412 Marney Drive
Coraopolis, PA 15108
January 7, 2001

Ms. Deborah Eskin, Counsel
State Board of Dentistry
Bureau of Professional and Occupational Affairs
Pennsylvania Department of State
P.O. Box 2649
Harrisburg, PA 17105-2649

Dear Ms. Eskin:

Thank you for allowing the Pennsylvania Dental Association (PDA) the opportunity to comment on the State Board of Dentistry's (SBOD) proposed anesthesia regulations, published in the December 8, 2001 edition of the *Pennsylvania Bulletin.* I commend the hard work made by the Sub-Committee on Anesthesia to address the issue of safe administration of anesthesia in the dental office.

My name is Dr. Walter Laverick and I am currently the vice president of the Pennsylvania Dental Society of Anesthesiology, Assistant Professor, School of Dental Medicine at the University of Pittsburgh, and a private practice office based anesthesiologist of 18 years. I have served as an officer of several dental anesthesia organizations, have attended many state board meetings of which anesthesia is of concern, and have presented to the Pennsylvania's House of Representatives Professional Licensure Committee with respect to HB 1394.

I have reviewed the proposed regulations and would like to make comments with respect to the following areas:

1. Office inspections
2. Office inspections of non-permit holders
3. Requirements of unrestricted permit holders
4. Non-dentist providers
5. Continuing dental/medical education

1. Office inspections. I express great concern as to what person(s) would be inspecting dental offices. I recommend that it be necessary to define an "authorized agent". In the draft regulations, Sections 33.335 (d)(2) and 33.336 (d)(2), there is no definition of "authorized agent." I believe that it be imperative that these individuals be current DMD/DDS permit holders.

2. Office inspections of non-permit holders. Section 33.341 (a)(2) pertaining to the duties of dentists who are not permit holders. It is not in the best interest of the public for the state to conduct office inspections of non-permit holders that employ the services of itinerant anesthesiologists with a varying frequency. The state should inspect the equipment and

ability of the itinerant provider, rather than inspect the office that does not possess the anesthesia-related equipment.

Requiring office inspections for non-permit holders who don't routinely offer anesthesia services will deter their ability to provide this service to their patients. This will immediately impede access to care, particularly to special needs and dental phobic patients. The authors of these regulations need to be reminded that hospital or surgical center access to general dentists is almost non-existent. The waiting list for "special needs" patients requiring anesthesia services at the University of Pittsburgh School of Dental Medicine is over one year. I am aware of House Bill 286, in that it would allow permit holders travel to office locations other than their own to administer anesthesia. The permit holder would ensure that the office location has the equipment required by board regulation, and properly trained staff (when anesthesia is being performed).

3. Requirements of unrestricted permit holders. Educational requirements should be in concert with the American Dental Association. Section 33.335- Requirements for unrestricted permit should read; *Successfully completed a post-graduate program for advanced training in anesthesiology and related academic subjects that conforms to Part II of the American Dental Association's Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry or subsequent edition.* This requires at least two years postgraduate training.

4. Non-dentist providers. Regulations as they are now proposed would allow any licensed physician to provide anesthesia in a dental office setting, even if that physician has no anesthesia training what so ever. I caution the board to consider directives that would require physicians or nurses to obtain an anesthesia permit also.

5. Continuing Medical/Dental education. I encourage the board to consider that permit (restricted and unrestricted) holders be required to produce documentation of appropriate continuing education.

Thank you for giving me the opportunity to make comments for these critical proposals. Please don't hesitate to contact me if I can make any additional contributions. I may best be reached via electronic mail wlaverick1@aol.com or by telephone 412/445-0110.

Respectfully,

Walter Laverick, D.M.D.
Vice President, Pennsylvania Dental Society of Anesthesiology
Assistant Professor, Anesthesiology
School of Dental Medicine
University of Pittsburgh

cc: Robert E. Nice, Executive Director, Independent Regulatory Review Commission
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The Honorable Mario J. Civera
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The Honorable Lisa Boscola
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Maxillofacial Prosthodontics
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Oral & Maxillofacial Surgery
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Periodontics
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Fax: 412-648-8594

Ms. Deborah B. Eskin
Council, State Board of Dentistry
P.O. Box 2649
Harrisburg, PA 17105-2649

RE: No. 16A-4601 (Dental Anesthesia Regulations)

Dear Ms. Eskin,

As a dental educator in the field of anesthesiology for the past 35 years, I am writing to express my concern relative to proposed changes to regulations governing the administration of anesthesia for dentistry.

Specifically, I take exception to the requirement that dentists engaged in the administration of general anesthesia and/or conscious-sedation be certified in Advanced Cardiac Life Support.

This opinion is based on the following points:

- Basic Life Support (CPR) certification may be obtained by anyone (e.g. Boy Scout)
- Anyone possessing a BLS certificate qualifies to become a BLS teacher (e.g. Boy Scout)
- Anyone possessing a certificate in BLS may become certified in ACLS (e.g. Boy Scout)
- Anyone certified in ACLS may become certified as an ACLS teacher (e.g. Boy Scout)

The problem I am having trouble resolving is "Why would someone with my level of education - D.D.S., Ph. D. in anesthesia/pharmacology – clinical training and experience and is also Board Certified in Dental Anesthesiology be required to be "certified " in what is an integral part of my specialty by a Boy Scout?

Are you aware of the fact that one might qualify to teach ACLS and yet never have even witnessed a cardiac arrest let alone participated in a resuscitation attempt?

In fact, the ACLS teacher that could issue certification to me might not be legally eligible to perform it since ACLS involves the administration of drugs that the individual (e.g. Boy Scout) is not licensed to do!

Further evidence of the absurdity of this provision of the regulation is that dental auxiliaries that assist in the administration of general anesthesia and/or conscious-sedation are also required to be certified in ACLS.

The level of knowledge possessed in resuscitation procedures by a Board Certified Dentist/Anesthesiologist far surpasses that presented in a weekend course in ACLS. Additionally, Board Certified individuals will have had hands on training and experience in dealing with this life or death situation.

Conversely, it is impossible for one with a limited scientific background (e.g. dental assistant) to comprehend the intricacies of a procedure that involves reading electrocardiograms, understanding acid/base balance and the like.

However, it is my opinion that all persons that have patient contact should be certified in Basic CPR, a procedure that is purely mechanical yet can be life saving in a dental or non-office setting.

A cardiac arrest is a catastrophe of monumental proportions. One is not going to be the least bit competent in managing this emergency by being certified in ACLS. Requiring any dentist or dental assistant to jump through this hoop is nothing but a waste of time and money.

Rather, emphasis must be placed on preventing the problem by encouraging diligent, constant patient monitoring through the use of appropriate equipment by licensed practitioners that – in the case of general anesthesia – are not also involved in the provision of dental care.

A second and even greater problem I have with the proposed regulation is that it is self-contradictory! The document frequently refers to mandatory compliance with the AAOMS Office Anesthesia Evaluation Manuel.

Are you aware of the fact that this manual identifies the "anesthesia team" as the oral surgeon, the "anesthesia assistant" and a dental assistant? No qualifications what so ever are spelled out for the "anesthesia assistant". The only member of the "anesthesia team" that is

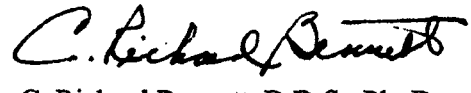
licensed to administer general anesthesia is the oral surgeon that is simultaneously performing the dental treatment – a function that is specifically prohibited under 33.340 Duties of dentists who are unrestricted permit holders, paragraph four – "while the dental procedures are performed by a dental licensee not involved in the anesthesia administration".

