

Regulatory Analysis Form		This space for use by IRRC
(1) Agency Department of State, Bureau of Professional and Occupational Affairs, State Board of Dentistry		RECEIVED 2007 NOV 14 PM 12:13 REVIEW COMMISSION IRRC Number: <u>2233</u>
(2) I.D. Number (Governor's Office Use) 16A-4610		
(3) Short Title Administration of General Anesthesia, Deep Sedation, Conscious Sedation and Nitrous Oxide/Oxygen Analgesia		
(4) PA Code Cite 49 Pa. Code Chapter 33, Subchapter E	(5) Agency Contacts & Telephone Numbers Primary Contact: Deborah B. Eskin, Counsel State Board of Dentistry (717) 783-7200 Secondary Contact: Joyce McKeever, Deputy Chief Counsel, Department of State (717) 783-7200	
(6) Type of Rulemaking (check one) <input checked="" type="checkbox"/> Proposed Rulemaking <input type="checkbox"/> Final Order Adopting Regulation <input type="checkbox"/> Final Order, Proposed Rulemaking Omitted	(7) Is a 120-Day Emergency Certification Attached? <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes: By the Attorney General <input type="checkbox"/> Yes: By the Governor	
(8) Briefly explain the regulation in clear and nontechnical language. These proposed amendments would enhance requirements for permit holders who administer general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia, specifically with reference to "appropriate monitoring equipment", in response to <u>Watkins v. State Board of Dentistry</u> .		
(9) State the statutory authority for the regulation and any relevant state or federal court decisions. The Board is authorized to adopt regulations concerning anesthesia under Sections 3(1) and 11.2(a) of the Dental Law (Law), Act of May 1, 1933, P.L. 216, <u>as amended</u> , 63 P.S. §§122(o), 130c.(a).		

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(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

The regulations are mandated by the Commonwealth Court opinion in the matter of Watkins v. State Board of Dentistry, 740 A.2d 760 (Pa. Cmwlth. 1999), which vacated and remanded the decision of the State Board of Dentistry imposing an eighteen month suspension on Dr. Watkins for failing to assure that his office contained "appropriate monitoring equipment".

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

The incident which triggered the disciplinary action in Watkins involved the administration of anesthesia by another dentist to a three and a half year old child in Dr. Watkins' office. The child lost all pulse during a procedure and was pronounced dead after being taken to the hospital. The regulations now require that the administration of anesthesia/analgesia to children age ten and under conform with the American Academy of Pediatric Dentistry's Guidelines for the Elective Use of Conscious Sedation, Deep Sedation and General Anesthesia in Pediatric Patients. Specific monitoring equipment and other provisions are required to enhance the safety of both children and adults while receiving general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia in dental offices.

(12) State the public health, safety, environmental or general welfare risks associated with nonregulation.

Nonregulation may subject children and adults to less than optimum standards, procedures and equipment when receiving general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia in dental offices.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

Proposed amendments will help protect the health and safety of children and adults receiving general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia in dental offices.

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(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

Permit holders may perceive that they are adversely affected if permit fees increase or fees are charged for office inspections and clinical evaluations.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

Permit holding dentists and nonpermit holding dentists who administer general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia in permit holding dentists' offices will be affected.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

In accordance with Executive Order 1996-1, the Board sent a draft of this proposed rulemaking on April 28, 2001 to 138 dental associations, schools and interested individuals for predraft comment. The Board considered these comments. A copy of the list of persons and groups who were involved is attached to this Regulatory Analysis Form.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

Specific estimates of costs will be developed as part of separate regulation packages to either increase permit fees or charge office inspection and clinical evaluation fees. At this time, specific estimates are not available.

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(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

This rulemaking will not involve any direct costs or savings to local government and will not involve any legal, accounting or consulting procedures.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required.

There should be no additional costs or savings to state government since the cost of implementing the regulation will be born by permit holders.

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(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY	FY +1	FY +2	FY +3	FY +4	FY +5
SAVINGS:	\$N/A	\$N/A	\$N/A	\$N/A	\$N/A	\$N/A
Regulated Community						
Local Government						
State Government						
Total Savings						
COSTS:	N/A	N/A	N/A	N/A	N/A	N/A
Regulated Community						
Local Government						
State Government						
Total Costs						
REVENUE LOSSES:	N/A	N/A	N/A	N/A	N/A	N/A
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

(20a) Explain how the cost estimates listed above were derived.

N/A

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(20b) Provide the past three year expenditure history for programs affected by the regulation.
N/A

Program	FY -3	FY -2	FY -1	Current FY

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

N/A.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

No nonregulatory alternatives were considered because of the fact that the decision in Watkins made it clear that regulatory changes would be needed.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

No alternate regulatory schemes were considered.

Regulatory Analysis Form

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

The Board is not aware of any federal standards that relate to the issues addressed in this rulemaking.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

This rulemaking should put Pennsylvania in the forefront of public health and safety measures related to anesthesia/analgesia provided to children and adults in dental offices. No competitive disadvantage with other states should occur. See attached chart labeled page 7A.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No other regulations and state agencies would be affected by these regulations.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

An early draft of this proposed rulemaking was sent out for public comment in accordance with paragraph (16) above. The Board holds monthly meetings at 124 Pine Street, Harrisburg, Pennsylvania 17101 at which all information relative to this rulemaking will be discussed.

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(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

The existing reporting requirement on deaths or "unusual incidents" has been amended to just "incidents" and to cover deaths or incidents resulting from the administration of deep sedation. This would increase reporting requirements for dentists, as dentists would be required to report all "incidents", rather than only "unusual incidents".

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

Special provisions have been enacted to protect children aged ten and under who receive general anesthesia, deep sedation and conscious sedation in dental offices.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

Because of the public health and safety issues involved and the direction of Commonwealth Court in Watkins, as well as considerable legislative concern, the Board urges that the proposed amendments be adopted as soon as possible.

(31) Provide the schedule for continual review of the regulation.

The proposed amendments have not been given a sunset date. The Board regularly evaluates the effectiveness of the proposed amendments following their adoption as final rulemaking.

