Original: 2233

PENNSYLVANIA SOCIETY OF ANESTHESIOLOGISTS

RECEIVED
JAN 14 2002
DOS LEGAL COUNSEL

January 11, 2002

VIA FIRST CLASS MAIL
Deborah B. Eskin, Counsel
State Board of Dentistry
P.O. Box 2649
Harrisburg, PA 17105-2649

VIA HAND DELIVERY
Deborah B. Eskin, Counsel
State Board of Dentistry
555 Walnut Street, 9th Floor
Harrisburg, PA 17105

Re: No. 16A-4610
Administration of General Anesthesia, Deep Sedation, Conscious Sedation

Dear Ms. Eskin:

These comments are submitted on behalf of the Pennsylvania Society of Anesthesiologists (PSA), in response to the proposed regulations published by the State Board of Dentistry (Board) at 31 Pennsylvania Bulletin 6691.

PSA generally supports and commends the efforts of the Board to assure the safe administration of anesthesia in dental offices. As more complex procedures, in particular those requiring general anesthesia, are performed in the office setting, patient safety must be the foremost consideration.

With the mandate for unqualified patient safety in mind, PSA supports the Board's proposed addition of §33.340(a)(8) to its anesthesia regulations. This section requires the permit holder to ensure that general anesthesia requiring intubation is administered by a qualified individual other than the dental license who is performing the dental procedure. It is impossible for the dentist performing the dental procedure to be effectively and simultaneously attentive to the general anesthesia procedure when he or she must focus on the dental procedure itself.

PSA believes, however, that the Board's must extend its proposal to include all situations where general anesthesia is administered, regardless of whether an endotracheal tube is used. Any time a patient loses consciousness, no matter how brief, a high degree of vigilance is mandatory. Only a qualified individual who is focused on the anesthesia function alone can fully protect the patient from potentially serious consequences.

PSA suggests that the Board modify the proposed regulations as follows:

§33.340. Duties of dentists who are unrestricted permit holders.

(a) A dentist who possesses an unrestricted permit issued under this subchapter shall ensure that:

.....

(8) General anesthesia ~~requiring intubation~~ is 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 dental procedures are performed by a dental licensee who is not involved in the administration of the general anesthesia.

Thank you for the opportunity to comment upon this important regulation. If you have any questions or would like to further discuss this matter, please feel free to contact me.

Sincerely,

Sean Kennedy, M.D.
President
Pennsylvania Society of Anesthesiologists

cc: The Honorable Mario J. Civera, Jr.
The Honorable Clarence D. Bell
Robert E. Nyce

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PENNSYLVANIA SOCIETY OF ANESTHESIOLOGISTS

RECEIVED
2002 JAN 11 PM 4:44
REVIEW COMMISSION

January 11, 2002

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Original 2233

Gary S. Davis, D.D.S.

420 East Orange Street • Shippensburg, PA 17257 • (717) 532-4513

To: The State Board of Dentistry

Attention: Deb Eskin & members of the board

Subject: Anesthetic Regulations

From: Gary S. Davis

RECEIVED
JAN 0 8 2002
DOS LEGAL COUNSEL

JAN - 7 2002

Gary S. Davis, D.D.S.

420 East Orange Street • Shippensburg, PA 17257 • (717) 532-4513

January 5, 2001

To Whom It May Concern:

Thank you for the opportunity to share my research and comments concerning the proposed anesthesia regulations. The majority of the proposed regulation is both scientifically and clinically sound. However, parts of the regulation concerning nitrous oxide/oxygen analgesia are unnecessary, overly burdensome, and are not in the best interest of the citizens of our Commonwealth.

It is my belief that the proposed anesthesia regulations concerning nitrous oxide/oxygen analgesia are over regulated and will result in a decrease of Permit II holders. This can only result into access to care problems and an increase of general anesthesia and conscious sedation procedures where a safer procedure like nitrous oxide analgesia could have been utilized. This action will also increase costs for patients in two ways. First, it will increase morbidity of anxious patients who will delay treatment and secondly it will increase patient costs due to the fact that conscious sedation, deep sedation, and general anesthesia procedures are more expensive.

Those supporting the added restrictions on Permit II holders state that there is a national trend toward informed consent and other regulations concerning nitrous oxide/oxygen analgesia (N2O/O2). My research of statutes and regulations in other states reveal that only 11 states even require that dentists have a permit for N2O/O2 analgesia and out of these, 3 require only that dentists take some type of unspecified course on administering N2O.
In fact, none of our neighboring states require a permit for N2O/O2 analgesia.

New York updated their law in 2000 concerning dental anesthesia certificates which states, "Nothing in this section shall limit a dentist's use of local anesthesia, a dentist's use of nitrous oxide, or any other substance or

JAN - 7 2002

agent for the purpose other than deep sedation, conscious sedation, or general anesthesia."

Illinois updated their regulations in 1998 and in their wisdom did not require a permit for nitrous and only require minimal monitoring of the patient by clinical observation and appropriate documentation.

According to the American Dental Association Department of State Government Affairs on the subject of informed consent from their State Legislative Report, May 2001, Volume 5, "No other state is believed to have such a requirement for nitrous oxide."

The following are my specific concerns with the proposed regulations:

33.337. (2) Requirements for Restricted Permit II

What documentation or information will a dentist need to attest that the equipment has been installed and calibrated according to manufacturer's guidelines and contains a fail safe system?

