RULES AND REGULATIONS

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF DENTISTRY

[49 PA. CODE CH. 33]

Administration of General Anesthesia, Deep Sedation, Conscious Sedation and Nitrous Oxide/Oxygen Analgesia

The State Board of Dentistry (Board) amends §§ 33.110 and 33.209 (relating to volunteer license; and preparing, maintaining and retaining patient records) and Subchapter E (relating to administration of general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia) to read as set forth in Annex A.

A. *Effective Date*

The final-form rulemaking will be effective upon publication in the *Pennsylvania Bulletin*.

B. *Statutory Authority*

The Board is authorized to adopt regulations concerning anesthesia under sections 3(o) and 11.2(a) of The Dental Law (act) (63 P. S. §§ 122(o) and 130c(a)).

C. *Background and Purpose*

The final-form rulemaking is in response to the act of November 25, 2002 (P. L. 1109, No. 135) (Act 135) and *Watkins v. State Board of Dentistry*, 740 A.2d 760 (Pa. Cmwlth. 1999), which held that the term "appropriate monitoring equipment" in § 33.340 (relating to duties of dentists who are unrestricted permitholders) is unconstitutionally vague. Shortly after the decision, the Board constituted an Anesthesia Committee (Committee). The 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. Several drafts of the proposed rulemaking were developed. On March 23, 2001, the Board approved the final draft for promulgation as proposed rulemaking. Proposed rulemaking was published at 31 Pa.B. 6691 (December 8, 2001).

Following the comment period, the Board and its Committee reviewed the comments received. The Committee met on March 14, 2002, to consider the suggestions and prepare responses. Just prior to that meeting, the Committee learned that Dr. Robert S. Muscalus, Physician General, had several concerns regarding the proposed rulemaking. Accordingly, the Committee invited Dr. Muscalus to address these concerns at the Committee's March 14, 2002, meeting. The entire Board entertained Dr. Muscalus's suggestions at the March 15, 2002, Board meeting.

A final rulemaking package approved by the Board was under internal Department of State (Department) review on November 25, 2002, when Act 135 was signed by the Governor and became effective December 25, 2002. The passage of Act 135 required that the Board's anesthesia regulations be rewritten.

Changes required by Act 135 and implementation issues were reviewed by the Department and the Committee, in particular implementation of the clinical evaluations and office inspections. The Board's current regulations, adopted in 1988, require clinical evaluations and office inspections for unrestricted and restricted I permitholders. However, clinical evaluations and office inspections have never been implemented due to the inability to find individuals or organizations willing to conduct them due to liability concerns.

The following options were explored: 1. *Commonwealth employee*—This option provides the protection of sovereign immunity for governmental employees. However, because of the complexity of the subject matter and the need for persons trained in dentistry, surgery and anesthesia, the costs of training current Department inspectors or hiring oral and maxillofacial surgeons (OMS) or unrestricted permitholders are prohibitive. It is not feasible to train current Department inspectors, none of whom have medical, dental or anesthesia backgrounds. If current inspectors were to perform the clinical evaluations and office inspections, the evaluations and inspections would have to be considerably simplified, which the Board believes would not accomplish the goal of public protection.

The Department had, in the past, made efforts to hire qualified dentists. However, none of these efforts produced a single dentist willing to accept employment at Commonwealth salaries.

2. *Independent contractor*—Nongovernmental agents may act for the government only as independent contractors and cannot be indemnified by the Commonwealth. Potential contractors were not found.

3. *Volunteer*—Volunteers would also be subject to contracts defining the scope of their activities and limits of authority, and liability coverage or a statutory exemption from certain types of liability would be necessary. The Board had been involved, both prior to and following the passage of Act 135, in discussions with the Pennsylvania Society of Oral and Maxillofacial Surgeons (PSOMS) concerning the possibility of the PSOMS conducting the clinical evaluations and office inspections for nonmember permitholders. The PSOMS, the only known organization to date with the experience and expertise to conduct the clinical evaluations and office inspections, has conducted clinical evaluations and office inspections for its members since 1975. The clinical evaluations and office inspections are performed by volunteer PSOMS members, who are provided with liability insurance coverage by the PSOMS' insurance carrier.

4. *Legislative amendment to the act to grant limited immunity to evaluators/inspectors*—The PSOMS prepared a draft amendment, which was supported by the Department. In May 2004, House Bill 2651 (P.N. 3950) was introduced. This bill would provide limited immunity for persons conducting clinical evaluations and office inspections and extends certain deadlines for Act 135 compliance. However, this bill was not enacted during the 2004 session.