Status of Health and Safety Standards
for Dental Anesthesia/Analgesia for
Adults and Children in Pennsylvania
and Surrounding States

	General Anesthesia Permit	Deep Sedation Permit	Conscious Sedation Permit	Nitrous Oxide/ Oxygen Analgesia Permit	CLS or ACLS	AAMS Standards	American Academy of Pediatric Dentistry Standards	Office Inspection	Specified Monitoring or Equipment
PA	yes	yes	yes	yes	ACLS	yes	yes	yes	yes
New York	certificate	certificate	certificate	no	ACLS/CLS	no	no	no	yes
New Jersey	yes	no	yes	no	Amer.Heart Assoc.'s Basic Life Support	no	no	yes	yes
West Virginia	yes	no	yes	no	no	no	yes	yes	yes
Ohio	yes	yes	yes	no	no	yes	no	yes	yes
Delaware	yes	yes	yes	yes	CLS	no	no	yes	yes

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Updated - May 12, 2000

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FACE SHEET
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REVIEW COMMISSION

2233

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Copy below is hereby approved as to
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[Signature]
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(DEPUTY ATTORNEY GENERAL)

OCT 24 2001

DATE OF APPROVAL

Copy below is hereby certified to be a true and correct
*copy of a document issued, prescribed or promulgated by:

STATE BOARD OF DENTISTRY
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-4610

DATE OF ADOPTION:

BY: *[Signature]*
Norbert O. Gannon, D.D.S.

TITLE: Chairman
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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Agencies.

[Signature]

DATE OF APPROVAL

(Deputy General Counsel
(Chief Counsel,
Independent Agency
(Strike inapplicable
title)

[] Check if applicable
Copy not approved.
Objections attached.

[] Check if
applicable. No Attorney
General approval or
objection within 30 day
after submission.

NOTICE OF PROPOSED RULEMAKING
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF DENTISTRY
49 Pa. Code, Chapter 33

SUBCHAPTER E. ADMINISTRATION OF GENERAL ANESTHESIA, DEEP SEDATION,
CONSCIOUS SEDATION AND NITROUS OXIDE/OXYGEN ANALGESIA

The State Board of Dentistry (Board) proposes revisions to its anesthesia regulations at 49 Pa. Code, Chapter 33, Subchapter E, administration of general anesthesia, conscious sedation and nitrous oxide/oxygen analgesia, as set forth in Annex A.

A. Effective Date

The amendments will be effective upon publication of final form regulations in the Pennsylvania Bulletin.

B. Statutory Authority

The Board is authorized to adopt regulations concerning anesthesia under Sections 3(1) and 11.2(a) of the Dental Law (Law), Act of May 1, 1933, P.L. 216, as amended, 63 P.S. §§ 122(o), 130c.(a).

C. Background and Purpose

The proposed amendments are in response to a Commonwealth Court opinion in the matter of Watkins v. State Board of Dentistry, 740 A.2d 760 (Pa. Cmwlth. 1999), which vacated and remanded the decision of the State Board of Dentistry imposing an eighteen month suspension on Dr. Watkins for failing to assure that his office contained “appropriate monitoring equipment”.

Dr. William E. Watkins had been charged with and found by the Board to have engaged in unprofessional conduct under Section 4.1(8) of the Dental Law, 63 P.S. § 123.1(8). The charge and finding of unprofessional conduct relevant to the above issue resulted from his failure to have the “appropriate monitoring equipment” required by Section 340(a)(2) of the Board’s regulations, 49 Pa.Code § 33.340(a)(2). The incident which triggered the disciplinary action involved the administration of anesthesia by another dentist to a 3-1/2 year old child in Dr. Watkins’ office. The child lost all pulse during a procedure and was pronounced dead after being taken to hospital.

At the formal hearing the Commonwealth presented experts who maintained that “appropriate monitoring equipment” which should have been, but was not, in the office included a pulse oximeter, a blood pressure apparatus, a stethoscope and an EKG machine.

In appealing his disciplinary suspension to the Commonwealth Court, Dr. Watkins argued that the Board’s regulation requiring “appropriate monitoring equipment” was unconstitutionally vague because it did not give notice to the practitioner of what equipment would be considered appropriate. After reviewing cases under which statutes or regulations were declared unconstitutionally vague, the court held that “the term ‘appropriate monitoring equipment’ is not defined in the regulation and what is ‘appropriate’ is subject to many different meanings. Watkins, 740 A.2d at 765 (emphasis added). Again, in footnote number 8 of the decision the Court focused on

the term “appropriate monitoring equipment”: “Because we have decided that the term “appropriate monitoring equipment” is too vague....Id. (emphasis added).

While the Board focused its attention primarily upon clarifying necessary monitoring equipment, it also updated and improved other anesthesia requirements, and attempted to respond to numerous legislative concerns.

The Watkins decision was issued by Commonwealth Court November 8, 1999. On December 2, 1999, the first meeting of the Dental Board’s Anesthesia Committee was held. This Committee was tasked with reviewing state of the art equipment, procedures and protocols for safe and effective delivery of anesthesia and analgesia in dental offices. An initial draft was prepared and presented to the Committee at its January 21, 2000 meeting. At subsequent meetings on March 9, 2000, a second draft was presented and reviewed and on March 12, 2000, a third draft was developed.

A fourth draft was completed on April 10, 2000, and on April 28, 2000, sent to 138 dental associations, schools and interested individuals for pre-draft comments. In response to pre-draft comments received, a fifth draft was prepared on May 30, 2000. Legal and Board changes resulted in a sixth draft on June 9, 2000 and a seventh draft on June 27, 2000. Further development was postponed temporarily until the Anesthesia Committee could review information concerning a new oral anesthesia and reports of child deaths due to anesthesia in another state, and consider appropriate regulation of deep sedation. As a result, on October 12, 2000, an eighth draft was prepared and discussed by the Committee with the full Board on December 1, 2000. From those discussions, a ninth draft was prepared on December 14, 2000, and reviewed by the Committee. This draft was provided to the entire Board on January 24, 2001. Board, legal, and additional legislative suggestions comprised a tenth draft on March 9, 2001 and a 10A draft on March 22, 2001. On March 23, 2001 the State Board of Dentistry approved draft 10B for promulgation as proposed rulemaking. On April 5, 2001, draft 10B was sent to the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee for review and comment prior to official promulgation as proposed regulations.