For example, nitrous has been used successfully in my office for over 20 years without any reported or discovered incidents of mortality or morbidity. Is this history sufficient for a dentist to attest that his equipment is safe? In addition, many other dentists and I have purchased our offices from a retiring dentist. How can I attest that the plumbing has been installed according to manufacturer's guidelines?

I would rather see language, which states:

a) A dentist shall attest:

i) that nitrous has been used safely without any reported or discovered incidents

or

ii) newly installed plumbing has been installed according to manufacturer's guidelines

b) All N2O/O2 equipment shall contain:

i) a fail safe system
ii) provide a minimum of 25% O2 at all times
iii) pin index and diametric index safety systems

iv) color coding for gases
v) a scavenging trace gas capability

c) NO requirements for calibration

In truth, flow meters have accuracies of plus or minus 2-7% according to Dr. Stanley F. Malamed in his second edition text Sedation: A Guide To Patient Management.

From a clinical "wet gloved" point of view from an average general dentist, it is obvious that calibration is a waste of time and money and does nothing to make administration of nitrous safer!

Once the proper flow rate for a patient is determined, the initial % of nitrous should always be low (approximately 20%). After 1-1.5 minutes at this rate, the nitrous is titrated up to around 30% and signs of anxiolysis such as tingling of the hands and feet, a flushing of the extremities and face, and of course analgesia are observed. If one or more of these signs are not observed, the nitrous concentration is increased another 5-10%.

The correct level of analgesia is determined not by the level of nitrous on the machine but rather by the signs and symptoms observed by the doctor.

This observation of the patient is also important in determining if the level of nitrous is too high. The simple reduction of nitrous by 5-10% rectifies the situation. One of the most important safety features of nitrous oxide analgesia is the fact that the patient remains conscious and is able to provide input on his/her well being. If the patient is uncomfortable or objects to the nitrous, the nitrous flow is terminated and oxygen continued for another 3-5 minutes.

Calibration will encourage dentists to use arbitrary fixed concentrations (usually 40-50%) instead of the proper technique of beginning with a low concentration and carefully titrating nitrous according to signs and symptoms. According to many experts, the absence of titration is the main reason that some patients experience an uncomfortable reaction to nitrous.

Calibration of nitrous oxide machines at first glance seems like a quick-fix answer to make administration safer for the citizens of Pennsylvania. However we all know that the safety of the patient depends

on the careful observations by the doctor! Calibration of flow meters would be as ridiculous as calibrating blood pressure cuffs. Do we expect all healthcare providers to calibrate blood pressure cuffs to those in the local emergency room? Calibration is simply burdensome over-regulation and nothing more.

33.338. (5) Expiration and Renewal of Permits

For the same line of reasoning as 33.337. this section should be changed to:

(5) a) An attestation on the renewal application that the nitrous equipment has:

i) a fail safe system
ii) provides at least 30% oxygen at all times
iii) pin index and diameter index safety system
iv) a scavenging trace gas capability
v) color coding of gases and gas lines
vi)

b) An attestation that there have been no reported or discovered incidents of morbidity or mortality resulting from the applicants administration of nitrous analgesia.

33.340. (b) Duties

At all dental appointments the patient's medical history should be updated and reviewed. The language seems to imply that a new written history is to be taken prior to each administration of nitrous oxide/oxygen analgesia.

Dentists use dialogue history when reviewing a patient's medical history and perform a visual inspection of the patient at each visit. In addition to this, there are no absolute contraindications to the use of nitrous oxide analgesia alone. Therefore, I question the need for a physical evaluation with the use of nitrous oxide/ oxygen analgesia.

AUTOMATIC COVER SHEET

DATE : JAN-07-02 01:10 PM

TO :

FAX #: 7877769

FROM : GARY DAVIS DDS

FAX #: 7175327679

6 PAGES WERE SENT

(INCLUDING THIS COVER SHEET)

AUTOMATIC COVER SHEET

DATE : JAN-07-02 01:13 PM

TO :

FAX #: 7877769

RECEIVED
JAN 0 8 2002
DOS LEGAL COUNSEL

FROM : GARY DAVIS DDS

FAX #: 7175327679

4 PAGES WERE SENT

(INCLUDING THIS COVER SHEET)

JAN - 7 2002

I believe a better regulation would read:

33.340. (b) Duties

(1) Prior to the administration of N2O/O2 analgesia,
the patient's medical history should be updated and reviewed.

33.340. (2)(iv) Suction Equipment with Oropharyngeal Suction

In my review of morbidity and mortality of nitrous oxide analgesia, I did not find any cases, which needed oropharyngeal suctioning. Remember that with N2O/O2 analgesia, a patient is conscious and all reflexes are intact!

Monitoring of a patient by observation is the major means of detecting nausea at a time when nitrous can be reduced by 5-10% and vomiting prevented. Every dentist knows the signs of impending vomiting which are pallor, sweating, cold clammy hands, increased salivation, and active swallowing.

If these signs appear, the proper response would be to stop nitrous flow and permit the patient to breathe 100% oxygen.

If vomiting occurs, the nasal hood should be removed and the patient's head should be turned to the side to prevent aspiration (basic CPR). ANY high volume-suctioning tip may be used to assist in the removal of vomitus or other foreign body.