As a result, the Board's second proposed rulemaking package sets up an "approved peer evaluation" system for clinical evaluations and office inspections. Although the regulations leave it open for any organization to apply to be an approved peer evaluation organization, the PSOMS was the only entity that the Board was currently aware of that had the resources and ability to conduct these highly technical and fairly lengthy evaluations and inspections.

Proposed rulemaking incorporating all changes required by Act 135 was published at 34 Pa.B. 1949 (April 10, 2004).

Publication was followed by a 30-day public comment period during which the Board received comments from five organizations and two individuals. The Board received public comments from the PSOMS; the Pennsylvania Dental Association (PDA); the Pennsylvania Society of Anesthesiologists (PSA); the Pennsylvania Association of Nurse Anesthetists (PANA); Highmark Inc. and its dental subsidiary, United Concordia Companies, Inc. (UCCI); and two individual dentists. The Board also received comments from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC) under the Regulatory Review Act (71 P. S. §§ 745.1—745.12). The Board did not receive comments from the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC).

Following the comment period, the Board and its Committee reviewed all comments received. The Board met on June 4, 2004, to consider the suggestions and prepare responses. However, since all comments had not been received by that date, the Board instructed its Committee to review all comments and to determine initial responses for this final rulemaking package. The Committee met by means of a teleconference on July 26, 2004. After considering all of the public comments, this final-form rulemaking was drafted and presented to the Board at its October 22, 2004, meeting. The Board subsequently voted to adopt the final-form rulemaking at its December 3, 2004, meeting.

D. Comment and Regulatory Review of Proposed Rulemaking

Volunteer Regulations

The HPLC and IRRC commented that the Board's existing volunteer license regulations need to be amended to conform to the amendments to the anesthesia regulations and to cross-reference the requirements for continuing anesthesia education and office inspections and clinical evaluations. In response, the Board amended § 33.110 to cross-reference certain provisions in §§ 33.336a and 33.337 (relating to requirements for unrestricted permit and restricted permit I; and requirements for restricted permit II) regarding the qualifications of the volunteer licensee to administer anesthesia. However, because volunteer license holders are required to provide their services only in an approved clinic, as defined by section 3 of the Volunteer Health Services Act (35 P. S. § 449.43), the Board did not extend the office inspection/clinical evaluation requirement to those facilities. The Board notes that as of January 2005, the Board has only three active volunteer dentist licensees and that none of these licensees hold an anesthesia permit.

Compliance with Act 135

The HPLC noted that Act 135 requires that as of April 1, 2004, all initial applications for permits and initial applications for renewal of permits include an office inspection and clinical evaluation. The Board notes that section 1 of Act 135 which amends section 11.2(b)(1) of the act requires that, beginning April 1, 2004, only initial permits to administer general anesthesia, deep sedation or conscious sedation (unrestricted permit and restricted permit I) require a clinical evaluation and office inspection. The Board acknowledges that this deadline has passed. Section 11.2(b)(6) requires that, as of April 1, 2005, unrestricted and restricted I permitholders seeking renewal for the biennial period beginning April 1, 2005, must have a clinical evaluation and office inspection. The Board intended this regulation to be effective prior to April 1, 2005, and has provided actual notice to each current holder of an unrestricted permit or a restricted permit I of Act 135 requirements regarding office inspection and clinical evaluations. The Board notes that section 11.2(b)(6) of the act allows the Board to waive the clinical evaluation and office inspection requirement for unrestricted and restricted I permit renewals beginning April 1, 2005, if the permitholder can demonstrate to the Board's satisfaction that he has satisfactorily undergone a clinical evaluation, administered by an organization acceptable to the Board, within the 6 years immediately preceding April 1, 2005. As of January 1, 2005, there were 466 unrestricted permitholders and 477 restricted I permitholders. According to the PSOMS, most of the 466 unrestricted permitholders are members of the PSOMS and many have satisfactorily undergone both a clinical evaluation and office inspection within the previous 6 years. In addition, the PSOMS is now offering inspections and clinical evaluations to nonmembers. The Board anticipated that a majority of these permitholders will have complied with the requirement prior to April 1, 2005.

The HPLC also noted that the proposed rulemaking was delivered to the Committee on March 31, 2004, 1 day before the statutorily imposed deadline. The Board acknowledges that unresolved issues and uncertainty regarding implementation of this final-form rulemaking has taken a considerable amount of time and effort on behalf of the Board and the Department. The Board would refer the HPLC to the efforts undertaken by the Board as outlined in Section C of this preamble to implement the Act 135 requirements in a timely manner. The Board feels that it has worked consistently on this final-form rulemaking from inception of the first proposed rulemaking through this final-form rulemaking. Given the technical nature of the final-form rulemaking and the varying opinions of the various organizations and other interested parties, the Board sought to assure that the final-form rulemaking safeguards the public's health and safety, while not unduly restricting access to care for the citizens of this Commonwealth.