I realize that not all dentists administering general anesthesia are Board Certified in the field. Should the State Board of Dentistry insist on the ACLS requirement a simple solution to the problem I have might be to simply state that the practitioner must posses certification in ACLS or its equivalent (e.g. Board Certification in Dental Anesthesiology).

As the Chairman of the oldest Anesthesia Department in a Dental School and the Director of the largest Dental Anesthesia Residency in the USA I know whereof I speak.

Many thanks for your consideration.

Sincerely yours,



C. Richard Bennett, D.D.S., Ph. D.
Professor and Chairman
Department of Anesthesiology

Original: 2233

Ambulatory Anesthesia
Associates

January 4, 2002

Deborah B. Eskin , Counsel
State Board of Dentistry
Bureau of Professional and Occupational Affairs
Pennsylvania Department of State
P.O. Box 2649
Harrisburg, PA 17105-2649

Dear Ms. Eskin,

Thank you for the opportunity to submit comments, suggestions and objections regarding the proposed anesthesia regulations published in the December 8, 2001 edition of the *Pennsylvania Bulletin*, reference No. 16A-4610 (Administration of General Anesthesia, Deep Sedation, Conscious Sedation and Nitrous Oxide/Oxygen Analgesia).

Before offering specific comments, I would like to make the following general recommendation. As a fulltime dentist anesthesiologist and partner in the largest private practice dedicated to providing mobile office-based anesthesia services in half a dozen counties in southwestern Pennsylvania, as a nationally recognized expert on the topic of office-based anesthesia for dentistry invited to speak at national meetings and serve on national committees sponsored by the largest professional societies of physician anesthesiologists, and having been asked by the Pennsylvania Dental Association's Council on Governmental Regulations to testify on this topic at hearings before the Pennsylvania House of Representatives Professional Licensure and Insurance Committees, I have followed the process of developing these new anesthesia regulations with great interest. As you know, to that end I have made myself available to the State Board of Dentistry by attending nearly every public meeting of the Board at which these new regulations were on the agenda and have submitted formal comments to the Board on several occasions regarding the earlier drafts of the proposed regulations.

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Richard Finder, DMD, MS Pat Franceschelli, DMD Walter Laverick, DMD Robert Nassif, DMD, MS
Diplomates, American Dental Board of Anesthesiology

In striving to achieve a consensus, I had hoped that the Board would have solicited more input from anesthesiologists with experience in the office-based setting, currently the fasting growing venue for the practice of anesthesia in medicine nationwide. However, a reading of the proposed regulations indicates that our mode of practice is barely acknowledged, in spite of its longstanding history in dentistry and its more recent endorsement in medicine by the American Society of Anesthesiologists. For example, the proposed regulations do not provide a practical framework regarding how anesthesiologists (dentist or physician) will be able to continue to offer our routine services for the public in dental offices that are not already equipped to provide these services. For instance, if a general dentist needed the occasional assistance of an anesthesiologist to conservatively treat a young child suffering with acute infection from neglected teeth who is unmanageable due to age, or to treat an individual with moderate-severe mental retardation who is also unmanageable without additional anesthesia services, or to treat an otherwise healthy adult requiring acute dental care who suffers from a severe gag reflex, etc., how would they comply with the proposed regulations? Could an inspection of their office be scheduled on short notice or would such patients need to be placed on antibiotics for several months? Or should these patients be admitted to a hospital for treatment in the operating room where costs will run in the thousands of dollars, assuming the dentist can even be granted temporary staff privileges and there is a hospital nearby that can accommodate the instrumentation required to provide general dentistry? Or would the only practical alternative be to refer these patients to an oral surgeon for needless extraction of the infected teeth under anesthesia? Does the Board purposely intend to restrict our mode of practice, and in turn hinder access to routine care for a wide range of dental patients with special needs, especially those in rural areas?

Our private practice has safely been providing anesthesia in over 100 dental offices for the past 20 years, without a single incidence of significant morbidity. Once the anesthesia providers in our practice have each been inspected and evaluated, in one or more of the offices where we bring in all of the monitoring and drug administration equipment (our company protocol already exceeds the proposed regulation's equipment list, by routinely including expired carbon dioxide monitoring and programmable drug infusion pumps), what is the benefit in terms of public safety in requiring that each additional office that we serve be inspected individually? We bring the same state of the art equipment and expertise to every office that we work in. We will bring this same equipment and expertise to a new office as described in the preceding paragraph. I again urge the board to recognize this scenario in the new regulations, and acknowledge those anesthesiologists (dentist or physician) who travel to office locations other than their own. Once an anesthesiologist has satisfactorily undergone inspection and evaluation, the inspection requirement should be waived for the non-permit holder's offices provided that the anesthesiologist ensures that each office has the required equipment when anesthesia is actually administered, and that the operating dentist and his staff are adequately trained to assist the anesthesiologist in the management of anesthesia-related emergencies. In our mode of practice, inspection and evaluation should be directed to us as the permit holders and not the many offices of non-permit holders where our

anesthesia services are provided. There is no epidemiological data to support the assumption that inspecting offices of non-permit holders will improve public safety. In contrast, the data demonstrates that anesthesiologists have an exemplary record of safety in providing anesthesia in non-permit holder's offices.

The proposed regulations do not adequately acknowledge a mode of practice that is growing rapidly nationwide. As the Board updates the anesthesia regulations why not bring them up to the present-day? The old anesthesia regulations referenced an outdated American Dental Association guideline that was updated over eight years ago, and they also contained a significant typographic error. These issues have not been addressed and so these errors have been carried over in the proposed regulations. I will include them in the following specific comments and make reference to corresponding portions of the Pennsylvania Code, Title 49 Professional and Vocational Standards, Chapter 33 State Board of Dentistry, Subchapter E Administration of General Anesthesia, Conscious Sedation and Nitrous Oxide/Oxygen Analgesia.

33.335. Requirements for unrestricted permit

(a) (1) To conform to the CURRENT Part II of the ADA "Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry", please change from successful completion of at least one year, to successful completion of at least two years...In 1993, the prescribed length was extended by the ADA to two years. Refer to "Length of Program" on p. 16 of the "Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry".

(2) There has NEVER been an "American Society of Dental Anesthesiology", please correct to "Fellow of the American Dental Society of Anesthesiology". Also, please add "Be certified as a Diplomat of the American Dental Board of Anesthesiology" in recognition of those dentist anesthesiologists who have completed an anesthesia residency program that CURRENTLY conforms with Part II of the ADA "Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry", and have subsequently passed the written and oral exams conducted by the American Dental Board of Anesthesiology.

(d) (1) Please see comments above regarding requiring inspection of non-permit holder's offices when anesthesiologists (dentist or physician) travel to office locations other than their own.

33.340 Duties of dentists who are unrestricted permit holders

(a) (2) (xii) Please add the ADA "Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia for Dentists" as a Standard. Refer under

"Monitoring and Documentation" for "Deep Sedation/General Anesthesia" on p. 10 of ADA "Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia for Dentists; additionally, both the CURRENT American Society of Anesthesiologists monitoring guidelines and the most recent NIH funded study of safety of anesthesia in dentistry include monitoring of expired carbon dioxide when deep sedation or general anesthesia are administered, why is this not included?

(8) What is the clinical significance of requiring separate license holder when general anesthesia is provided with intubation? Intubation secures and protects the airway. Yet when general anesthesia is provided with an unintubated airway, where the airway is unsecured and less protected there is no requirement for a separate license holder? This is illogical and not supported by epidemiological research? Why has this been added?