I believe it is important at this point to state that vomiting is not a problem when nitrous oxide analgesia is used properly. I have never had a patient vomit as a result of nitrous oxide analgesia and in a study at USC School of Dentistry only twelve cases of vomiting were reported in over 3500 procedures. This is less than 0.342%!

It is the position of the head that determines the likelihood of aspiration not what type of suction tip a dentist has in the bottom drawer of his operatory.

33.340. (b)(viii) Emergency Airway Equipment and Medications

The treatment of any adverse reaction to nitrous oxide analgesia is the decrease of nitrous concentration or the administration of 100 % oxygen. The need for any other medications in relation to the administration of

JAN - 7 200

nitrous oxide analgesia is not only unnecessary, but also a danger to the patient. The predominate opinion in the treatment of emergencies in the dental office is to minimize drugs and to activate the EMS system! Since there are no adverse reactions to nitrous oxide that require treatment with airway equipment or IV drugs, this is an unnecessary and burdensome regulation.

33.340. (b)(xii) Signed Informed Consent

After carefully reviewing all of the potential side effects of nitrous oxide analgesia and reviewing court opinion on informed consent, I find no indications for a signed informed consent.

Prior to 1997, it was law in Pennsylvania that a physician must obtain informed consent before performing a surgical or operative procedure. (See Sinclair V. Block, 434Pa, 633A.2d 1137(1993)). The rational was that the performance of a surgical procedure without consent constitutes an assault or a battery because the patient is usually unconscious and UNABLE TO OBJECT.

As of January 25, 1997, our legislature codified the law of informed consent in the Healthcare Services Malpractice Act which states that informed consent (written consent is not stated?) is to be obtained prior to performing surgery, including the related administration of anesthesia. (811-A, (a)(1))

According to Pennsylvania regulation and ADA guidelines, nitrous oxide/oxygen analgesia is not a sedation procedure and is not a surgical procedure, therefore written informed consent is not indicated. Given that previous case law supported the rational that informed consent was required because the patient was usually unconscious and unable to object during the procedure and since the patient is not unconscious and is able to object at any time during the procedure, informed written consent is not indicated by Pennsylvania statute.

I do not pretend to be an expert of the law, however it seems to me that this regulation concerning nitrous oxide/oxygen analgesia is in direct opposition to existing law.

It is my opinion that these appropriate changes be made on informed consent.

33.342. (f)(1)

I can't speak for all areas of the state, but in my area it is quite difficult to schedule a contractor, electrician, or a plumber within 30 days! I believe that if a dentist is making a sincere attempt to correct deficiencies, formal administrative procedures should not be initiated, especially if his/her permit has been subject to an immediate temporary suspension or if the noncompliance does not present a clear danger to public health or safety.

I would like to see language, which states a re-inspection, will occur in a reasonable and negotiated timeline.

Because of the proven safety record of nitrous oxide/oxygen analgesia and the inability of the SBOD's agents to routinely inspect all offices,

I recommend that Permit II holders be exempt from routine inspections. However, if there are complaints from patients or a report of morbidity or mortality, Permit II holders should have an automatic inspection with notice.

Thank you for the opportunity to share these comments.

Gary S. Davis, D.D.S

Gary S. Davis, DDS

JAN - 7 2002

Original: 2233

SPRUILL & WONG DDS PC 717-245-0061

WILLIAM T. SPRUILL, DDS, MAGD
LILLIAN M. WONG, DDS, FAGD

520 SOUTH PITT STREET
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Deborah B. Eskin, Counsel
State Board of Dentistry
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Harrisburg, PA 17105-2649

January 7, 2002

RECEIVED
JAN 08 2002
DOS LEGAL COUNSEL

RE: Comment on No.16A-4610 Proposed Rulemaking for Administration of General Anesthesia, Deep Sedation, Conscious Sedation and Nitrous Oxide/Oxygen Analgesia

Dear Counsel Eskin,
Dr. Norbert O. Gannon and members of the Pennsylvania State Board of Dentistry:

First let me personally thank the Board for their diligent efforts to review these regulations, for the opportunity to provide input and in the face of the public and legislative pressure since the Watkins decision for the comprehensive revisions of the sections on general anesthesia, deep sedation and conscious sedation.

However, there are several concerns with the requirements for nitrous oxide/oxygen analgesia. The proposed regulations in this regard are unnecessary, and create an inappropriate and undue burden on permit II holders. The regulations as proposed would not provide any additional protection to the citizens of the commonwealth but would create a significant barrier to dental care by restricting the availability of this nearly benign modality. Pennsylvania already has one of the most restrictive practice environments in the country. More requirements will result in fewer permit II holders. The fiscal impact will be an increase in dental morbidity as phobic patients delay necessary treatment and increased treatment costs if they opt for treatment under the more expensive modalities of sedation or anesthesia. There is also the cost of work loss time from the recovery period with anesthesia and sedation.

When regulations for anesthetic modalities were first promulgated in Pennsylvania more than a decade ago, nitrous oxide/oxygen analgesia was inappropriately swept along with other true anesthetic modalities. When doctors provide anxiolysis or analgesia with nitrous oxide/oxygen the patient is conscious, responsive, and conversant and has all protective reflexes intact. Nitrous oxide/oxygen analgesia is neither anesthesia nor sedation and does not require similar treatment in regulation.