Noting that Act 135 permits the Board to contract with dental schools, organizations and individuals to perform clinical evaluations and office inspections, the HPLC questioned why the proposed rulemaking did not mention contracting with any of those entities. IRRC agreed that it does not appear that the Board has exercised the option to contract with other entities or individuals to carry out the mandates of Act 135, and requested an explanation as to why it has not pursued the contracting option, whether there were other organizations that should be recognized as qualified peer evaluation organizations and how the Board intends to address the liability issue. The HPLC also requested an explanation as to why the Board had not explored the possibilities listed in section 11.2(b)(1) of the act with respect to who may conduct the clinical evaluations and office inspections.

The Board has made numerous attempts to identify viable options for providing the office inspections and clinical evaluations as outlined in Section C of this preamble. Additionally, under the direction of the Commissioner of Professional and Occupational Affairs, the Board is also, in addition to publishing this final-form rulemaking, working simultaneously on a Request for Proposal (RFP) for independent contractors; again attempting to hire anesthesia trained dentists at Commonwealth salaries; supporting a statutory amendment to grant immunity to inspectors and an extension of time for

Act 135 compliance; and issuing temporary permits as authorized by section 11.2(c) of the act to initial applicants until April 1, 2005.

Moreover, none of the three dental schools in this Commonwealth have indicated an interest in providing the clinical evaluations and office inspections. After more than 5 years of study, the only organization identified by the Board that is willing and able to conduct the required inspections and evaluations is the PSOMS. However, the Board continues to actively seek qualified providers and would welcome inquiries from other qualified organizations under § 33.336b(b) (relating to approved peer evaluation organizations for administering evaluations and office inspections).

With regard to the liability issue, the Board would still support the legislation that was proposed in the last legislative session that would limit inspectors' liability. However, given the fact that the PSOMS has been able to obtain the necessary liability coverage to extend their existing peer evaluation program to nonmembers, the Board believes that the liability issue previously raised should not be an impediment to other organizations who wish to become approved peer review organizations.

Notice to Licensees

The HPLC requested information as to whether the Board has provided any notice or information to licensees regarding the clinical evaluations and office inspections. Information has been provided to licensees in the Board's newsletter mailed to each licensee during the summer of 2004. In addition, a special notice was sent to all unrestricted and restricted I permitholders in August 2004 to notify them of the requirements that they obtain an office inspection and clinical evaluation prior to renewing their anesthesia permits in 2005.

Individuals as Peer Review Evaluators

IRRC questioned whether individual permitholders could apply to conduct peer evaluations. Section 11.2(b)(1) the act allows the Board to contract with dental schools, organizations or individuals to perform the clinical evaluations and office inspections. While authorized by the act to contract with individuals, the regulations have now been amended to require peer evaluator teams consisting of at least two individuals due to the highly technical and lengthy inspection and evaluation process. Therefore, the Board elected not to amend the regulations to include "individuals" as peer evaluators.

Peer Review Organizations—Restricted Permit I Holders

IRRC, the PDA and Dr. Walter Laverick, D.M.D. recommended that other dental organizations representing the specialties of pediatric dentistry, periodontology, and the like, be permitted to apply to become an organization to conduct office inspections and clinical evaluations of restricted permit I offices to ensure that dentists of the same specialties and permit types are available to conduct inspections and evaluations for permit level I holders. The PDA commented that restricting the pool of potential peer evaluators to only those who hold an unrestricted permit places an undue burden on those permitholders who make up approximately 1/2 of the affected permitholders. The Board has addressed this comment by amending the regulations to allow restricted permit I holders to conduct office inspections and clinical evaluations of restricted permit I holders and applicants, but only when part of a team that is comprised of at least one unrestricted permitholder.