(9) What is the meaning of "Monitoring equipment is 'installed'..."? The state of the art monitoring equipment that we utilize is built to be transported, for use by mobile office-based anesthesiologists, by emergency medical technicians in helicopters, for patient transport from operating rooms to intensive care units, etc. These monitors can cost over $10,000 and cannot practically be installed at every office location where we provide services. Again, there is no epidemiological data to support an assumption that installation of a device improves patient safety. Safety is more closely related to the training of the individual who is monitoring the patient.

33.341 Duties of dentists who are not permit holders

(a) (2) Please see comments above regarding requiring inspection of non-permit holder's offices when anesthesiologists (dentist or physician) travel to office locations other than their own.

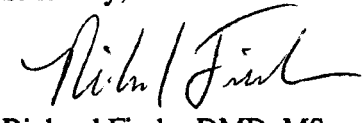
(5) Please see comments above regarding requiring "installed" monitoring equipment.

The next recommendation relates to an area not addressed by the proposed regulations - the issue of unregulated physicians providing anesthesia services in non-permit holder dental offices. We already have physician groups advertising in the "Pennsylvania Dental Journal" and in the "The Bulletin" of the Dental Society of Western Pennsylvania. Here in Pennsylvania, any physician by virtue of their medical degree is deemed "qualified" to administer deep sedation/general anesthesia. I encourage the Board to consider additions to the proposed regulations which would protect the public as well as the dental profession, by requiring physicians who wish to administer anesthesia in dental offices, to document anesthesia training and obtain an unrestricted permit from the Board. In California, office anesthesia provided by physicians is more common. Since 1999, California physicians have been required to obtain a permit from the Dental Board to administer general anesthesia in a dentist's office.

My final comment relates to Continuing Education. Why don't the proposed regulations include a requirement for anesthesia CE as a prerequisite to renew a permit? Thanks to continuous innovations in pharmacology, monitoring, etc., the safety of office-based anesthesia continues to improve. The public will surely benefit from such a reasonable addition to the regulations.

I hope my comments will prove helpful. I am happy to be of further assistance if I have been unclear with respect to any of the issues presented. Good luck in your deliberations and I look forward to a positive update of our regulations

Sincerely,



Richard Finder DMD, MS

cc: Robert E. Nice, Executive Director, Independent Regulatory Review Commission
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The Honorable Clarence D. Bell
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January 4, 2002

RECEIVED
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DOS LEGAL COUNSEL

Deborah B. Eskin , Counsel
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Dear Ms. Eskin,

Thank you for the opportunity to submit comments regarding the proposed rule making reference No. 16A-4610 (Administration of General Anesthesia, Deep Sedation, Conscious Sedation and Nitrous Oxide/Oxygen Analgesia). I had an opportunity to review the proposed changes in the Pa. Regulations for anesthesia use in dentistry. This document and the changes have been around for some time and appear to address some problems that existed in the previous law. It appears to have been motivated by the disaster in Wilksboro and subsequent law suits. Let me comment and address a few of the changes that I would recommend.

1. The reporting requirement is essential if we are ever to determine the risks and appropriate actions to assure public safety. The term used in the document relating to "medical care" should be more specific, otherwise a great deal of the morbidity associated with anesthesia use will never be reported. Currently our most reliable data regarding adverse events/deaths comes from the British and Canadian literature. It may not apply to anesthesia care in Pa. or the US.

I addressed this issue to Rep. Civera in a letter dated 11/1999. Unfortunately, I never received a response to my letter.

2. Defining appropriate monitoring equipment and monitoring requirements is also important and needed. Clearly, the rare serious adverse events in anesthesia are invariably due to **respiratory failure**. The NIH study results that we published in the JADA last Spring establishes the respiratory impairment associated with deep sedation (see: Dionne RA, Yagiela JA, Moore PA, Gonty A, Zuniga J, Beirne OR, and The

Coolaborative Sedation Study Group: Comparing efficacy and safety of four intravenously sedative regimens in dental outpatients. J Am Dent Assoc 2001;132:740-751.)

Within the monitoring section of the newly proposed regulations, oximetry is recommended. This electronic monitor is rather slow in recognizing respiratory problems. Capnography is a better monitor. A trained anesthesia provider who was dedicated to continuous auditory respiratory monitoring would be a more rational approach. Obviously this opens up the issue of the safety of having only one person functioning as both dental surgeon and the anesthesiologist.

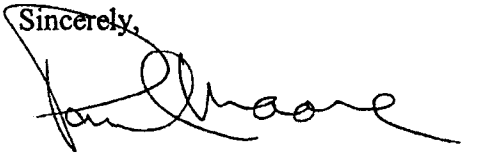
3. The office inspection requirements (including an unspecified clinical evaluation) have the potential of being burdensome for us anesthesiolgist types who do not function exclusively at one site. Provisions for inspecting the anesthesiologist are more appropriate. Limiting the regulations to offices does not consider the needs of practitioners who are infrequent users of our services.

If the intent of the regulations is to limit anesthesia services to oral surgeon's offices and hospitals, I believe the availability of anesthesia services for the broad spectrum of dental care currently using our services, would be significant reduced. When you see that the regulations rely on AAOMS, ADA and AAPD protocols with little mention of ASDA and ADSA, you must wonder if any anesthesiologists were represented on the committee?

4. The wording for the requirement of informed consent <u>for the anesthesia</u> has been addressed in the new regulations although I think this could be strengthened. Didn't the surgeon in Wilkboro case claim that informed anesthesia consent was not needed?

Thanks for giving me the oportunity to respond to the proposed regulations.

Sincerely,



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Ambulatory Anesthesia Associates

January 4, 2002

Deborah B. Eskin , Counsel
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Pennsylvania Department of State
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33.340 Duties of dentists who are unrestricted permit holders

(a) (2) (xii) Please add the ADA "Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia for Dentists" as a Standard. Refer under

"Monitoring and Documentation" for "Deep Sedation/General Anesthesia" on p. 10 of ADA "Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia for Dentists; additionally, both the CURRENT American Society of Anesthesiologists monitoring guidelines and the most recent NIH funded study of safety of anesthesia in dentistry include monitoring of expired carbon dioxide when deep sedation or general anesthesia are administered, why is this not included?

(8) What is the clinical significance of requiring separate license holder when general anesthesia is provided with intubation? Intubation secures and protects the airway. Yet when general anesthesia is provided with an unintubated airway, where the airway is unsecured and less protected there is no requirement for a separate license holder? This is illogical and not supported by epidemiological research? Why has this been added?

(9) What is the meaning of "Monitoring equipment is 'installed'..."? The state of the art monitoring equipment that we utilize is built to be transported, for use by mobile office-based anesthesiologists, by emergency medical technicians in helicopters, for patient transport from operating rooms to intensive care units, etc. These monitors can cost over $10,000 and cannot practically be installed at every office location where we provide services. Again, there is no epidemiological data to support an assumption that installation of a device improves patient safety. Safety is more closely related to the training of the individual who is monitoring the patient.

33.341 Duties of dentists who are not permit holders

(a) (2) Please see comments above regarding requiring inspection of non-permit holder's offices when anesthesiologists (dentist or physician) travel to office locations other than their own.

(5) Please see comments above regarding requiring "installed" monitoring equipment.