D. Description of Amendments

The revisions to Subchapter E make substantive and editorial changes to Sections 33.331-333.342.

§33.331. Definitions.

The Board proposes to add a definition for deep sedation derived from 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. This was done in recognition of the fact that even though sedation is on a continuum, deep sedation is a defined stage between

general anesthesia and conscious sedation. The AAPD, the American Association of Oral and Maxillofacial Surgeons (AAOMS) and the American Dental Association (ADA) all recognize distinctions between general anesthesia and deep sedation.

Deep sedation is a state of depressed consciousness accompanied by a partial loss of protective reflexes, including the ability to continually maintain an airway independently. General anesthesia is a state of unconsciousness accompanied by a partial or complete loss of protective reflexes, including the ability to continually maintain an airway independently. ADA Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia for Dentists (emphasis added). Because of the partial loss of protective reflexes with deep sedation, and the necessity to have similar monitoring and resuscitation equipment as with general anesthesia, deep sedation was grouped with general anesthesia under the unrestricted permit. Consequently, only a licensee holding an unrestricted permit may administer general anesthesia or deep sedation.

§ 33.332. Requirement of permit to administer general anesthesia, conscious sedation or nitrous oxide/oxygen analgesia.

This amendment would clarify that a permit is required to administer deep sedation in a dental office.

§ 33.333. Types of permits.

This amendment would clarify that an unrestricted permit is required to administer deep sedation.

§ 33.334. Application for permit.

This section makes permit application requirements applicable to permission to administer deep sedation.

§ 33.335. Requirements for unrestricted permit.

This amendment would remove one of the three possible requirements that must be met for securing an unrestricted permit, specifically that of having administered general anesthesia on a regular basis in the course of dental practice for five years prior to January 1, 1986. The 1985 “grandparenting” clause of Section 11.2(b) of the Law, 63 P.S. §130c(d), tracked in the regulation is no longer necessary.

All permit applicants would be required to have successfully completed and maintained current certification in Advanced Cardiac Life Support (ACLS) and attest that the administration of general anesthesia, deep sedation, and conscious sedation will be conducted in conformance with the American Association of Oral and Maxillofacial Surgeons’ (AAOMS) Parameters and Pathways

2000: Clinical Practice, Guidelines for Oral and Maxillofacial Surgery, Anesthesia in Outpatient Facilities. For administration to children age ten and under, applicants would have to attest that the administration will be conducted in conformance with the AAPD Guidelines for the Elective Use of Conscious Sedation, Deep Sedation and General Anesthesia in Pediatric Dental Patients.

The dental office of an unrestricted permit holder would have to pass an inspection conducted in accordance with the AAOMS Office Anesthesia Evaluation Manual and the American Dental Association's (ADA) Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia for Dentists. A reinspection would occur at least every six years, and the make, model and serial number of all equipment would have to be available and noted in the inspection report.

Unrestricted permit holders would have to pass a clinical evaluation as part of the office inspection conducted in accordance with the AAOMS Office Anesthesia Evaluation Manual.

§ 33.336. Requirements for restricted permit I.

This section would remove one of the two possible requirements for securing a restricted permit I, specifically that of having administered conscious sedation on a regular basis in the course of dental practice for five years prior to January 1, 1986. As described above, the section is no longer necessary.

Restricted permit I applicants would be required to have successfully completed and maintained current certification in ACLS and attest that the administration of conscious sedation will be conducted in accordance with the AAOMS Parameters and Pathways 2000: Clinical Practice, Guidelines for Oral and Maxillofacial Surgery, Anesthesia in Outpatient Facilities.

Applicants administering conscious sedation to children age ten and under would have to attest that the administration is conducted in accordance with the AAPD Guidelines for the Elective Use of Conscious Sedation, Deep Sedation and General Anesthesia in Pediatric Patients.

Dental offices of restricted permit I holders would have to pass an inspection in accordance with the AAOMS Office Anesthesia Manual and the ADA Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia for Dentists. Reinspection would have to be done at least every six years and the make, model and serial number of all equipment must be available.

Restricted permit I applicants would have to pass a clinical evaluation as part of the office inspection conducted in accordance with the AAOMS Office Anesthesia Evaluation Manual.

§ 33.337. Requirements for restricted permit II.

This section would remove one of the two possible requirements that must be met for securing a restricted permit II, specifically that of having administered nitrous oxide/oxygen

analgesia on a regular basis in the course of dental practice for five or more years prior to January 1, 1986 for the reasons set forth above. Also, the Board proposes to reduce the number of required hours of undergraduate or postgraduate didactic instruction and clinical experience in a conforming program from 40 to 20.

Restricted permit II holders would have to attest that they have written office procedures for administering nitrous oxide/oxygen analgesia and handling emergencies and that the equipment has been installed and calibrated according to the equipment manufacturer's guidelines and contains a failsafe system.

§ 33.338. Expiration and renewal of permits.

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

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

This section has been amended to require that a history be taken prior to the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia.

The equipment list for unrestricted permit holders has been amended to require suction equipment with appropriate oropharyngeal suction; age appropriate monitoring equipment, procedures and documentation conforming to the AAOMS Office Anesthesia Evaluation Manual/AAPD Guidelines for the Elective Use of Conscious Sedation, Deep Sedation and General Anesthesia in Pediatric Dental Patients; a pulse oximeter; an ECG; an automatic blood pressure monitoring device; an automatic external defibrillation device; results of patient history and physical evaluations; and signed patient consent.

This section was also amended to require that both the permit holder and auxiliary personnel assisting unrestricted permit holders in the administration of general anesthesia, deep sedation or conscious sedation (deletes reference to nitrous oxide/oxygen analgesia) be currently certified in ACLS.

A proposed amendment to this section would require 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 dental procedures are performed by a dental licensee not involved in the anesthesia administration.