Criteria for Review of Peer Review Organizations

IRRC requested an explanation as to how the criteria were developed for reviewing a peer review organization application. The Board developed some of the criteria by reviewing the criteria used by other professional board and commissions, which use similar evaluation systems, and other criteria were developed by the Board independently. IRRC also requested an explanation as to how the Board will determine an applicant's compliance with the criteria in paragraphs (3), (5) and (8) regarding technical competence to administer evaluations and inspections, standards for satisfactory completion of an office inspection and clinical evaluation and procedures to facilitate fair, unbiased and equitable office inspections and evaluations. IRRC suggested that the Board specify the documentation an applicant must produce to demonstrate compliance with these paragraphs. The Board has developed specific requirements for inspections and evaluations, which have currently been incorporated in the RFP. The Board expects to require the same types of documentation from applicants for peer review organizations under the regulations as they would of potential contractors under the RFP. These currently include a management summary, work plan, statement of experience and qualifications, statement of personnel assigned to the program, description of training provided to peer evaluators, description of facilities and equipment dedicated to the program and similar information. Sample inspection and evaluation forms, curricula vitae of peer evaluators, written protocols for performance of inspections and evaluations are all examples of documentation that may be provided. However, the Board has declined to list all of the documents that could possibly be utilized to comply with this section in the regulations. Organizations that wish to apply to become approved peer review organizations will be provided guidelines to assist them in preparing their applications when requested.

Continuing Education

The HPLC commented on the reduction of hours of continuing education for permitholders and requested the Board's rationale for this reduction. Act 135, not the Board, has reduced the number of hours of continuing education required as a condition of permit renewal by specifying a certain number of hours of continuing education in anesthesia (restricted—15 hours; restricted I—15 hours; nonpermitholders allowing anesthesia in offices—5 hours) and crediting the continuing anesthesia education toward the permitholder's 30 hours of continuing education required for licensure under section 3(j.2)(2) of the act. The Board had recommended that anesthesia permitholders be required to obtain the anesthesia continuing education hours in addition to the 30 hours of continuing education already required for a dental license.

Educational Requirements

IRRC requested the basis for reducing the required number of hours of instruction and clinical experience in § 33.336 (relating to requirements for restricted permit I) from 80 to 60, and for reducing the required number of hours of instruction and clinical experience from 40 to 14 in § 33.337. These reductions were done to comply with changes to the American Dental Association's (ADA) *Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry* (Guidelines).

BLS/ACLS/PALS

The HPLC noted that the requirement in Act 135 that assistants be certified in cardiopulmonary resuscitation

(CPR). The Committee sought clarification that Basic Life Support (BLS) includes CPR. BLS generally includes adult, child and infant CPR, as well as rescue breathing for those persons who have stopped breathing but are not in cardiac arrest, and training on foreign body airway obstruction and the use of automatic external defibrillators.

C. Richard Bennett, D.D.S., Ph.D., a teacher of dental anesthesiology for the past 37 years, commented that the training received by dental anesthesiologists far exceeds that obtained in an Advanced Cardiac Life Support (ACLS) or Pediatric Advanced Life Support (PALS) course. Dr. Bennett questioned "why the state insists on installing a false sense of security by requiring that dentists be trained in ACLS," believing that this will allow dentists to manage catastrophic emergencies such as cardiac arrests. Dr. Bennett commented that with proper patient evaluation, selection and attentive patient monitoring, catastrophic emergencies such as cardiac arrest should be preventable. The Board agrees that proper patient evaluation, selection and monitoring are of utmost importance in the administration of anesthesia in dental offices, which is one reason the final-form rulemaking is needed. The Board has required all dentists who want to obtain permits to deliver anesthesia to adult and pediatric patients to hold current certifications in ACLS and PALS as a minimum standard. Certainly many dental professionals in this Commonwealth obtain more advanced training in this area and are to be commended.

Recordkeeping Requirements

The HPLC pointed out that Act 135 requires dentists to maintain records of the physical evaluation, as well as records of the medical history and type of anesthesia utilized, but the proposed rulemaking was silent with respect to this requirement. IRRC also noted that the rulemaking is silent regarding recordkeeping requirements for peer review organizations. Current § 33.209 (relating to preparing, maintaining and retaining patient records) requires dentists to maintain a dental record for each patient that accurately, legibly and completely reflects the evaluation and treatment of the patient. It further requires a description of all treatment and services rendered and information with regard to any controlled substances or other drugs prescribed, administered or dispensed. Section 33.209(a)(7) specifically requires information with regard to the information of local anesthesia, nitrous oxide, oxygen analgesia, conscious sedation or general anesthesia. Section 33.209(b) requires that a patient's dental record be retained by a dentist for a minimum of 5 years from the date of the last dental entry. IRRC recommended that the proposed rulemaking specify how long records must be maintained and in what form, include deep sedation in § 33.209, and insert cross-references to § 33.209 in § 33.340 and §§ 33.340a and 33.340b (relating to duties of dentists who are restricted permit I holders; and duties of dentists who are restricted permit II holders). The Board has amended these sections to specifically mention the physical evaluation, medical history and type of anesthesia utilized, as well as adding the term "deep sedation."