The next recommendation relates to an area not addressed by the proposed regulations - the issue of unregulated physicians providing anesthesia services in non-permit holder dental offices. We already have physician groups advertising in the "Pennsylvania Dental Journal" and in the "The Bulletin" of the Dental Society of Western Pennsylvania. Here in Pennsylvania, any physician by virtue of their medical degree is deemed "qualified" to administer deep sedation/general anesthesia. I encourage the Board to consider additions to the proposed regulations which would protect the public as well as the dental profession, by requiring physicians who wish to administer anesthesia in dental offices, to document anesthesia training and obtain an unrestricted permit from the Board. In California, office anesthesia provided by physicians is more common. Since 1999, California physicians have been required to obtain a permit from the Dental Board to administer general anesthesia in a dentist's office.

My final comment relates to Continuing Education. Why don't the proposed regulations include a requirement for anesthesia CE as a prerequisite to renew a permit? Thanks to continuous innovations in pharmacology, monitoring, etc., the safety of office-based anesthesia continues to improve. The public will surely benefit from such a reasonable addition to the regulations.

I hope my comments will prove helpful. I am happy to be of further assistance if I have been unclear with respect to any of the issues presented. Good luck in your deliberations and I look forward to a positive update of our regulations

Sincerely,

Richard Finder DMD, MS

cc: Robert E. Nice, Executive Director, Independent Regulatory Review Commission
The Honorable Mario J. Civera
The Honorable Clarence D. Bell
Albert H. Masland, Commissioner, Bureau of Professional & Occupational Affairs
Norbert O. Gannon, DDS, Chair, State Board of Dentistry
Thomas W. Braun, DMD
Susan E. Calderbank, DMD
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Neil F. Gardner, DDS
Beverly B. Hawkins, RDH
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Richard C. Howells, DDS
John V. Reitz, DDS
Joseph Sembrot, Esquire
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Lisa M. Burns

Original: 2233

PINNACLE ORAL & MAXILLOFACIAL SURGERY ASSOCIATES, INC.
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570-346-0794
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January 4, 2002

Norbert O. Gannon, D.D.S.
Commonwealth of Pennsylvania
Department of State
Bureau of Professional and Occupational Affairs
State Board of Dentistry
PO Box 2649
Harrisburg, PA 17105-2649

Dear Dr. Gannon:

I am writing regarding the current guidelines on anesthesia which have been sent to various practitioners about the state. I am fundamentally in agreement with all the guidelines, however I feel that the allowing of unscheduled visits for the purposes of inspection in the office without guidelines is inappropriate. It allows the State Bureaucrat to run amuck with unchecked and unlimited powers. I am certainly in favor of office inspections on a scheduled basis for those routine inspections they should be scheduled at the mutual convenience of the State Board and the individual practitioner. I can understand the need for inspections sometimes on a very sudden basis, but I believe that those basis's for such inspection should be spelled out clearly by the State Board of Dentistry who are on the risk of protensionally having major abuses of power on the part of the State Board.

I have personal experience with the State Board presenting themselves in my office unannounced on a minor complaint. This I felt was inappropriate and I had absolutely no time to respond to any claims, also I was busy treating patients and I felt that this was inappropriate and this could of been handled in my particular case through the mail and an appropriate response submitted and a appropriate documentation in a more organized manner. It is clearly evident therefore that the State Board must place requirements that would allow immediate inspection in an office and not give "carte blanche" to any individual Bureaucrat.

I look forward to any comments or questions that you might have regarding this matter.

Sincerely,

Kenneth G. Miller, D.M.D.
KGM/kp

JAN - 7 2002

Original: 2233

PENNSYLVANIA ASSOCIATION OF NURSE ANESTHETISTS

908 NORTH SECOND STREET • HARRISBURG, PA 17102
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Deborah B. Eskin
Counsel
State Board of Dentistry
P.P. Box 2649
Harrisburg, Pennsylvania 17105-2649

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

DATE: January 4, 2002

Dear Ms. Eskin,

The Pennsylvania Association of Nurse Anesthetists (PANA) appreciates this opportunity to comment on the Proposed Rulemaking of the Board of Dentistry- 49 PA Code Ch. 33. PANA, representing over 2300 Certified Registered Nurse Anesthetist's (CRNA's) in Pennsylvania, is always concerned with issues addressing patient safety while receiving anesthesia. We commend your comprehensive clarification of what appropriate monitoring equipment is necessary in a dental office where anesthesia is being administered as well as your updated and improved general requirements regarding anesthesia administration. In fact, your proposal of appropriate monitoring equipment is similar to the American Association of Nurse Anesthetists (AANA) "Office-Based Anesthesia Guidelines". We would be happy to provide you with a copy.

Our concern lies with section 33.340a "Duties of dentists who are restricted permit I holders.", part (4) "Certified registered nurse anesthetists to whom are delegated the duties of administering conscious sedation: (1) Perform their duties under the direct on-premises supervision of the permit holder, who shall assume full responsibility for the performance of the duties." In particular, we are concerned with the proposed requirement of **"direct on-premises supervision"** and the intonation that the supervising dentist is to **"assume full responsibility"** for the duties of the CRNA.

Section 21.17 of the Pennsylvania State Board of Nursing regulation clearly identifies the role of the CRNA and the relationship between the CRNA and a physician or dentist. 21.17 (3) states "The certified nurse anesthetist is authorized to administer anesthesia **in cooperation with a surgeon or dentist**. The nurse anesthetist's performance shall be under the overall direction of the chief or director of anesthesia services. In situations or health care facilities where these services are not mandatory, the nurse anesthetist's performance shall be under the **overall direction of the surgeon or dentist** responsible for the patient's care."

Physical presence is also addressed in Section 21.17. It states in subsection (4) "Except as otherwise provided in 28Pa. Code 123.7(c) (relating to dental anesthetist and nurse anesthetist qualifications), when the operating/ anesthesia team consists entirely of nonphysicians, such as a dentist and a certified registered nurse anesthetist, the registered nurse anesthetist shall have to her by physical presence **or electronic communication** an anesthesiologist or consulting physician of her choice."

When a CRNA administers anesthesia he or she is practicing nursing, as the administration of anesthesia is a proper function of a registered nurse and is fully regulated by the Pennsylvania State Board of Nursing. Under the State Board of Nursing regulations the CRNA is held responsible for his or her actions and are themselves fully liable.

In section 33.340 (4), regarding unrestricted permit holders, CRNA's who are delegated the duties of administering general anesthesia, deep sedation, or conscious sedation, or nitrous oxide/ oxygen analgesia are identified as being fully qualified to administer anesthesia with the only requirement being current ACLS certification. There is neither mention of on-premises supervision nor the assumption of full responsibility by the permit holder for the performance of the CRNA as there is in 33.340a (4) where the CRNA is being delegated the duties of administering conscious sedation only. There is no mention of the relationship between the CRNA and the dentist who possesses a restricted permit II.

Thank you for the opportunity to provide comments. Do not hesitate to contact PANA Government Relations Consultant, Ted Mowatt, or myself if you have any questions.

Sincerely,

Susan Humes, CRNA
President
Pennsylvania Association of Nurse Anesthetists

cc: Rep. Mario Civera
Rep. William Rieger
Sen. Clarence Bell
Sen. Lisa Boscola

Original: 2233

PENNSYLVANIA SOCIETY OF DENTIST ANESTHESIOLOGISTS

Deborah B. Eskin, Counsel
State Board of Dentistry
Bureau of Professional and Occupational Affairs
Pennsylvania Department of State
P.O. Box 2649
Harrisburg, PA 17105-2649

January 3, 2002

Reference No. 16A-4610

Via Electronic Mail
Via Facsimile

Dear Ms. Eskin,

Thank you for giving the Pennsylvania Society of Dentist Anesthesiologists (PSDA) the opportunity to comment on the State Board of Dentistry's (SBOD) proposed anesthesia regulations published in the December 8, 2001 edition of the *Pennsylvania Bulletin*. The PSDA applauds the efforts made on this issue by the Sub-Committee on Anesthesia.