All monitoring equipment would have to be installed and calibrated according to equipment manufacturer guidelines, in proper working condition prior to administration, and used during the administration of general anesthesia.

Any equipment used for the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia must pass an inspection through the Board's authorized agents in accordance with the AAOMS Office Anesthesia Manual. The make, model and serial number of all equipment must be available and noted on the inspection report

§ 33.340a. Duties of dentists who are restricted permit I holders.

This section would be amended to require that a history be taken and a patient be given a physical evaluation to determine his/her suitability to receive conscious sedation or nitrous oxide/oxygen analgesia.

Equipment requirements would be amended, and would conform to the new equipment requirements for an unrestricted permit. Auxillary personnel and the certified registered nurse anesthetists assisting the permit holder in the administration of conscious sedation, as well as the permit holder, must be currently certified in ACLS.

Requirements for reporting and other equipment requirements are the same as for unrestricted permit holders.

§ 33.340b. Duties of dentists who are restricted permit II holders.

This section is amended to require that patients be given a physical evaluation prior to the administration of nitrous oxide/oxygen analgesia.

Equipment and operating room requirements are similar to those of restrictive permit I holders, with the exception that restricted permit II holders are not required to have a recovery area, patient transport equipment, an oximeter, an ECG, an automatic blood pressure monitoring device, automatic defibrillation device, and results of patient history.

§ 33.341. Duties of dentists who are not permit holders.

This section would require that a permit may not be issued unless the dental office has been inspected and meets the appropriate equipment and facility requirements.

Anyone administering general anesthesia, deep sedation or conscious sedation must possess current certification in ACLS.

A nonpermit holding dentist would be required to verify with the permit holder that all

monitoring equipment is present in the nonpermit holder's office, is properly calibrated and in proper working condition, and is being used during the administration of general anesthesia.

All equipment transported to a non-permit holder dentist's office would have to pass an inspection through the Board's authorized agents in accordance with the AAOMS Office Anesthesia Manual. The make, model and serial number of all equipment must be available and noted on the inspection report.

§ 33.342. Inspection of dental offices.

Under the proposal, subsection (f) has been amended to provide that a permit may be subject to an immediate temporary suspension and other disciplinary action if inspection reveals that the dental office is not in compliance with equipment, facility or procedure requirements prescribed in §§ 33.340(a)(2), 33.340a.(a)(2) or 33.340b.(a)(2), (relating to duties of dentists who are permit holders) and such noncompliance presents an immediate and clear danger to public health and safety.

E. Compliance With Executive Order 1996-1

The Board reviewed this rulemaking and considered its purpose and likely impact upon the public and the regulated population under the directives of Executive Order 1996-1. The regulation addresses a compelling public interest as described in this Preamble and otherwise complies with Executive Order 1996-1.

F. Fiscal Impact and Paperwork Requirements

Some of the provisions of this proposed rulemaking will have a fiscal impact upon permit holders. It may be necessary to set fees for office inspections and clinical evaluations or to raise existing permit fees to cover the cost of the issuance of a permit. In addition, requirements for current certification in ACLS and some additional required monitoring equipment may entail increased costs to permit holders. At this stage, it is not possible to estimate the fiscal impact with precision; however, cost data will be available at a later date.

G. Sunset Date

The Board continuously monitors its regulations. Therefore, no sunset date has been assigned.

H. Regulatory Review

Under section 5(a) of the Regulatory Review Act, the Act of June 30, 1989, P.L. 73, No. 19 (71 P.S. §§745.1-745.15), the Board submitted a copy of this proposed regulation on November 14, 2001 to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the

House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee. In addition to submitting the proposed rulemaking, the Board has provided the Commission and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Board in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, if IRRC has any objections to any portion of the proposed rulemaking, it will notify the Board within 10 days of the close of the Committees' review period. The notification shall specify that regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the regulations, by the Board, the General Assembly and the Governor, of objections raised.

H. Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed regulation to Deborah B. Eskin, Counsel, State Board of Dentistry, P.O. Box 2649, Harrisburg, Pennsylvania 17105-2649 within thirty (30) days following publication of the proposed regulation in the Pennsylvania Bulletin. Please reference No. 16A-4610 (Administration of General Anesthesia, Deep Sedation, Conscious Sedation and Nitrous Oxide/Oxygen Analgesia) when submitting comments.

ANNEX A
TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS
PART I. DEPARTMENT OF STATE
Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS
CHAPTER 33. STATE BOARD OF DENTISTRY

Subchapter E. ADMINISTRATION OF GENERAL ANESTHESIA,
DEEP SEDATION, CONSCIOUS SEDATION AND
NITROUS OXIDE/OXYGEN ANALGESIA

§ 33.331. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

AAOMS – American Association of Oral and Maxillofacial Surgeons.

AAPD – American Academy of Pediatric Dentistry.

ACLS – Advanced Cardiac Life Support.

ADA – American Dental Association.

Conscious sedation - A minimally depressed level of consciousness that is produced by a pharmacologic method, a nonpharmacologic method, or a combination of both, in which the patient retains the ability to maintain an airway independently and continuously and to respond appropriately to physical stimulation or verbal command.

Deep sedation - A controlled, pharmacologically induced state of depressed consciousness from which the patient is not easily aroused and which may be accompanied by a partial loss of protective reflexes, including the ability to maintain a patent airway independently and/or respond purposefully to physical stimulation or verbal command.

General Anesthesia - A controlled state of unconsciousness, including deep sedation, that is produced by a pharmacologic method, a nonpharmacologic method, or a combination of both, and that is accompanied by a complete or partial loss of protective reflexes that include the patient's inability to maintain an airway independently and to respond purposefully to physical stimulation or verbal command.

Nitrous oxide/oxygen analgesia - The diminution or elimination of pain in the conscious patient through the use of nitrous oxide/oxygen.

§ 33.332. Requirement of permit to administer general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia.

(a) *Permit required for administration of anesthetic modality in dental office.* [Effective January 9, 1990, a] A dentist shall possess a current permit issued by the Board under this subchapter before administering, or supervising the administration of, general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia in a dental office.