Peer Review Organization Records

The HPLC and IRRC suggested that peer review organizations be required to maintain records of office inspections and clinical evaluations performed. The Board agrees and has updated the final-form rulemaking accordingly.

Definitions

The HPLC recommended that the addresses of organizations listed in § 33.331 (relating to definitions) be deleted as the addresses are subject to change. The Board has removed the addresses.

IRRC and PANA suggested that the Board include language in § 33.331 recognizing the successor volumes for each of the documents (American Association of Oral and Maxillofacial Surgeons (AAOMS) *Parameters and Pathways 2000 Clinical Practice Guidelines for Oral and Maxillofacial Surgery, Anesthesia in Outpatient Facilities* (Guidelines), AAOMS *Office Anesthesia Manual* (Manual), American Academy of Pediatric Dentistry (AAPD) *Guidelines for the Elective Use of Conscious Sedation, Deep Sedation and General Anesthesia in Pediatric Dental Patients* (Guidelines) and ADA Guidelines) so it is not necessary to revise the regulation each time a manual or set of guidelines is updated. The Board appreciates that this option would certainly be easier, but in the interest of providing specific notice to permitholders and mindful of the cautionary instruction of the Commonwealth Court in *Watkins*, the Board believes that the sounder choice is to specify the edition to be used in the evaluation process. Further, the Board believes that its review and approval of any successor editions will assure that changes in standards conform to the legislative intent of Act 135.

IRRC suggested the Board revise the definition of "physician" to be consistent with the definition in the Medical Practice Act of 1985 (63 P. S. §§ 422.1—422.51a). The PSA suggested the following definition of physician: "A Pennsylvania licensed medical or osteopathic physician who is currently certified by the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology, or is credentialed to administer anesthesia in a hospital or ambulatory surgical facility licensed by the Department of Health." The Board has adopted the PSA's definition of: physician. The Board was concerned that the definition of physician contained in the Medical Practice Act of 1985 was too broad.

IRRC suggested that the definition of "communications equipment" be revised for clarity purposes. The Board has revised the definition and added examples in an attempt to clarify that each operating room in which anesthesia is administered must have equipment capable of being utilized by voice, video or electronic data transmission to elicit a response in an emergency.

IRRC suggested that the Board define the term "authorized agent." The Board has defined "authorized agent" as "any organization or individual that the Board has officially authorized to act as its agent in carrying out the mandates of the Board, The Dental Law or this chapter." This definition is broad enough to encompass peer evaluation organizations, independent contractors that may be identified through the RFP process or inspectors and investigators acting through the Department's Bureau of Enforcement and Investigation.

Dentist Administering Anesthesia in State or Federal Facility

IRRC suggested that § 33.332(b) (relating to requirement of permit to administer general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia) be amended by inserting "for dental procedures" after "nitrous oxide/oxygen analgesia" for clarity. The PSA recommends the following changes: "(b) Permit not required for administration of anesthetic modality for dental procedures in other facilities. A dentist is not required to possess a permit under this subchapter before adminis-

tering, or supervising the administration of, general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia for dental procedures in a state or federally regulated facility other than a dental office, and a permit issued under this subchapter does not permit the administration of general anesthesia, deep sedation, conscious sedation, or nitrous oxide/oxygen analgesia for non-dental procedures." The PDA recommends § 33.332(b) be amended by inserting the words "for dental procedures" prior to ". . . in a State or Federally regulated facility other than a dental office . . ."

This final-form rulemaking establishes the requirements for licensed dentists to administer anesthesia in dental offices. Subsection (b) is meant to acknowledge the fact that the administration of anesthesia by dentists or other health care professionals in facilities such as general and special hospitals and ambulatory surgical facilities is regulated by the Department of Health and is outside of the scope of these regulations. The regulations of the Department of Health contemplate that a dentist anesthetist may provide anesthesia services for practitioners as diverse as surgeons, obstetricians, dentists, podiatrists and so forth. See 28 Pa. Code § 123.7 (relating to dental anesthetist and nurse anesthetist qualifications). Therefore, the Board has declined to adopt this suggestion.

Proof of Successful Clinical Evaluations/Office Inspections

IRRC questioned why an applicant for an initial permit was required to submit an "original letter" from a peer review organization. The Board has amended this section to require documentation from the peer review organization that indicates whether the applicant has satisfactorily completed the clinical evaluation and office inspection.

IRRC also questioned why a "written report of the results of the clinical evaluation/office inspection" is also required, if the applicant produces a letter demonstrating satisfactory completion of the clinical evaluation/office inspection. A written report of the results is required because Act 135 specifically requires a written report of the results of *all* inspections and evaluations (emphasis added). See section 11.2(b)(1) of the act. In addition, the requirement will assist the Board in assuring that the inspections and evaluations are conducted by the peer review organizations in conformance with the regulations and the guidelines.