The Pennsylvania Society of Dentist Anesthesiologists (PSDA) is the Pennsylvania component of the American Society of Dentist Anesthesiologists (ASDA). Membership in our organization is open to all dentists who have completed a postdoctoral anesthesiology training program that satisfied Part II of ADA's "Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry" (1 full year of anesthesia residency prior to July 1, 1993 and 2 full years thereafter). The majority of our membership limits their practice to providing pain and anxiety control for dentistry. The PSDA represents the most highly trained dentists providing anesthesia for dentistry in PA.

The PSDA has reviewed the proposed regulations and offers the following suggestions:

- Section 33.335 Requirements for unrestricted permit.

  33.335 (a) (1) Should read:

  Successfully completed ~~at least one year in~~ a post-graduate program for advanced training in anesthesiology and related academic subjects that conforms to Part II of the American Dental Association's Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry or subsequent edition.

  33.335 (a) (2) Should read:

  Possess current certification as a ~~Diplomat~~ Diplomat of the American Board of Oral and Maxillofacial Surgeons or a Fellow of the ~~American Society of Dental Anesthesiology~~ American Dental Society of Anesthesiology, or be eligible for examination by the American Board of Oral and Maxillofacial Surgeons.

To recognize individuals who have successfully completed a post-graduate program for advanced training in anesthesiology and related academic subjects that conform to Part II of the American Dental Association's Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry, and/or have passed the written and oral exams conducted by the American Dental Board of Anesthesiology or are eligible to do so:

The PSDA suggests adding:

"or be certified as a Diplomat of the American Dental Board of Anesthesiology or be eligible for examination by the American Dental Board of Anesthesiology"

- Section 33.340a (a) (3) (iv) Duties of dentists who are restricted permit I holders.
- Section 33.340b (a) (3) (iv) Duties of dentists who are restricted permit II holders.

Auxiliary personnel should NOT be required to obtain certification in ACLS. Certification in ACLS would require that auxiliaries administer cardiac medications and this would be a violation of the current dental regulation under Section 33.205a.

It is appropriate to require that auxiliaries obtain certification in BLS.

- Section 33.335 (d) (2) Requirements for unrestricted permit.
- Section 33.336 (d) (2) Requirements restricted permit I.

"Authorized agents" conducting office inspections should be dental professionals with experience in the administration of anesthesia in the dental office.

- Section 33.341 Duties of dentists who are not permit holders.

Section 33.341 (a) (2)

Inspection and evaluation of the individual itinerant anesthesiologists (Dentist/Physician) and their equipment would better serve to assure public safety and NOT limit access to care.

The itinerant anesthesiologist (Dentist/Physician) should ensure that each office has the required equipment when anesthesia is administered, and that the operating dentist and his staff are adequately trained to assist the anesthesiologist in the management of anesthesia-related emergencies.

Office inspections of non-permit holder offices that employ the services of itinerant anesthesiologists (Dentist/Physician) are redundant and not cost effective.

Once an office has successfully passed an inspection/evaluation process, what is to prevent the non-permit holder/owner of the office from using the services of an anesthesiologist that has not been evaluated/inspected and that may be practicing below the standard of care?

In Pennsylvania any physician, by virtue of their medical degree, is deemed "qualified" to administer deep sedation/general anesthesia under their

medical license. The Board should require physicians who wish to administer anesthesia in dental offices to document anesthesia training and obtain an unrestricted permit from the Board. Many other state dental boards have already taken this step to ensure the safe administration of anesthesia in dental offices by these individuals.

Section 33.341 (a) (4) Should read:

Either the dentist who performs the dental procedure or the ~~certified registered nurse anesthetist~~, physician or other unrestricted permit holder who administers the general anesthesia, deep sedation or conscious sedation possesses a current certification in ACLS.

A certified registered nurse anesthetist can NOT be employed by a non-permit holder. This would violate Section 33.340a (a) (4) that states:

Certified registered nurse anesthetists to whom are delegated the duties of administering conscious sedation:

Perform their duties under the direct on-premises supervision of the permit holder...

Do not perform duties that are beyond the scope of the permit holder's authority.

Thank you for allowing the PSDA to offer comments on this very important issue. If the PSDA can be of further assistance, or if you have any questions, I can be reached at (412) 937-1900 or via electronic mail at ivseddoc@sgi.net.

Respectfully,

Pat M. Franceschelli, D.M.D.
President,
Pennsylvania Society of Dentist Anesthesiologists

cc: The Honorable Clarence D. Bell
Lisa M. Burns
The Honorable Mario J. Civera
The Honorable Joseph Markosek
Albert H. Masland, Commissioner, Bureau of Professional & Occupational Affairs
John R. McGinley, Chair, Independent Regulatory Review Commission
Robert E. Nice, Executive Director, Independent Regulatory Review Commission
Beth Zampogna, Capital Associates

Original 2233

PENNSYLVANIA SOCIETY OF DENTIST ANESTHESIOLOGISTS

Deborah B. Eskin, Counsel
State Board of Dentistry
Bureau of Professional and Occupational Affairs
Pennsylvania Department of State
P.O. Box 2649
Harrisburg, PA 17105-2649

January 3, 2002

Reference No. 16A-4610

Via Electronic Mail
Via Facsimile

Dear Ms. Eskin,

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To recognize individuals who have successfully completed a post-graduate program for advanced training in anesthesiology and related academic subjects that conform to Part II of the American Dental Association's Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry, and/or have passed the written and oral exams conducted by the American Dental Board of Anesthesiology or are eligible to do so:

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Section 33.341 (a) (2)

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A certified registered nurse anesthetist can NOT be employed by a non-permit holder. This would violate Section 33.340a (a) (4) that states:

Certified registered nurse anesthetists to whom are delegated the duties of administering conscious sedation:
Perform their duties under the direct on-premises supervision of the permit holder...
Do not perform duties that are beyond the scope of the permit holder's authority.

Thank you for allowing the PSDA to offer comments on this very important issue. If the PSDA can be of further assistance, or if you have any questions, I can be reached at (412) 937-1900 or via electronic mail at ivseddoc@sgi.net.

Respectfully,

Pat M. Franceschelli, D.M.D.
President,
Pennsylvania Society of Dentist Anesthesiologists

cc: The Honorable Clarence D. Bell
Lisa M. Burns
The Honorable Mario J. Civera
The Honorable Joseph Markosek
Albert H. Masland, Commissioner, Bureau of Professional & Occupational Affairs
John R. McGinley, Chair, Independent Regulatory Review Commission
Robert E. Nice, Executive Director, Independent Regulatory Review Commission
Beth Zampogna, Capital Associates

ORIGINAL: 2233

Pennsylvania Society of Oral and Maxillofacial Surgeons

Roger P. Spampata, DMD – President
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Lansdale, PA 19644
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Established 1964

VIA HAND DELIVERY AND U.S. MAIL

January 2, 2002

Ms. Deborah Eskin
Counsel, State Board of Dentistry
Bureau of Professional and Occupational Affairs
Department of State
124 Pine Street
P.O. Box 2649
Harrisburg, PA 17105

Re: Proposed Rulemaking of the State Board of Dentistry #16A-4610 - Administration of General Anesthesia, Deep Sedation, Conscious Sedation and Nitrous Oxide/Oxygen Analgesia

Dear Ms. Eskin:

I am writing on behalf of the Pennsylvania Society of Oral and Maxillofacial Surgeons (PSOMS), a non-profit organization representing the majority of oral and maxillofacial surgeons practicing in Pennsylvania. PSOMS is also a component society of the American Association of Oral and Maxillofacial Surgeons (AAOMS), which presently has over 6,000 members.