The American Dental Association Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia in Dentistry states, "when the intent is anxiolysis only, and the appropriate dosage of agents is administered, then the definition of enteral and/or combination inhalation-enteral conscious sedation (combined conscious sedation) does not apply." (Emphasis added). The accepted national guidelines only apply to nitrous

5 pages in this fax.

oxide/oxygen "when used in combination with sedative agents [that] may produce anxiolysis, conscious or deep sedation or general anesthesia."

Nationwide, according to the ADA, 14 states expressly provide that administration of nitrous oxide is not considered conscious sedation and shouldn't be treated as such.19 states allow dental hygienists to administer nitrous oxide/oxygen analgesia, 34 states allow hygienists to monitor patients using it and 25 states allow dental assistants to monitor patients on nitrous oxide/oxygen analgesia. Conversely, Pennsylvania is one of only 11 states nationwide that require a permit for nitrous administration. 9 of 13 Northeast Regional Board states have no permit requirement but consider the basic dental license sufficient.

Finally I offer two graphs from the American Dental Association's Future of Dentistry Report (Attachment A). Please compare Minnesota and Pennsylvania in the first graph of Dentist-to-Population Ratio by State. Notice that Minnesota has the lowest ratio in the nation while Pennsylvania has a slight gain for the time period even though Pennsylvania has 3 dental schools. The second graph shows Productivity-Adjusted Dentist-to-Population Ratio by State, a measure of efficiency per dentist per population. Again, Minnesota is the lowest in the nation while PA achieved a modest gain of 6%.

Minnesota Dental Association past President Dr. Kim Harms explained, "legislative initiatives created a poor practice environment causing our dentists to look elsewhere to set up their practices. It is important to note that dentist to population ratio rose from the 1970's until 1993 when so-called health care reform initiatives started. Although we have our own dental school, students are choosing to locate their practices out side the state. With debts approaching $100,000 why would they take the chance of practicing in a 'dentist unfriendly' environment."

Understanding the impact of additional regulations on workforce and access issues is critical. The number of dental school graduates declined 23% from 1986 to 1996. Last year, America's dental schools graduated approximately 4000 dentists. Nearly 6000 dentists left active practice due to death and retirement while the US population grew by 2 1/2 million.

Pennsylvania is following that trend. The most recent licensure renewal cycle completed in March 2001 saw a 10% reduction in licensees. Granted it was the first license renewal cycle that had a continuing education requirement for relicensure and allowed an inactive license category but none-the-less there are fewer care providers than a short while ago. PA clearly will be competing for health care providers for decades to come in many fields. There is no reason to drive dental graduates to other states.

To improve the regulations there are several proposals that should be eliminated.

Proposed 33.337 (b)(1) "...written office procedures for administering nitrous oxide/oxygen analgesia and handling emergencies resulting therefrom:"
I searched the ADA and the AAOMS for adverse incident reports to justify this proposal for N2O2, without result. Existing 33.341. (b) requires permit holders to report any "unusual incidents ...or injury ... resulted from the administration of ... nitrous oxide/oxygen analgesia." I have never had and incident in 22 years of practice. I have never heard of a reported incident. Are there incidents reported in compliance with 33.341.(b) to justify the additional practice restrictions in the proposed regulations?

Proposed 33.337 (b)(2) "...that the equipment for administering the nitrous oxide/oxygen analgesia has been installed and calibrated according to the manufacturer's guidelines and contains a failsafe system."
All systems commercially available are made with failsafe systems as the industry standard. Permit holders can attest to the fact that they have purchased such a unit but how can they attest that their plumber supervised by the general contractor and the architect installed the equipment according to manufacturer's specifications unless they are a plumber, a contractor or architect? The regulation may ask that permit holders attest to anything, but practically speaking these are not matters that are under the licensee's control.

Proposed 33.340b.(2)(iv) "...appropriate oropharyngeal suction." Anxiolysis with N2O2 alone is not sedation. Patients have all their protective reflexes intact. And routine dental suction is readily available at the dental chair.

Existing 33.340b (a)(2)(viii) "Emergency airway equipment and medications, including intravenous emergency equipment."
This requirement is appropriate for special situations where dentists use intra-venous conscious sedation, intra-muscular sedation or general anesthesia. Many state boards have such regulations. For Restricted Permit II holders it is perhaps the most egregious of the unnecessary requirements proposed and is beyond any proportionality relative to risk and should be eliminated.

I recently heard Dr. Stanley Malamed in the rdental.com presentation of Medical Emergencies in the Dental Office State "there is no state in the U.S. that has a list of drugs and equipment that are to be available in every dental practice In all 50 states where a dentist uses local anesthesia, local anesthesia with nitrous oxide/ oxygen analgesia and/or oral sedation there is no mandated list of drugs. In fact there are few countries in the world which require a mandated list of drugs for all dentists."

Proposed 33.340b(2)(xi) "Signed patient consent." Since patients are conscious and can object at any time there is no statutory requirement for informed consent. It is appropriate to discuss aspects of treatment with initial consent to treat at the beginning of a series of dental treatment appointments but a procedure specific signed patient consent at each visit as is appropriate with a general anesthetic episode is inappropriate for restricted permit II holders. This requirement singles Pennsylvania out as the most restrictive practice environment in the nation as "No other state is believed to have such a requirement for nitrous oxide."(American Dental Association Department of State Government Affairs-State Legislative Report, May 2001, Volume 5).