IRRC noted that under § 33.336e(b) (relating to confidentiality of peer evaluation reports), a peer review organization is required to notify the Board "as to whether the clinical evaluation and office inspection report has been accepted or rejected by the peer evaluation organization." IRRC suggested that the language be changed to reflect that the applicant has "successfully completed the clinical evaluation/office inspection" to clearly reflect its intent. The Board agrees and has inserted this clarification. The Board has also added language that clarifies the requirement that the peer evaluation organization must submit a written report of the results of all inspections and evaluations.

Guidelines for Clinical Evaluations and Office Inspections

PANA suggested omitting the AAPD and the AAOMS Guidelines and model compliance in accordance with the ADA Guidelines, as in most other states. The organization suggested that the regulations would require dentists and anesthesia providers to be familiar with up to three sets of guidelines, and it is unclear under which circumstances one guideline would prevail over another. The Board believes that the regulations clearly specify that an OMS applicant for an unrestricted or restricted permit I must conform to the AAOMS standards for adult and pediatric patients. A general dentist applicant must conform to the ADA Guidelines for adult patients and the AAPD Guidelines for pediatric patients. Therefore, an OMS would only need to be familiar with one set of guidelines. A general dentist who administers anesthesia to both adult patients and pediatric patients would need to be familiar with two sets of guidelines. When those guidelines and these regulations conflict, the regulations would control. The Board has reviewed all of the guidelines and feels that this requirement is appropriate and provides clear guidance to permitholders and applicants.

IRRC requested the reason a separate attestation for unrestricted permitholders and restricted permit I holders was necessary under § 33.336a(b). The Board has required the attestation as additional assurance that the appropriate guidelines will be followed. The attestation will be part of the application form and will not impose an undue burden on applicants.

Equipment Maintenance

IRRC and the PSA suggested that the renewal applicant be required to show that equipment has been properly maintained, as well as calibrated in § 33.338(b)(4) (relating to expiration and renewal of permits) and § 33.340(a)(9). The PDA recommends that § 33.338(b)(4) be amended by the words "and maintained" after ". . . properly calibrated." The PDA believes that periodic preventive maintenance, as well as calibration, is an accepted standard of practice and should apply to equipment in dental offices. The Board has added a maintenance requirement to all affected sections of the regulations.

The HPLC noted that under Act 135, nonpermitholders shall certify that the equipment used is in compliance with the safety measures adopted in the act and that § 33.341(a)(5) (relating to duties of dentists who are not permitholders) as proposed merely requires the nonpermitholder to verify with the permitholder that the equipment meets the statutory standards regarding safety. This section requires that a nonpermitholder provide a written certification to the Board that the office complies with the equipment and facility requirements of the regulations have been met. The Board has amended this section to require the nonpermitholder to obtain written certification from the permitholder that all monitoring equipment and equipment used to administer general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia is present in the nonpermitholder's office, is properly installed, maintained and calibrated and that monitoring equipment is being used during the administration of general anesthesia. The nonpermitholder shall also receive a written certification that the permitholder has satisfactorily completed a clinical evaluation and the equipment transported to the nonpermitholder's office has been inspected as required.

One commentator asked why so much emphasis is placed on calibration of a nitrous oxide machine, while no mention of calibration a general anesthesia machine or a vaporizer is made. The regulations include a requirement that all monitoring equipment and all equipment used to administer general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia be installed, calibrated and maintained according to the equipment manufacturer's guidelines, contain a fail-safe system and be in proper working order. However, this comment

brought to light a revision needed in § 33.338 (relating to expiration and renewal of permits), which required an attestation on the biennial renewal notice regarding the installation, calibration and maintenance of nitrous oxide/oxygen analgesia equipment, but failed to mention equipment used to administer general anesthesia, deep sedation or conscious sedation. This section has been revised to require an attestation to that effect covering all of these equipment types, as applicable to the level of permit.

Medical History and Physical Evaluation

IRRC suggested that § 33.340(a)(1) be amended to specify that the permitholder must take the medical history and conduct the physical evaluation, subsection (a)(12) should be deleted and the same clarification made in §§ 33.340a(a)(1) and 33.340b(a)(1). The PSA also commented regarding section 1 of Act 135, which amends section 11.2 of the act and requires permitholders to conduct the physical evaluation. The PSA points out that State hospitals and ambulatory surgical facilities require that physicians perform the physical evaluation and take the medical history, and recommends that § 33.340(a)(12) be amended by adding "or a physician" and deleting "CRNA." The Board agrees with IRRC that Act 135 requires the permitholder who administers the anesthesia to take the medical history and conduct the physical evaluation. Therefore, the regulations have been amended to meet that requirement. The scope of these regulations does not extend to hospitals or ambulatory surgical facilities, therefore, the Board has declined to adopt the PSA's suggestion.