PSOMS is an active stakeholder in the development of the State Board of Dentistry's (Board) proposed rulemaking #16A-4610. In May 2000, we submitted pre-draft input on draft #5 of these regulations focusing on the burdensome requirement included in then section 33.340(a)(8) – we thank the Board for its revisions made in subsequent drafts. We also submitted comments on March 16, 2001, requesting the Board's clarification of the phrase "authorized agents" as it relates to the process for office inspections and clinical evaluations. Copies of both comments are enclosed for your convenience in referring to them.

Our primary concern with the proposed rulemaking continues to be the office inspection and clinical evaluation process. It is absolutely critical that they be performed fairly and accurately.

The most appropriate means to ensure that this is accomplished is to have the evaluation performed by a dentist comprehensively trained in the delivery of general anesthesia.

PSOMS endorses the evaluation process referenced in the proposed rulemaking that is described in AAOMS' *Office Anesthesia Evaluation Manual.* This manual was designed with the intent that a practicing oral and maxillofacial surgeon would perform the evaluation. As we have noted in our previous comments, the *Manual* was first published in 1975 to support the association's commitment to the health and safety of dental consumers and has been updated approximately every five years to keep current with progress in the specialty.

PSOMS has successfully implemented a peer review process for its members - the majority of oral and maxillofacial surgeons in Pennsylvania – for over twenty years. We urge the Board to continue using an already established peer review process for the clinical evaluation component of the proposed rulemaking. It is PSOMS' understanding that the Bureau of Professional and Occupational Affairs already accepts and utilizes a peer review program for the State Board of Accountancy, as referenced in PA Code 49 §11.83. At a recent meeting between our public affairs consultants and Commissioner Masland and Deputy Commissioner Williams, PSOMS was invited to submit a proposal to the Board outlining how a peer review process could be implemented. We appreciate this opportunity and will respond in the near future.

In addition to our primary concern outlined above, the following are PSOMS' specific comments and concerns regarding the Board's proposed rulemaking. The underlined text indicates language that PSOMS is recommending be added to the current proposed regulations.

SPECIFIC COMMENTS:

1. §33.335(c)

This section requires that the administration of general anesthesia, deep sedation or conscious sedation to children age 10 and under be done in conformance with the American Academy of Pediatric Dentistry's (AAPD) *Guidelines for the Elective Use of Conscious Sedation, Deep Sedation and General Anesthesia in Pediatric Dental Patients* or subsequent edition. According to AAPD guidelines, "the 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 and related subjects beyond the undergraduate medical or dental curriculum who is responsible for anesthesia and monitoring of the patient, 2) a treating dentist, responsible for the provision of dental services, 3) other personnel to assist the operator as necessary."

The AAPD guidelines are intended for the audience of pediatric dentists who, unlike oral and maxillofacial surgeons, are not generally trained in the delivery of anesthesia. Oral and maxillofacial surgeons, however, are comprehensively trained in both the delivery of general anesthesia as well as the delivery of surgical care; therefore, requiring oral and maxillofacial surgeons to adhere to the AAPD guidelines when treating pediatric patients is unnecessary and could limit access to care.

PSOMS recommends that an exception in this section be created for a permit holder who is an oral and maxillofacial surgeon who has completed an approved post-doctoral program and has been given an educational certificate attesting to their completion of the program. We would also request that this exception be included in §33.338(b)(4) relating to expiration and renewal of permits and in §33.340(a)(2)(xii) relating to monitoring equipment, procedures and documentation.

2. §33.335(d)(2)

This section requires an applicant for an unrestricted permit to undergo a clinical evaluation performed by the Board through its "authorized agents". PSOMS recommends that the Board clarify the meaning of "authorized agents." We will also address this concern in greater detail when we submit our proposal for implementing a peer review inspection and evaluation process.

3. §33.336(d)(2)

This section requires an applicant for a restricted permit I to undergo a clinical evaluation performed by the Board through its "authorized agents". PSOMS recommends that the Board clarify the meaning of "authorized agents." We will also address this concern in greater detail when we submit our proposal for implementing a peer review inspection and evaluation process.

4. §33.340(a)(2)(xvi) and §33.340a(a)(2)(xvi)

These sections require unrestricted and restricted permit I holders to have an automatic external defibrillation device (AED). PSOMS recommends that the language be changed to read "a defibrillation device." A cardiac defibrillation device combined with the requisite Advanced Cardiac Life Support (ACLS) training for the anesthesia or conscious sedation provider is the necessary combination for treating cardiac dysrhythmias using ACLS treatment algorithms. In fact, a provider following ACLS treatment algorithms for several of the cardiac emergencies described in the ACLS manual *cannot* use an AED.

5. §33.340(a)(3)(iv) and §33.340a(a)(3)(iv)

These sections require auxiliary personnel who assist the unrestricted or restricted permit I holder in the administration of general anesthesia, deep sedation or conscious sedation to be currently certified in ACLS. The certification period for ACLS is on a 2-year cycle and requires extensive preparation for this difficult test. PSOMS is concerned with consumer safety and emergency preparedness, however, we do not believe that either such safety or preparedness requires *auxiliary personnel* be trained in ACLS. PSOMS requests that this requirement be changed from ACLS certification to Basic Life Support (BLS) certification. We are confident that this level of certification protects and insures consumer safety without requiring an unnecessarily burdensome process for the additional members of our anesthesia and sedation teams.

6. §33.340 (a)(8)

This section provides that any general anesthesia requiring intubation be "administered by the permit holder, certified registered nurse anesthetist, physician, or other unrestricted permit holder to whom is delegated the duties of administration" while the unrestricted permit holder performs the dental procedures. As we have stated in previous comments submitted to the Board on these proposed regulations, the administration of anesthesia is a complicated and sophisticated process. Various training and credentialing in its use and administration have been developed for physicians as well as oral and maxillofacial surgeons and anesthesiologists. PSOMS believes that anesthesia cannot be adequately administered by someone unfamiliar with its intricacies. Therefore, the term "physician" in this phrase is too restrictive and must be expanded to read "qualified physician, anesthesiologist, or other unrestricted permit holder to whom is delegated the duties of administration".

7. §33.341(a)(2)

This section requires that an initial office inspection be performed at the dental office of a non-permit holder prior to the first time general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia will be administered. PSOMS believes that the offices of non-permit holders where anesthesia will be delivered should meet the same requirement as permit holders and undergo an office inspection at least once every 6 years after the initial inspection.

8. §33.341(a)(4)

This section states that "either the dentist who performs the dental procedure or the certified registered nurse anesthetist, physician or other unrestricted permit holder who administers the general anesthesia ... be certified in ACLS." Again, the term "physician" in this phrase is too restrictive and needs to be expanded to read "qualified physician or anesthesiologist, or other unrestricted permit holder to whom is delegated the duties of administration" for the reasons stated above.

PSOMS appreciates your time and consideration in this matter. We request that our recommendations be addressed in the final rulemaking proposed by the Board and we look forward to continuing our work with you and the Board for the benefit of Pennsylvania's consumers.

If you have any questions regarding these comments, please feel free to contact me (215-368-8104) or our public affairs consultants, Jay Layman and Beth Zampogna at Capital Associates, Inc. (717-234-5350).