(b) *Permit not required for administration of anesthetic modality in other facilities.* A dentist is not required to possess a permit under this subchapter before administering, or supervising the administration of, general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia in a State- or Federally-regulated facility other than a dental office.

(c) *Failure to comply.* A dentist's failure to comply with subsection (a) will be considered unprofessional conduct and will subject the dentist to disciplinary action under section 4.1 of the act (63 P.S. §123.1).

§ 33.333. Types of permits.

The Board will issue the following permits to licensees qualified under this subchapter:

(1) *Unrestricted permit.* A permit which authorizes the holder to administer general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia.

(2) *Restricted permit I.* A permit which authorizes the holder to administer conscious sedation or nitrous oxide/oxygen analgesia.

(3) *Restricted permit II.* A permit which authorizes the holder to administer nitrous oxide/oxygen analgesia.

§ 33.334. Application for permit.

(a) A dentist who desires to obtain a permit to administer general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia shall submit an application on a form provided by the Board, pay the permit fee prescribed in § 33.339 (relating to fees for issuance of permits) and meet the requirements for the permit applied for as prescribed in this subchapter.

(b) Application forms may be obtained from the State Board of Dentistry, Post Office Box 2649, Harrisburg, Pennsylvania 17105-2649.

§ 33.335. Requirements for unrestricted permit.

(a) To secure an unrestricted permit, a dentist shall have [be certified] possess current certification:

(1) Successfully completed at least 1 year in a postgraduate 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; or

(2) [Be certified] Possess current certification as a Diplomat of the American Board of Oral and Maxillofacial Surgeons, a Fellow of the American Association of Oral and Maxillofacial Surgeons or a Fellow of the American Society of Dental Anesthesiology, or be eligible for examination by the American Board of Oral and Maxillofacial Surgeons.

[(3) Administered general anesthesia on a regular basis in the course of his dental practice for at least 5 years prior to January 1, 1986, if the applicant:

(i) Is competent to administer general anesthesia.

(ii) Administers general anesthesia in a properly equipped dental office as prescribed in § 33.340(a)(2) (relating to duties of dentists who are permit holders.)

[(b) To determine whether the requirements of subsection (a)(3) are satisfied, the Board will require the applicant to undergo a clinical evaluation and office inspection conducted by the Board through its authorized agents. The clinical evaluation and office inspection will be conducted in accordance with the American Association of Oral and Maxillofacial Surgeons' *Office Anesthesia Evaluation Manual*.

(c) A dentist who applies for a permit under subsection (a)(3) shall do so by January 9, 1990.]

(3) All applicants, prior to the administration of general anesthesia, deep sedation or conscious sedation, must have successfully completed and maintained current certification in ACLS and attest that the administration of general anesthesia, deep sedation and conscious sedation will be conducted in conformance with the standards outlined in the AAOMS Parameters and Pathways 2000: Clinical Practice, Guidelines for Oral and Maxillofacial Surgery, Anesthesia in Outpatient Facilities or subsequent edition.

(4) If the applicant desires to administer general anesthesia, deep sedation or conscious sedation to children age ten and under, prior to such administration, the applicant shall attest that the administration of general anesthesia, deep sedation and conscious sedation will be conducted in conformance with the standards outlined in the AAPD *Guidelines for the Elective Use of Conscious Sedation, Deep Sedation and General Anesthesia in Pediatric Dental Patients* or subsequent edition.

(b) Office inspection.

- (1) The dental office where the applicant intends to exercise an unrestricted permit must meet the requirements of § 33.340(a)(2) (relating to duties of dentists who are unrestricted permit holders), and the office must pass an inspection conducted by the Board through its authorized agents in accordance with the requirements of the AAOMS *Office Anesthesia Evaluation Manual* or subsequent edition and the ADA *Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia for Dentists* or subsequent edition. Reinspection will take place at least every six years, or more frequently, as necessary. The make, model and serial number of all equipment must be available and noted on the inspection report.
- (2) As part of the office inspection, the applicant must pass a clinical evaluation conducted by the Board through its authorized agents in accordance with the requirements of the AAOMS *Office Anesthesia Evaluation Manual* or subsequent edition.

§ 33.336. Requirements for restricted permit I.

(a) To secure a restricted permit I, a dentist shall have [done one of the following]:

(1) Successfully completed a course on conscious sedation comprising at least 80 hours of undergraduate or postgraduate didactic instruction and clinical experience in a program that conforms to Part I (for an undergraduate program) or Part III (for a post graduate program) of the American Dental Association's *Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry* or subsequent edition.

[(2) Administered conscious sedation on a regular basis in the course of his dental practice for 5 or more years prior to January 1, 1986, if the applicant:

- (i) Is competent to administer conscious sedation.

(ii) Administers conscious sedation in a properly equipped dental office as prescribed in § 33.340(a)(2) (relating to duties of dentists who are permit holders).]

[(b) To determine whether the requirements of subsection (a)(2) are satisfied, the Board will require the applicant to undergo a clinical evaluation and office inspection conducted by the Board through its authorized agents. The clinical evaluation and office inspection will be conducted in accordance with the American Association of Oral and Maxillofacial Surgeons' *Office Anesthesia Evaluation Manual*.

(c) A dentist who applies for a permit under subsection (a)(2) shall do so by January 9, 1990.]

(2) All applicants, prior to the administration of conscious sedation, must have successfully completed and maintained current certification in ACLS and attest that such administration will be conducted in conformance with the standards outlined in the AAOMS *Parameters and Pathways 2000: Clinical Practice, Guidelines for Oral and Maxillofacial Surgery, Anesthesia in Outpatient Facilities* or subsequent edition.

(3) If the applicant desires to administer conscious sedation to children age ten and under, prior to such administration, the applicant shall attest that the administration of conscious sedation will be conducted in conformance with standards outlined in the AAPD *Guidelines for the Elective Use of Conscious Sedation, Deep Sedation and General Anesthesia in Pediatric Patients* or subsequent edition.

(b) Office inspection.