Thank you again for the opportunity to share my perspective on this isue. If I may be of assistance please do not hesitate to ask.

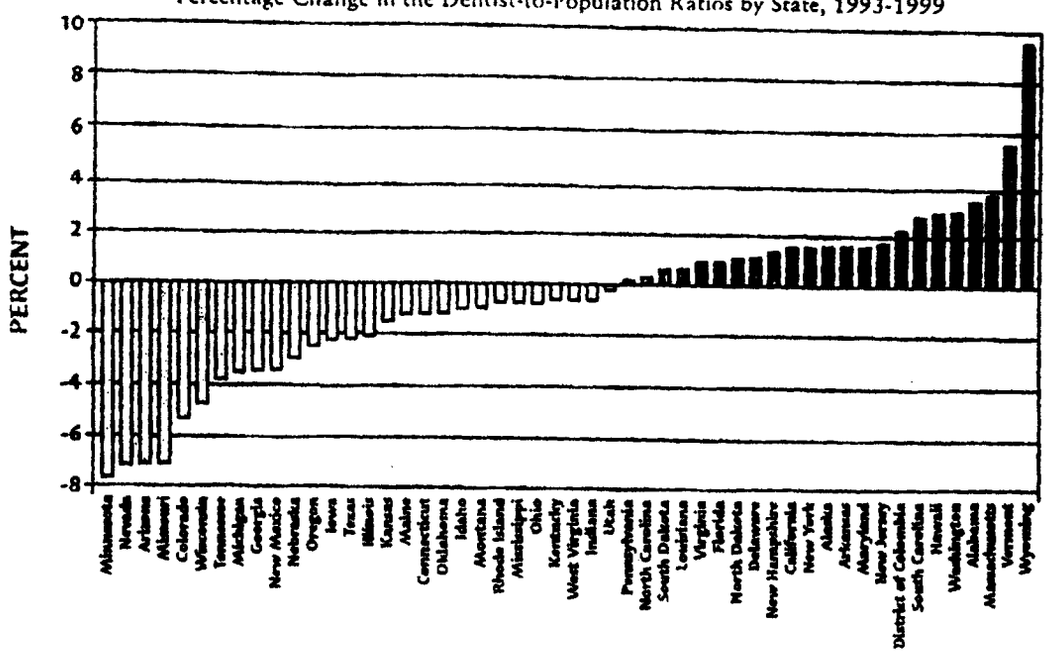
Sincerely,

William T. Spruill, DDS

Attachment A

FIGURE 3.6

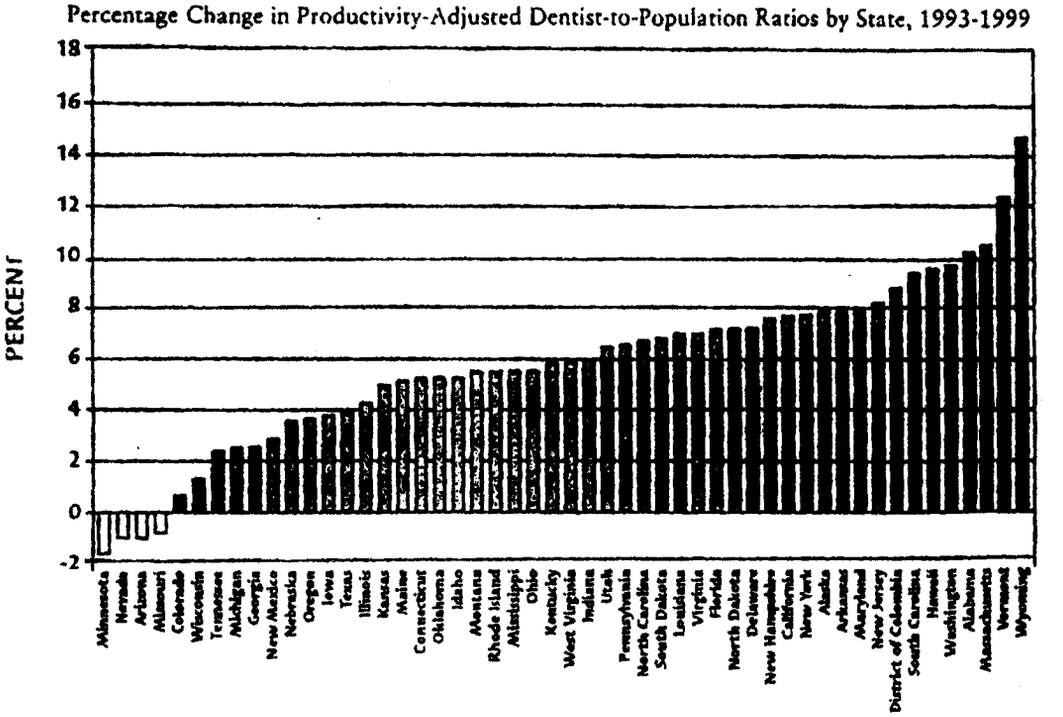
Percentage Change in the Dentist-to-Population Ratios by State, 1993-1999



Source: ADA, *Distribution of Dentists*; and U.S. Department of Commerce, Bureau of the Census, 1990 and 2000 Census.