Sincerely,

Roger P. Spampata, D.M.D.
President
Pennsylvania Society of Oral and Maxillofacial Surgeons

Enclosures

cc: John R. McGinley, Chairman, Independent Regulatory Review Commission
The Honorable Mario Civera
The Honorable William Rieger
The Honorable Clarence Bell
The Honorable Lisa Boscola
Al Masland, Commissioner, Bureau of Professional & Occupational Affairs
PSOMS Executive Committee
Carol O'Brien, American Association of Oral and Maxillofacial Surgeons
Marisa Fenice, Pennsylvania Dental Association

Pennsylvania Society of Oral and Maxillofacial Surgeons

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Established 1964

ORIGINAL: 2233

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

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

Eskin, Deborah

From: Burns, Lisa
Sent: Wednesday, January 02, 2002 7:41 AM
To: Eskin, Deborah
Subject: FW: Proposed anesthesia/analgesia

-----Original Message-----
From: S & M Everett [mailto:meverett@ptd.net]
Sent: Wednesday, December 26, 2001 01:38 PM
To: dentistr@pados.dos.state.pa.us
Subject: Proposed anesthesia/analgesia regulations

To whom it may concern:

I am strongly opposed to changes regarding the use of nitrous oxide. I will cease to provide this service if the regulations are passed as currently proposed. The children of Pa will suffer, as they are referred to pedo dentists and oral surgeons for treatment. Their will be bottlenecks as there are not enough specialists to handle all the referrals. Referrals for extractions rise versus trying to treat in the general dental offices. There are more concerns with local anesthesia that nitrous.
meverett@ptd.net

Original: 2233

University of Pittsburgh

School of Dental Medicine
Office of the Dean

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

January 2, 2002

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

Reference Number: 16A/4610 (Administration of General Anesthesia, Deep Sedation, Conscious Sedation, and Nitrous Oxide/Oxygen Analgesia)

Dear Ms. Eskin:

As Dean and Professor of Oral and Maxillofacial Surgery at the University of Pittsburgh, I am responding to the Dental Board's proposed rulemaking pertaining to the administration of anesthesia published in the Pennsylvania Bulletin. In general, I commend the Board's work and the multiple drafts which have been developed. There are, however, several items which I believe deserve additional attention.

My principal concern with the proposed rulemaking is the office inspection and clinical evaluation process. It is absolutely critical that the clinical evaluation be completed in a fair and accurate way that ensures patient safety. Therefore, this evaluation must be performed by a person comprehensively trained in the delivery of general anesthesia and dentistry or its specialties.

The evaluation process referenced in the proposed rulemaking is the process outlined in the **AAOMS Office Anesthesia Evaluation Manual** and was designed for practicing oral and maxillofacial surgeons to perform the evaluation.

In addition to the concerns outlined above, I would like to make additional specific comments.

- §33.335 (c)
  This section requires that the administration of general anesthesia, deep sedation, or conscious sedation to children 10 and under be done in conformance with the American Academy of Pediatric Dentistry's (AAPD) Guidelines for the Elective Use of Conscious Sedation, Deep Sedation, and General Anesthesia in Pediatric

Dental Patients or subsequent edition. According to AAPD guidelines, "the 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 and related subjects beyond the undergraduate medical or dental curriculum who is responsible for anesthesia and monitoring of the patient, 2) a treating dentist responsible for the provision of dental services, 3) other personnel to assist the operator as necessary.

The AAPD guidelines are intended for pediatric dentists who are not comprehensively trained in the delivery of anesthesia. Oral and maxillofacial surgeons, however, are comprehensively trained in the delivery of general anesthesia as well as the delivery of surgical care. Requiring surgeons to adhere to the AAPD guidelines when treating pediatric patients is unnecessary, costly, and could limit access to care. I recommend that an exception in this section be created for a permit holder who is board certified or board eligible in oral and maxillofacial surgery.

- §33.335 (d) (2)
  This requires an applicant for an unrestricted permit to undergo a clinical evaluation performed by the Board through its "authorized agents". I believe that the Board clarify "authorized agents" to mean unrestricted permit holders with at least 5 years experience in the administration of dental anesthesia.

- §33.336 (d) (2)
  This requires an applicant for a restricted permit I to undergo a clinical evaluation performed by the Board through its "authorized agents". Again, I believe the Board should clarify "authorized agents" to mean restricted permit I holders with at least 5 years experience in the administration of conscious sedation.

- §33.340 (a) (3) (iv) and §33.340a (a) (3) (iv)
  These sections require auxiliary personnel who assist the unrestricted or restricted permit I holder in the administration of general anesthesia, deep sedation, or conscious sedation to be currently certified in ACLS. This seems vague and implies all personnel in the treatment room. I believe the more appropriate verbiage should indicate the requirement of BLS for all personnel and ACLS for anyone directly involved in the administration of the anesthetic. The certification period for ACLS is on a 2-year cycle and requires extensive preparation for this difficult ACLS test. I am confident that the level of

certification outlined above (BLS for treatment personnel, ACLS for anesthesia givers only) would protect and insure consumer safety without requiring an unnecessarily burdensome process for the additional members of our anesthesia and sedation teams.

- §33.340 (a) (8)
  This section provides that any general anesthesia requiring intubation be "administered by the permit holder, certified registered nurse anesthetist, physician, or other unrestricted permit holder to whom is delegated the duties of administration" while the unrestricted permit holder performs the dental procedures. I believe that the term "physician" in this phrase be clarified to read "qualified physician, anesthesiologist".

- §33.341 (a) (2)
  This section requires that an initial office inspection be performed on the dental office of a non-permit holder prior to the first time general anesthesia, deep sedation, conscious sedation, or nitrous oxide/oxygen analgesia will be administered. I believe that the offices of non-permit holders where anesthesia will be delivered should meet the same requirement as permit holders and undergo an office inspection at least once every 6 years after the initial inspection.

- §33.341 (a) (4)
  This section states that "either the dentist who performs the dental procedure of the certified registered nurse anesthetist, physician, or other unrestricted permit holder who administers the general anesthesia...be certified in ACLS." I believe the term "physician" in this phrase should be clarified to read "qualified physician or anesthesiologist".

Thank you for the opportunity to comment. Please feel free to contact me with any questions.

Sincerely,

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

TWB\lt

cc: Dr. Norbert Gannon

Original: 2233

Pennsylvania Society of Oral and Maxillofacial Surgeons

Roger P. Spampata, DMD – President
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Lansdale, PA 19644
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Established 1964

VIA HAND DELIVERY AND U.S. MAIL

January 2, 2002

Ms. Deborah Eskin
Counsel, State Board of Dentistry
Bureau of Professional and Occupational Affairs
Department of State
124 Pine Street
P.O. Box 2649
Harrisburg, PA 17105

Re: Proposed Rulemaking of the State Board of Dentistry #16A-4610 - Administration of General Anesthesia, Deep Sedation, Conscious Sedation and Nitrous Oxide/Oxygen Analgesia

Dear Ms. Eskin:

I am writing on behalf of the Pennsylvania Society of Oral and Maxillofacial Surgeons (PSOMS), a non-profit organization representing the majority of oral and maxillofacial surgeons practicing in Pennsylvania. PSOMS is also a component society of the American Association of Oral and Maxillofacial Surgeons (AAOMS), which presently has over 6,000 members.