(1) The dental office where the applicant intends to exercise a restricted permit I must meet the requirements of § 33.340a.(a)(2) (relating to duties of dentists who are restricted permit I holders), and the office must pass an inspection conducted by the Board through its authorized agents in accordance with the requirements of the AAOMS *Office Anesthesia Evaluation Manual* or subsequent edition and the ADA *Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia for Dentists* or subsequent edition. Reinspection will take place at least every six years, or more frequently, as necessary. The make, model and serial number of all equipment must be available and noted on the inspection report.

(2) As part of the office inspection, the applicant must pass a clinical evaluation conducted by the Board through its authorized agents in accordance with the requirements of the AAOMS *Office Anesthesia Evaluation Manual* or subsequent edition.

§ 33.337. Requirements for restricted permit II.

(a) To secure a restricted permit II, a dentist shall have [done one of the following: (1) S]successfully completed a course in nitrous oxide/oxygen analgesia comprising at least [40] 20 hours of undergraduate or postgraduate didactic instruction and clinical experience in a program that conforms to Part I (for an undergraduate program) or Part III (for a postgraduate program) of the American Dental Association's *Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry* or subsequent edition.

[(2) Administered nitrous oxide/oxygen analgesia on a regular basis in the course of his dental practice for 5 or more years prior to January 1, 1986, if the applicant:

(i) Is competent to administer nitrous oxide/oxygen analgesia. The Board will consider an applicant competent if there are no reported or discovered incidents of mortality or morbidity resulting from the applicant's administration of nitrous oxide/oxygen analgesia.

(ii) Administers nitrous oxide/oxygen analgesia in a properly equipped dental office as prescribed in § 33.340(a)(2) (relating to duties of dentists who are permit holders).

(b) A dentist who applies for a permit under subsection (a)(2) shall do so by January 9, 1990.]

(b) All applicants who administer nitrous oxide analgesia to adults or children shall attest to the following:

(1) that the applicant has written office procedures for administering nitrous oxide/oxygen analgesia and handling emergencies resulting therefrom; and

(2) that the equipment for administering the nitrous oxide/oxygen analgesia has been installed and calibrated according to the equipment manufacturer's guidelines and contains a fail-safe system.

§ 33.338. Expiration and renewal of permits.

(a) A permit issued by the Board under this subchapter will expire at the same time as the permit holder's dental license but may be renewed biennially at the same time the dental license is renewed.

(b) A dentist who desires to renew a permit shall submit the following:

- (1) a renewal application on a form provided by the Board; [and pay]
- (2) the permit renewal fee[.],
- (3) proof of current certification in Advanced Cardiac Life Support (ACLS)(for unrestricted permits and restricted I permits)
- (4) an attestation, on the renewal application, as appropriate to the type of permit requested, that the administration of general anesthesia, deep sedation and conscious sedation has been conducted during the preceding biennial period for adults (if appropriate) with the standards outlined in the AAOMS Guidelines and Parameters of Care for Oral and Maxillofacial Surgery, Anesthesia in Outpatient Facilities or subsequent edition; and for children (if appropriate) in conformance with standards outlined in the AAPD Guidelines for the Elective Use of Conscious Sedation, Deep Sedation and General Anesthesia for Pediatric Patients or subsequent edition.
- (5) an attestation, on the renewal application, that the nitrous oxide/oxygen analgesia equipment has been installed and calibrated according to the equipment manufacturer's guidelines and contains a fail-safe system.

§ 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:
 - (1) Prior to the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia a history is taken and the patient is given a physical evaluation sufficient to determine the patient's suitability to receive general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia.
 - (2) The dental office in which the permit holder administers general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia on an outpatient basis contains the following:

- (i) An operating room.
- (ii) An operating table or chair.
- (iii) A lighting system.
- (iv) Suction equipment with appropriate oropharyngeal suction.
- (v) Oxygen and supplemental gas delivery systems, including primary and back-up sources and a fail-safe control mechanism.
- (vi) A sterilization area.
- (vii) A recovery area.
- (viii) A gas storage area and scavenger system.
- (ix) Emergency airway equipment and medications, including intravenous emergency equipment.
- (x) Communications equipment.
- (xi) Patient transport equipment.
- (xii) [Appropriate m]Monitoring equipment, procedures, and documentation to conform to the age of the patient and the AAOMS Office Anesthesia Evaluation Manual or subsequent edition and the AAPD Guidelines for the Elective Use of Conscious Sedation, Deep Sedation, and General Anesthesia in Pediatric Dental Patients or subsequent edition.
- (xiii) Pulse oximeter.
- (xiv) ECG.
- (xv) Automatic blood pressure monitoring device.
- (xvi) Automatic external defibrillation device.
- (xvii) Results of patient history and physical evaluation.
- (xviii) Signed patient consent.

(3) Auxiliary personnel who assist the permit holder in the administration of general anesthesia, deep sedation or conscious sedation [or nitrous oxide/oxygen analgesia]:

- (i) Are trained to perform the duties that the permit holder delegates to them, if the duties do not require the professional judgment and skill of the permit holder and do not involve the administration of general anesthesia, deep sedation or conscious sedation [or nitrous oxide/oxygen analgesia].
- (ii) Perform their duties under the direct on-premises supervision of the permit holder, who shall assume full responsibility for the performance of the duties.
- (iii) Do not render assistance in areas that are beyond the scope of the permit holder's authority.

(iv) Are currently certified in Advanced Cardiac Life Support (ACLS).

(4) Certified registered nurse anesthetists to whom are delegated the duties of administering general anesthesia, deep sedation, or conscious sedation [nitrous oxide/oxygen analgesia]

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

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

(iii) Are currently certified in Advanced Cardiac Life Support (ACLS).

(5) He possesses a current certification [to administer cardiopulmonary resuscitation (CPR)] in Advanced Cardiac Life Support (ACLS).

(6) The Board receives a complete report of a death or [unusual] incident requiring medical care and resulting in physical or mental injury that directly resulted from the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia by the permit holder or by a certified registered nurse anesthetist working under the supervision of the permit holder. The permit holder shall submit the report within 30 days of the death or [unusual] incident.

(7) The Board receives prior notice of the first time that a dental office of the permit holder will be used for the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia.

(8) Any 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.