FIGURE 3.7

Percentage Change in Productivity-Adjusted Dentist-to-Population Ratios by State, 1993-1999



Source: ADA, *Distribution of Dentists*; U.S. Department of Commerce, Bureau of the Census, 1990 and 2000 Census; and Beazoglou et al, 2001.

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Proposed 33.340b.(2)(iv) "...appropriate oropharyngeal suction." Anxiolysis with N2O2 alone is not sedation. Patients have all their protective reflexes intact. And routine dental suction is readily available at the dental chair.

Existing 33.340b (a)(2)(viii) "Emergency airway equipment and medications, including intravenous emergency equipment."
This requirement is appropriate for special situations where dentists use intra-venous conscious sedation, intra-muscular sedation or general anesthesia. Many state boards have such regulations. For Restricted Permit II holders it is perhaps the most egregious of the unnecessary requirements proposed and is beyond any proportionality relative to risk and should be eliminated.

I recently heard Dr. Stanley Malamed in the rdental.com presentation of Medical Emergencies in the Dental Office State "there is no state in the U.S. that has a list of drugs and equipment that are to be available in every dental practice In all 50 states where a dentist uses local anesthesia, local anesthesia with nitrous oxide/ oxygen analgesia and/or oral sedation there is no mandated list of drugs. In fact there are few countries in the world which require a mandated list of drugs for all dentists."

Proposed 33.340b(2)(xi) "Signed patient consent." Since patients are conscious and can object at any time there is no statutory requirement for informed consent. It is appropriate to discuss aspects of treatment with initial consent to treat at the beginning of a series of dental treatment appointments but a procedure specific signed patient consent at each visit as is appropriate with a general anesthetic episode is inappropriate for restricted permit II holders. This requirement singles Pennsylvania out as the most restrictive practice environment in the nation as "No other state is believed to have such a requirement for nitrous oxide."(American Dental Association Department of State Government Affairs-State Legislative Report, May 2001, Volume 5).

Thank you again for the opportunity to share my perspective on this isue. If I may be of assistance please do not hesitate to ask.

Sincerely,

William T. Spruill, DDS

Original: 2233

Pennsylvania Dental Association

January 7, 2001

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JAN 0 7 2002

DOS LEGAL COUNSEL

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

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:

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.* The PDA appreciates the efforts made by the Sub-Committee on Anesthesia to address the issue of safe administration of anesthesia in the dental office.

The PDA has reviewed the proposed regulations and would like to make the following recommendations:

- As the draft regulations presently read in Sections 33.335 (d)(2) and 33.336 (d)(2), there is no definition of "authorized agent." The PDA would like the regulations to read that those "authorized agents" conducting office inspections are dental professionals of the specialty under evaluation. The PDA also believes that agents in possession of an anesthesia permit should conduct inspections of dentists with the same level permit. This would ensure that those most knowledgeable about a particular specialty ascertain whether permit holders are in compliance with state regulations. For instance, a pediatric dentist's office should have the benefit of an inspection by an agent versed in the pediatric dental specialty.

The PDA recommends that office inspections and clinical evaluations for unrestricted permit holders reflect the peer review model described in the American Association of Oral and Maxillofacial Surgeons' (AAOMS) *Office Anesthesia Evaluation Manual.* A similar program should also be applied to restricted permit I holders, in order to ensure fairness and accuracy in the inspection and evaluation process. Allowing for other permit holders of the same specialty to serve in this capacity guarantees that guidelines have been met and patients are protected.

- The PDA recommends amending Section 33.335 (b), to read in part: "All applicants, prior to the administration of general anesthesia [or] deep sedation ~~*or conscious sedation*~~ shall have successfully completed and maintained current certification in [Advanced Cardiac Life Support (ACLS)]...."

The PDA believes that certification in ACLS is a reasonable requirement for the administration of general anesthesia and deep sedation. However, Basic Life Support (BLS) is sufficient for the first three of four levels in the administration of conscious sedation, as well as nitrous oxide/oxygen analgesia.

The PDA believes that requiring ACLS for the administration of conscious sedation may result in a reduction of the number of permit holders in the Commonwealth, thereby hindering access to care for consumers. Currently, there are no clinical guidelines to substantiate the premise that ACLS certification is

necessary for permit level I holders. The American Association of Oral and Maxiollfacial Surgeons (AAOMS) *recommends* that dentists trained to administer general anesthesia maintain certification in ACLS. Thus, *requiring* ACLS for permit I and auxiliary personnel is unnecessary. It may ultimately result in a provider's decision not to apply for an anesthesia permit.

The PDA is also concerned that auxiliary personnel do not have the sufficient educational background in areas including pharmacology, anatomy, and physiology, to competently handle certification in ACLS. In order to perform ACLS each team member is taught to perform life saving techniques by diagnosing the problem and prescribing treatment. For example, auxiliaries are prohibited by law from administering the drug lidocaine, which is a local anesthetic. Yet certification in ACLS would mean that auxiliaries would learn how to administer lidocaine, a technique clearly in violation of the current dental regulation under Section 33.205a. It is more appropriate to amend Sections 33.340 (a)(3)(iv) and 33.340a (a)(3)(iv) to require that auxiliaries obtain certification in BLS. Auxiliaries should maintain their current practice of deferring to advanced medical personnel in the case of an emergency situation.