PSOMS is an active stakeholder in the development of the State Board of Dentistry's (Board) proposed rulemaking #16A-4610. In May 2000, we submitted pre-draft input on draft #5 of these regulations focusing on the burdensome requirement included in then section 33.340(a)(8) – we thank the Board for its revisions made in subsequent drafts. We also submitted comments on March 16, 2001, requesting the Board's clarification of the phrase "authorized agents" as it relates to the process for office inspections and clinical evaluations. Copies of both comments are enclosed for your convenience in referring to them.

Our primary concern with the proposed rulemaking continues to be the office inspection and clinical evaluation process. It is absolutely critical that they be performed fairly and accurately.

The most appropriate means to ensure that this is accomplished is to have the evaluation performed by a dentist comprehensively trained in the delivery of general anesthesia.

PSOMS endorses the evaluation process referenced in the proposed rulemaking that is described in AAOMS' *Office Anesthesia Evaluation Manual.* This manual was designed with the intent that a practicing oral and maxillofacial surgeon would perform the evaluation. As we have noted in our previous comments, the *Manual* was first published in 1975 to support the association's commitment to the health and safety of dental consumers and has been updated approximately every five years to keep current with progress in the specialty.

PSOMS has successfully implemented a peer review process for its members - the majority of oral and maxillofacial surgeons in Pennsylvania – for over twenty years. We urge the Board to continue using an already established peer review process for the clinical evaluation component of the proposed rulemaking. It is PSOMS' understanding that the Bureau of Professional and Occupational Affairs already accepts and utilizes a peer review program for the State Board of Accountancy, as referenced in PA Code 49 §11.83. At a recent meeting between our public affairs consultants and Commissioner Masland and Deputy Commissioner Williams, PSOMS was invited to submit a proposal to the Board outlining how a peer review process could be implemented. We appreciate this opportunity and will respond in the near future.

In addition to our primary concern outlined above, the following are PSOMS' specific comments and concerns regarding the Board's proposed rulemaking. The underlined text indicates language that PSOMS is recommending be added to the current proposed regulations.

SPECIFIC COMMENTS:

1. §33.335(c)

This section requires that the administration of general anesthesia, deep sedation or conscious sedation to children age 10 and under be done in conformance with the American Academy of Pediatric Dentistry's (AAPD) *Guidelines for the Elective Use of Conscious Sedation, Deep Sedation and General Anesthesia in Pediatric Dental Patients* or subsequent edition. According to AAPD guidelines, "the 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 and related subjects beyond the undergraduate medical or dental curriculum who is responsible for anesthesia and monitoring of the patient, 2) a treating dentist, responsible for the provision of dental services, 3) other personnel to assist the operator as necessary."

The AAPD guidelines are intended for the audience of pediatric dentists who, unlike oral and maxillofacial surgeons, are not generally trained in the delivery of anesthesia. Oral and maxillofacial surgeons, however, are comprehensively trained in both the delivery of general anesthesia as well as the delivery of surgical care; therefore, requiring oral and maxillofacial surgeons to adhere to the AAPD guidelines when treating pediatric patients is unnecessary and could limit access to care.

PSOMS recommends that an exception in this section be created for a permit holder who is an oral and maxillofacial surgeon who has completed an approved post-doctoral program and has been given an educational certificate attesting to their completion of the program. We would also request that this exception be included in §33.338(b)(4) relating to expiration and renewal of permits and in §33.340(a)(2)(xii) relating to monitoring equipment, procedures and documentation.

2. §33.335(d)(2)

This section requires an applicant for an unrestricted permit to undergo a clinical evaluation performed by the Board through its "authorized agents". PSOMS recommends that the Board clarify the meaning of "authorized agents." We will also address this concern in greater detail when we submit our proposal for implementing a peer review inspection and evaluation process.

3. §33.336(d)(2)

This section requires an applicant for a restricted permit I to undergo a clinical evaluation performed by the Board through its "authorized agents". PSOMS recommends that the Board clarify the meaning of "authorized agents." We will also address this concern in greater detail when we submit our proposal for implementing a peer review inspection and evaluation process.

4. §33.340(a)(2)(xvi) and §33.340a(a)(2)(xvi)

These sections require unrestricted and restricted permit I holders to have an automatic external defibrillation device (AED). PSOMS recommends that the language be changed to read "a defibrillation device." A cardiac defibrillation device combined with the requisite Advanced Cardiac Life Support (ACLS) training for the anesthesia or conscious sedation provider is the necessary combination for treating cardiac dysrhythmias using ACLS treatment algorithms. In fact, a provider following ACLS treatment algorithms for several of the cardiac emergencies described in the ACLS manual *cannot* use an AED.

5. §33.340(a)(3)(iv) and §33.340a(a)(3)(iv)

These sections require auxiliary personnel who assist the unrestricted or restricted permit I holder in the administration of general anesthesia, deep sedation or conscious sedation to be currently certified in ACLS. The certification period for ACLS is on a 2-year cycle and requires extensive preparation for this difficult test. PSOMS is concerned with consumer safety and emergency preparedness, however, we do not believe that either such safety or preparedness requires *auxiliary personnel* be trained in ACLS. PSOMS requests that this requirement be changed from ACLS certification to Basic Life Support (BLS) certification. We are confident that this level of certification protects and insures consumer safety without requiring an unnecessarily burdensome process for the additional members of our anesthesia and sedation teams.

6. §33.340 (a)(8)

This section provides that any general anesthesia requiring intubation be "administered by the permit holder, certified registered nurse anesthetist, physician, or other unrestricted permit holder to whom is delegated the duties of administration" while the unrestricted permit holder performs the dental procedures. As we have stated in previous comments submitted to the Board on these proposed regulations, the administration of anesthesia is a complicated and sophisticated process. Various training and credentialing in its use and administration have been developed for physicians as well as oral and maxillofacial surgeons and anesthesiologists. PSOMS believes that anesthesia cannot be adequately administered by someone unfamiliar with its intricacies. Therefore, the term "physician" in this phrase is too restrictive and must be expanded to read "qualified physician, anesthesiologist, or other unrestricted permit holder to whom is delegated the duties of administration".

7. §33.341(a)(2)

This section requires that an initial office inspection be performed at the dental office of a non-permit holder prior to the first time general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia will be administered. PSOMS believes that the offices of non-permit holders where anesthesia will be delivered should meet the same requirement as permit holders and undergo an office inspection at least once every 6 years after the initial inspection.

8. §33.341(a)(4)

This section states that "either the dentist who performs the dental procedure or the certified registered nurse anesthetist, physician or other unrestricted permit holder who administers the general anesthesia ... be certified in ACLS." Again, the term "physician" in this phrase is too restrictive and needs to be expanded to read "qualified physician or anesthesiologist, or other unrestricted permit holder to whom is delegated the duties of administration" for the reasons stated above.

PSOMS appreciates your time and consideration in this matter. We request that our recommendations be addressed in the final rulemaking proposed by the Board and we look forward to continuing our work with you and the Board for the benefit of Pennsylvania's consumers.

If you have any questions regarding these comments, please feel free to contact me (215-368-8104) or our public affairs consultants, Jay Layman and Beth Zampogna at Capital Associates, Inc. (717-234-5350).

Sincerely,

Roger F. Spampata, D.M.D.
President
Pennsylvania Society of Oral and Maxillofacial Surgeons

Enclosures

cc: John R. McGinley, Chairman, Independent Regulatory Review Commission
The Honorable Mario Civera
The Honorable William Rieger
The Honorable Clarence Bell
The Honorable Lisa Boscola
Al Masland, Commissioner, Bureau of Professional & Occupational Affairs
PSOMS Executive Committee
Carol O'Brien, American Association of Oral and Maxillofacial Surgeons
Marisa Fenice, Pennsylvania Dental Association