(9) All monitoring equipment is installed and calibrated according to the equipment manufacturer's guidelines; is in proper working condition prior to the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia; and is being used during the administration of general anesthesia.

(10) Any equipment transported to a non-permit holder dentist's office for the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia by a permit holder must pass an inspection by the Board through its authorized agents in accordance with the requirements of the AAOMS *Office Anesthesia Manual* or subsequent edition. The make, model and serial number of all equipment must be available and noted on the inspection report.

(b) A dentist's failure to comply with this section will be considered unprofessional conduct and will subject the dentist to disciplinary action under section 4.1 of the act (63 P.S. §123.1).

§ 33.340a. Duties of dentists who are restricted permit I holders.

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

(1) Prior to the administration of conscious sedation or nitrous oxide/oxygen analgesia, a history is taken and the patient is given a physical evaluation sufficient to determine the patient's suitability to receive conscious sedation or nitrous oxide/oxygen analgesia.

(2) The dental office in which the permit holder administers conscious sedation or nitrous oxide/oxygen analgesia on an outpatient basis contains the following:

(i) An operating room.

(ii) An operating table or chair.

(iii) A lighting system.

(iv) Suction equipment with appropriate oropharyngeal suction.

(v) Oxygen and supplemental gas delivery systems, including primary and back-up sources and a fail-safe control mechanism.

(vi) A sterilization area.

(vii) A recovery area.

(viii) A gas storage area and scavenger system.

(ix) Emergency airway equipment and medications, including intravenous emergency equipment.

(x) Communications equipment.

(xi) Patient transport equipment.

(xii) Monitoring equipment, procedures, and documentation to conform to the age of the patient and the AAOMS *Office Anesthesia Evaluation Manual* or subsequent edition and the AAPD *Guidelines for the Elective Use of Conscious Sedation, Deep Sedation, and General Anesthesia in Pediatric Dental Patients* or subsequent edition.

- (xiii) Pulse oximeter.
- (xiv) ECG.
- (xv) Automatic blood pressure monitoring device.
- (xvi) Automatic external defibrillation device.
- (xvii) Results of patient history and physical evaluation.
- (xviii) Signed patient consent.

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

- (i) Are trained to perform the duties that the permit holder delegates to them, if the duties do not require the professional judgment and skill of the permit holder and do not involve the administration of conscious sedation.
- (ii) Perform their duties under the direct on-premises supervision of the permit holder, who shall assume full responsibility for the performance of the duties.
- (iii) Do not render assistance in areas that are beyond the scope of the permit holder's authority.
- (iv) Are currently certified in Advanced Cardiac Life Support (ACLS).

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

- (i) Perform their duties under the direct on-premises supervision of the permit holder, who shall assume full responsibility for the performance of the duties.
- (ii) Do not perform duties that are beyond the scope of the permit holder's authority.
- (iii) Are currently certified in Advanced Cardiac Life Support (ACLS).

(5) He possesses a current certification in Advanced Cardiac Life Support (ACLS).

(6) The Board receives a complete report of a death or incident requiring medical care and resulting in physical or mental injury that directly resulted from the administration of conscious sedation or nitrous oxide/oxygen analgesia by the permit holder or by a certified registered nurse anesthetist working under the supervision of the permit holder. The permit holder shall submit the report within 30 days of the death or incident.

(7) The Board receives prior notice of the first time that a dental office of the permit holder will be used for the administration of conscious sedation or nitrous oxide/oxygen analgesia.

(8) All monitoring equipment is installed and calibrated according to the equipment manufacturer's guidelines, contains a fail-safe system and is in proper working condition prior to the administration of conscious sedation or nitrous oxide/oxygen analgesia.

(9) Any equipment transported to a non-permit holder dentist's office for the administration of conscious sedation or nitrous/oxide oxygen analgesia by a permit holder must pass an inspection by the Board through its authorized agents in accordance with the requirements of the AAOMS *Office Anesthesia Manual* or subsequent edition. The make, model and serial number of all equipment must be available and noted on the inspection report.

(b) A dentist's failure to comply with this section will be considered unprofessional conduct and will subject the dentist to disciplinary action under section 4.1 of the act (63 P.S. § 123.1).

§ 33.340b. Duties of dentists who are restricted permit II holders.

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

(1) Prior to the administration of nitrous oxide/oxygen analgesia a history is taken and the patient is given a physical evaluation sufficient to determine the patient's suitability to receive nitrous oxide/oxygen analgesia.

(2) The dental office in which the permit holder administers nitrous oxide/oxygen analgesia on an outpatient basis contains the following:

(i) An operating room.

(ii) An operating table or chair.

(iii) A lighting system.

(iv) Suction equipment with appropriate oropharyngeal suction.

(v) Oxygen and supplemental gas delivery systems, including primary and back-up sources and a fail-safe control mechanism.

(vi) A sterilization area.

- (vii) A gas storage area and scavenger system.
- (viii) Emergency airway equipment and medications, including intravenous emergency equipment.
- (ix) Communications equipment.
- (x) Monitoring equipment, procedures, and documentation to conform to the age of the patient and the AAOMS *Office Anesthesia Evaluation Manual* or subsequent edition and the AAPD *Guidelines for the Elective Use of Conscious Sedation, Deep Sedation, and General Anesthesia in Pediatric Dental Patients* or subsequent edition.
- (xi) Results of patient history and physical evaluation.
- (xii) Signed patient consent.

(b) A dentist's failure to comply with this section will be considered unprofessional conduct and will subject the dentist to disciplinary action under section 4.1 of the act (63 P.S. § 123.1).

§ 33.341. Duties of dentists who are not permit holders.

(a) [Effective January 9, 1990, a] A dentist who does not possess a permit issued under this subchapter may not allow general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia to be administered on an outpatient basis in his dental office unless the following conditions are met:

- (1) The Board receives prior notice of the first time that the dental office will be used for the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia.
- (2) The dental office has been inspected and meets the appropriate equipment and facility requirements prescribed in either § 33.340(a)(2), or § 33.340a(a)(2) or § 33.340b(a)(2) (relating to duties of dentists who are permit holders) and the Board receives a written certification from the dentist to that effect.
- (3) The general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia, are administered by one of the following:
 - (i) The holder of a permit under this subchapter.
 - (ii) A Pennsylvania-licensed medical or osteopathic physician who is currently credentialed to administer anesthesia in a hospital licensed by the Department of Health.