The PDA would also recommend regulations allowing pediatric dentists the option of maintaining certification in Pediatric Advanced Life Support (PALS). According to the 1996 *American Academy of Pediatric Dentistry's Guidelines for the Elective Use of Pharmacological Conscious Sedation and Deep Sedation in Pediatric Patients*, conscious sedation is defined as "...a controlled, pharmacologically induced, minimally depressed level of consciousness that retains the patient's ability to maintain a patent airway independently and continuously...The drugs, dosages, and techniques used should carry a margin of safety which is unlikely to render the child non-interactive and non-arousable." Normally, complications come from airway obstruction, not cardiac difficulties at these levels of conscious sedation. The PDA believes that certification in PALS should be an additional option for dentists administering general anesthesia or deep sedation to children.

- The PDA recommends amending Section 33.335, pertaining to the requirements for unrestricted permit holders to read as follows: (1) *Successfully completed at least ~~1~~ two year[s] 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.*

Requiring dentists to complete two years of advanced training would be in compliance with the recommendations made by the American Dental Association in Part II of its *Guidelines,* which reads in part: "The trainee must receive the equivalent of two calendar years of training, on a consecutive or divided basis, as the minimum time required to provide an acceptable clinical and didactic program in comprehensive pain and anxiety control..."

- The PDA recommends amending language in Section 33.341 (a)(2) pertaining to the duties of dentists who are not permit holders. The PDA believes it is unnecessary for the state to conduct office inspections of non-permit holder offices that employ the services of itinerant anesthesiologists on an irregular basis. Rather than inspect the office that does not hold the anesthesia-related equipment, it would be more beneficial for dental professionals of the same specialty to inspect the itinerant provider's equipment.

Requiring office inspections for non-permit holders who only ask for anesthesia services a few times a year may discourage dentists, who may incur the cost of an office inspection in order to utilize the services of itinerant providers. This will ultimately affect access to care, particularly for those patients living in rural areas, as well as those with special needs or dental phobias. The regulations should allow itinerant providers to conduct inspections of one another's equipment, similar to the peer review program for other unrestricted permit holders and restricted permit I holders, before transport to the non-permit holder's office. It is incumbent on the non-permit holder to ascertain that itinerant providers, as well as the auxiliary personnel involved with the procedure, are in compliance with board regulation. The PDA recommends

the promulgation of regulations that reflect the following language found in House Bill 286, legislation introduced in the Pennsylvania General Assembly in 1999:

> Section 2. (4): *Permit holders who travel to office locations other than their own to administer anesthesia shall ensure that the office location has the equipment required by board regulation, and that the staff is properly trained to handle anesthesia-related emergencies...A licensee who does not possess a permit issued pursuant to this section shall not allow general anesthesia, conscious sedation or nitrous oxide/oxygen analgesia to be administered on an outpatient basis in his or her dental office unless the office is in compliance with board regulations, including those regulations pertaining to equipment requirements and staffed with a supervised team of auxiliary personnel capable of appropriately managing procedures and emergencies incident to the administration of anesthesia."*

The PDA has worked in collaboration with members of the Pennsylvania General Assembly and other dental organizations on a legislative remedy that provides for safety of anesthesia practice in the dental office. The PDA supports HB 286, sponsored by Representative Kevin Blaum (D-Luzerne), and believes this legislation serves as a reasonable guideline from which to promulgate regulations. The PDA appreciates the continued efforts of the legislature, as well as the State Board of Dentistry, to draft policies that protect both providers and patients.

If you have any questions or concerns, or require more information, please call the Government Relations Department at (717) 234-5941. The PDA looks forward to working with the SBOD in its continued efforts to ensure safe delivery of anesthesia in the dental office.

Sincerely,

ANDREW J. KWASNY DMD, MSD
Chair, Council on Government Relations

cc: John R. McGinley, Chair, 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 and Occupational Affairs
Dr. George A. Kirchner, President
Dr. Richard Finder
PDA Board of Trustees
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Camille Kostelac-Cherry, Esquire, CEO
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Beth Zampogna, Capital Associates

Original: 2233

7 Jan. 2002

Edward L. Witek, Jr., DMD, President
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7329 National Pike Ste. 1
Uniontown, PA 15401
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[redacted]

Deborah B. Eskin, Counsel
State Board of Dentistry
P.O. Box 2469
Harrisburg, PA 17105-2649

RE: No. 16A-4610 (Administration of General Anesthesia, Deep Sedation, etc.)

Dear Ms. Eskin.

The Pennsylvania Academy of General Dentistry has reviewed the proposed rulemaking of the State Board of Dentistry and offers the following observations:

§ 33.340B(a)(2)(iv) requires suction equipment with [illegible] oropharyngeal suction for permit II holders. It is our belief that this is unnecessary and unduly burdensome. Existing in-office suction devices should be deemed adequate. Therefore, we feel that this should be deleted from the proposed regulations.

