemaking (PaBulletin page 6693, column 2, 5th paragraph) it states "...restricted permit II holders are not required to have...results of patient history."
Yet, as I said, it is listed in 33.340b(a)(2)(xi) and again in 33.342(d)(2) "...records and documents related..." This last reference is the office inspection section so it may be that this pertains to Gen ans, Deep sed, Cons sed, and not N2O2.
Thanks for helping,
Dr. Spruill