(4) Either the dentist who performs the dental procedure or the certified registered nurse anesthetist, physician or other unrestricted permit holder [person] who administers the general anesthesia, [or] deep sedation, or conscious sedation [or nitrous oxide/oxygen analgesia] possesses a current certification [to administer cardiopulmonary resuscitation (CPR)] in Advanced Cardiac Life Support (ACLS).

(5) The non-permit holder dentist verifies with the permit holder that all monitoring equipment is present in the non-permit holder's office, is properly installed and calibrated according to the equipment manufacturer's guidelines, contains a fail-safe system and is in proper working condition prior to the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia, and is being used during the administration of general anesthesia.

(6) Any equipment transported to a non-permit holder dentist's office for the administration of general anesthesia, deep sedation, conscious sedation or nitrous/oxide analgesia by a permit holder must pass an inspection by the Board through its authorized agents in accordance with the requirements of the AAOMS *Office Anesthesia Manual* or subsequent edition. The make, model and serial numbers of all equipment must be available and noted on the inspection report.

(b) A dentist shall submit to the Board a complete written report on a death or [unusual] an incident requiring medical care and resulting in physical or mental injury that directly resulted from the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia in his dental office. The report shall be submitted within 30 days of the death or [unusual] an incident.

* * * *

§ 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, 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), (relating to duties of dentists who are permit holders).

(b) *Special inspections.* In addition to the routine inspections authorized by subsection (a), the Board, through its authorized agents, may conduct a special inspection of a dental office:

- (1) Upon a death or injury related to the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia in the office.
- (2) Upon a complaint that the office or the dentist who operates the office is not in compliance with this subchapter.
- (3) Upon a reasonable belief that conditions exist in the office that pose a danger to the health or safety of the public.
- (4) As a follow-up to a previous inspection that revealed the office's non-compliance with the equipment and facility requirements prescribed in §§ 33.340(a)(2), 33.340a.(a)(2) or 33.340b.(a)(2) (relating to duties of dentists who are permit holders).

(c) *Notice of inspection.* Prior to the start of a routine or special inspection of a dental office, the Board's authorized agents will advise the dentist whose office is being inspected that the inspection is being made under this section and is limited in scope by this section.

(d) *Access during inspection.* For purposes of a routine or special inspection, a dentist shall give the Board's authorized agents access to:

- (1) Areas of the dental office where general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia are administered.
- (2) Equipment, supplies, records and documents relating to the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia.
- (3) Interviews with auxiliary personnel.

(e) *Guideline for inspection.* A routine inspection, with or without prior notice, will be conducted under provisions pertaining to office facilities, and equipment and procedures in the AAOMS *Office Anesthesia Evaluation Manual* or subsequent edition, and the ADA *Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia for Dentists* or subsequent edition.

(f) *Inspection showing noncompliance.*

- (1) If a routine or special inspection reveals that a dental office is not in compliance with the equipment, [and] facility or procedure requirements prescribed in §§ 33.340(a)(2), 33.340a.(a)(2) or 33.340b.(a)(2), [the Board will give the dentist whose office was inspected] written notice of the deficiencies and of the deadline for correcting the deficiencies will be given to the dentist whose office was inspected. A reinspection will

take place within 30 days, and, if noncompliance is still shown, formal administrative charges may be initiated.

- (3) If a routine or special inspection reveals that a dental office is not in compliance with the equipment, facility or procedure requirements prescribed in §§ 33.340(a)(2), 33.340a.(a)(2) or 33.340b.(a)(2), and such noncompliance presents an immediate and clear danger to the public health and safety, the permit holder's permit may be subject to an immediate temporary suspension and other disciplinary action.



**COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF DENTISTRY**

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HARRISBURG, PA 17105-2649

November 14, 2001

The Honorable John R. McGinley, Chairman
Independent Regulatory Review Commission
14th Floor, Harristown 2
333 Market Street
Harrisburg, PA 17101

RE: Proposed Regulation
State Board of Dentistry
Anesthesia (16A-4610)

Dear Chairman McGinley:

Enclosed is a copy of a proposed rulemaking package of the State Board of Dentistry pertaining to anesthesia.

The Board will be pleased to provide whatever information your Committee may require during the course of its review of the rulemaking.

Sincerely,

Norbert O. Gannon, D.D.S., Chairman
State Board of Dentistry

NOG:DBE:apm

Enclosures

c: John T. Henderson, Jr., Chief Counsel
Department of State
Albert H. Masland, Commissioner
Bureau of Professional and Occupational Affairs
Joyce McKeever, Deputy Chief Counsel
Department of State
Christal Pike-Nase, Regulatory Counsel
Gerald S. Smith, Senior Counsel in Charge
Bureau of Professional and Occupational Affairs
Deborah B. Eskin, Counsel
State Board of Dentistry
State Board of Dentistry

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE
REGULATORY REVIEW ACT**

I.D. NUMBER: 16A-4610

SUBJECT: State Board of Dentistry - Administration of General Anesthesia, Deep Sedation,
Conscious Sedation and Nitrous Oxide/Oxygen Analgesia

AGENCY: DEPARTMENT OF STATE

TYPE OF REGULATION

- Proposed Regulation
- Final Regulation
- Final Regulation with Notice of Proposed Rulemaking Omitted
- 120-day Emergency Certification of the Attorney General
- 120-day Emergency Certification of the Governor
- Delivery of Tolled Regulation
 - a. With Revisions
 - b. Without Revisions

RECEIVED
 DEPARTMENT OF STATE
 1001 NOV 14 PM 12:13

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
11-14-01	<i>Lorinda Clark</i>	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
11/14/01	<i>Frank J. Zuber</i>	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
11/14/01	<i>St. Belmont</i>	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
11/14/01	<i>James J. Moran</i>	LEGISLATIVE REFERENCE BUREAU

October 31, 2001