§ 33.340b(a)(2)(viii) requires emergency airway [illegible] and medications including intravenous emergency equipment for permit II holders. It is our opinion that the reference to medications and intravenous emergency equipment is incongruous with the scope of a restricted permit II holder. Requiring permit II holders to administer I.V. medications may likely do more harm and clearly is in the realm of a permit I or unrestricted permit holder. Further, requiring permit II holders to have I.V. equipment and necessary drugs puts them in the tenuous position of legal jeopardy. That is, if they have the equipment, are they not required to use it in an emergency? Does their training in Nitrous Oxide/Oxygen analgesia accord them the proficiency to start a parenteral [illegible] and administer medications?

§ 33.340b(a)(2)(xi) requires results of patient history and physical evaluation. This is confusing and in contradistinction with the "Description of Amendments" in the preamble which states that, "This section is intended to require that patients be given a physical evaluation prior to the administrations of nitrous oxide/oxygen analgesia." Further, this section also states that, "permit II holders are *not* required to ... have results of a patient history." Which is correct? Will permit II holders be required to perform a physical evaluation and a patient history and record such results, or will a physical evaluation only be required? It is our opinion that the latter be enacted, i.e. that the patient be given a physical evaluation prior to the administration of nitrous oxide/oxygen analgesia.

While the Pennsylvania Academy of General Dentistry understands the scope of the Board to promulgate these regulations, and while we are cognizant of the Wheatley v State Board of Dentistry case, we feel it necessary to state our position that nitrous oxide/oxygen analgesia is a safe and effective modality uniquely different from general anesthesia, deep sedation and conscious sedation and should not be treated with the same harshness as these other modalities. A literature search could reveal no incidents resulting in morbidity or mortality related to the administration of nitrous oxide/oxygen analgesia in a proper dental setting. Therefore, further regulations of this modality are not warranted on a scientific basis.

Finally, I would like to stress that the PAOD has held this position from the beginning of this process and I refer you to our pre-draft input letter written by our past president, Dr. Martin Schroeder. I am appending a copy of this letter reflecting our position for your review. While some regulation is good and can protect the public, unnecessary regulation is burdensome and will not provide any more public safety.

The PAOD thanks the State Board for allowing our input. We hope that our suggestions are taken constructively and acted upon accordingly.

Respectfully submitted,

Edward L. Witek, Jr., DMD, FAGD

Executive Director

Pennsylvania Academy of General Dentistry

JAN - 7 2002

Original: 2233

NORTH PENN DENTAL ARTS

Family Dentistry/Anesthesia

Stanley J. Heleniak, D.M.D.

Dentist Anesthesiologist
Diplomate, American Dental Board of Anesthesiology
Fellow, American Dental Society of Anesthesiology

January 7, 2002

Deborah B. Eakin Esq.
Counsel,
P.A. State Board of Dentistry
P.O. Box 2649
Harrisburg, PA 17105-2649

Dear Ms. Eakin:

Attached are my personal comments regarding the boards' proposed changes to the dental anesthesia regulations. Thank you.

Yours,

Stanley J. Heleniak DMD

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JAN - 7 2002

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Member of the Pennsylvania Dental Association

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DOS LEGAL COUNSEL

33.331 Definitions

Definition should be added to define and describe oral or enteral sedation and combinations of enteral and nitrous oxide. These can easily lead to states of deep sedation and general anesthesia. These techniques and issues are addressed in the ADA guidelines and training requirements.

33.332

An amendment should clarify that a permit is required to administer enteral sedation and combinations with nitrous oxide.

33.333 Types of Permits

Either a new permit category for enteral sedation and combinations with nitrous oxide or conscious sedation, unrestricted permits needed depending on levels of anesthesia attained with drugs and dosages used.

33.335 Requirements for Unrestricted Permits

Other than requirements for ACLS & PALS be mandated that administration of anesthesia be in accordance with only ADA guidelines or they are all inclusive for anesthesia for all ages and all dental specialties.

Permit holders should pass a clinical exam, but not an AAMOS exam as this is designed for OMFS and is prejudicial to all other dentists providing unrestricted anesthesia and practices for other specialties of dentistry.

Physicians administrating anesthesia should obtain a permit and abide by all the aforementioned requirements and be an anesthesiologist in good standing.

33.340 Equipment lists or recommendations should be is accordance with ADA guidelines for reasons stated previously and should include ETCO2 monitoring, an AEO can be substituted for by a standard defibrillator. These items may change with time as standards of care change and clinical situations dictate.

It would be inappropriate for all persons involved in assisting the permit holder be ACLS certified since customary levels of education of staffs would not make ACLS understandable and possible. Dental assistants are not trained to paramedic or R.N. level. Others directly involved in anesthetic administrations such as CRNA's or physician anesthesiologist must be ACLS & PALS certified.

If general anesthesia is being administrated, it does not make any difference if intubated or not. Actually non intubating GA where the operator is also anesthetist is more risky due to airway insecurity. Any reference to AAMOS should be dropped as this is specific to OMFS only.

33.341 Duties of Non Permit Holders

The dentist permit holder and his/her equipment should have been inspected and certified only, not the non permit holders office. The facility does not perform the anesthesia, the permit holder does.

33.340b Duties of Restricted II Holders

2. viii Competency in the use of emergency airway equipment and meds, including IV equipment needs to be verified, otherwise to have and not be able to use is of no value and should be eliminated as a requirement.

JAN - 7 2002

Original 2233

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
John R. McGinley, Chair, Independent Regulatory Review Commission
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The Honorable Clarence D. Bell
The Honorable Lisa Boscola
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