Auxiliary Personnel

IRRC requested clarification of the term "auxiliary personnel" in § 33.340a(3). Auxiliary personnel are defined in § 33.1 (relating to definitions) as "persons who perform dental supportive procedures authorized by the act and this chapter under the general or direct supervision of a dentist." The Board has amended the final-form rulemaking to make it clear that auxiliary personnel assist the permitholder in the administration of anesthesia, and that they must be trained to carry out the tasks delegated to them, provided that those tasks do not involve the actual administration of the anesthesia.

Person Dedicated Solely to Anesthesia Administration/Monitoring

IRRC requested clarification as to why § 33.340(a)(8) requires that general anesthesia or deep sedation administered to a pediatric patient be administered by a person dedicated solely to the administration and monitoring of anesthesia. Michael G. Warfel, Vice President, Government Affairs, Highmark, expressed a general concern that the individual designated as the "anesthetizer/sedator/monitor" is the same person as the "dentist/operator" and that this concern is heightened in pediatric dental cases. He recommends that two distinct providers perform these services for all patients, not just pediatric patients. Michael Warfel suggested that true anesthesia, under which the patient is actually paralyzed and cannot breathe on his own, requires a separate anesthetist from the provider. The PSA recommends that the standard levels of practice within the medical community should be maintained in dental practice as well, and recommends that any patient under general anesthesia or deep sedation, no matter what their age, should have the anesthetic administered by someone dedicated solely to their monitoring and anesthetic administration. Conversely, the PDA recommends deleting § 33.340(a)(8) entirely, questioning why this is a requirement only for unrestricted permitholders who have completed postgraduate programs that conform with Part II of the ADA Guidelines, when these practitioners have the most extensive training in the administration of anesthesia. The PDA believes that this requirement is impractical and will hinder dental patients' access to care. The Board believes that the regulations adequately protect the health and safety of an adult patient without requiring a separate person dedicated to administering and monitoring anesthesia. Pediatric patients, however, can present more difficulties with anesthesia, and therefore the regulations require a separate provider whenever general anesthesia or deep sedation is administered to a pediatric patient.

Inspection of Nonpermit Holder Office and Equipment Transported There

IRRC commented that § 33.340(a)(10) requires that nonpermitholders' offices and equipment transported to the nonpermitholder's office be inspected by an approved peer review organization. IRRC requested clarification as to when the transported equipment was to be inspected since, it would not necessarily be in the nonpermitholder's office at the time of the office inspection. With regard to § 33.341(a)(2), IRRC, the PDA and Dr. Laverick suggested that the inspection of the nonpermitholder's office is not necessary. They believe that the inspection of the permitholder's equipment is sufficient, and note that Act 135 does not require inspections of nonpermitholders' offices. IRRC and the PDA opined that the permitholder should be responsible for ensuring that all appropriate equipment and facility requirements are met. IRRC and the PDA suggest that the provision in § 33.341(a)(5) requiring the nonpermitholder to verify with the permitholder that the equipment is installed properly and calibrated should be deleted as only permitholders should be responsible for verifying that the standards are met. IRRC and the PDA were also concerned that this subsection did not specify what type of verification is required. The HPLC suggested that the verification be in writing.

The PDA recommends an initial process when itinerant anesthesia providers are evaluated and their equipment is inspected and certified before they visit multiple nonpermitholders' offices and that the nonpermitholder's office is not inspected. The PDA suggests that to subsequently coordinate an inspection and evaluation simultaneously with each nonpermitholders' request for an itinerant's services would needlessly delay dental treatment and compromise patients' oral health and that this will be particularly detrimental to children and special needs patients who often require immediate care. The PDA also contends that requiring redundant inspections of the same mobile equipment in different non-permitholder's offices would also be too costly for the non-permitholder and it would be more cost-effective to have the unrestricted permitholder submit verification for each nonpermitholder's office that equipment standards are met, and that auxiliary office personnel have been trained appropriately by the permitholder. This process will not disrupt the patient's ability to access dental care in a timely manner. Nonitinerant permitholders are not required to be reinspected each time they experience turnover of staff that assist in the administration of anesthesia. In a similar fashion, the permitholder is charged with training the new staff. The PDA also recommends deletion of § 33.341(a)(5), which requires the nonpermitholder to verify with the permitholder that all monitoring equipment is properly installed and calibrated, because

only permitholders should have to verify that the standards for equipment are met.

The Board has amended these sections to require itinerant permitholders to satisfactorily complete a clinical evaluation, and to require the equipment transported to nonpermitholders' offices be inspected. As part of the clinical evaluation, the permitholder would be required to certify that each office location has the equipment required by the regulations and that the staff has been properly trained to handle anesthesia-related emergencies. This eliminates the need for redundant inspections of every office in which an itinerant permitholder provides services. In addition, the regulations have been amended to require the nonpermitholder to receive a written certification from the permitholder that the equipment used to administer general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia and all monitoring equipment is present, properly installed, maintained and calibrated and in proper working order. In addition, the nonpermitholder shall receive a written certification from the permitholder that the permitholder has satisfactorily completed a clinical evaluation and the equipment transported to the nonpermitholder's office has satisfactorily passed an inspection.

Certified Registered Nurse Anesthetists (CRNAs)

IRRC points out that § 33.340a(a)(4)(i) requires CRNAs to perform under the "direct on-premises supervision of the permitholder, who shall assume full responsibility for the performance of the duties." The same language appears in § 33.340a(3)(ii). IRRC questioned the need for these provisions since the State Board of Nursing regulations specify supervision requirements applicable to CRNAs in § 21.17(3) and (4) (relating to anesthesia). IRRC suggested that the Board amend these sections to cross-reference the supervision requirements for CRNAs. PANA sees the regulations as providing a disincentive to utilize CRNAs to administer anesthesia by requiring dentists to obtain the same permit level while working with a CRNA that he must obtain if administering anesthesia personally but not requiring this when a dentist utilizes an anesthesiologist or another permitted dentist. PANA recommends removing the requirement that CRNAs be under the direct supervision of the dentist in §§ 33.340(a)(4)(i) and (ii) and 33.340a(a)(4)(i) and (ii).

The Board has the authority to specify the requirements for CRNAs practicing under a dentist's anesthesia permit. Permits are issued to dentists to administer anesthesia on an out-patient basis in dental offices. CRNAs practicing in a dental office setting are practicing under the dentist's permit, that is, they are delegated the duties of administering anesthesia by the dentist who holds the permit. Since 1988, the Board's regulations have required CRNAs to perform their anesthesia administration duties under the direct on-premises supervision of the permitholder, who assumes full responsibility for the performance, and do not perform duties beyond the scope of the permitholder's authority. Therefore, the Board has declined to adopt PANA's suggestion.

Renewal Fees

IRRC questioned why renewal fees for permits under this subchapter are twice as much as the initial issuance fees. In general, the fees for initial issuance of licenses and permits reflect the actual cost of processing the applications. However, the bulk of the Board's revenues comes from renewal fees for licenses and permits. These fees are set at a level that supports the overall operations of the Board, including administrative costs, legal expenses and enforcement and investigation. The Board has proposed rulemaking increasing renewal fees across all categories of licenses and permits, published at 34 Pa.B. 5596 (October 9, 2004), in which they proposed an increase in the renewal fee for restricted permit II to $50. That increase is also incorporated in this final-form rulemaking.

General Impact of the Final-Form Rulemaking

Dr. Bennett commented that the proposed rulemaking, with the emphasis on sophisticated monitors, are unduly restrictive, confusing and will not contribute to patient safety. Dr. Laverick suggested that the proposed rulemaking would limit access to dental care to groups with the greatest need, that is, "dental phobic" individuals with special physical and mental needs and fearful pediatric patients. He opined that the proposed rulemaking would allow these patients unfettered access to care in offices of OMSs, as they should, but impose excessive or redundant requirements for these same patients treated in the offices of general dentists. He argues that as these patients will or can only have dental treatment if they are deeply sedated or anesthetized and if the only venue for this service is an OMS, the dental treatment most often provided will be extraction.

In response, the Board notes that the final-form rulemaking has been driven primarily by the *Watkins* case, in which Commonwealth Court found the requirement for "appropriate monitoring equipment" to be unconstitutionally vague, and the requirements of Act 135. The Board has endeavored to focus its regulatory efforts on defining the term "appropriate monitoring equipment" and on a combined clinical evaluation and office inspection of unrestricted and restricted permit I holders based upon standards which it believes will provide the best public protection while not unduly restricting access to care.

E. *Description of Amendments*

The amendments to Subchapters B and C (relating to licensure of dentists and dental hygienists; and minimum standards of conduct) and Subchapter E make substantive and editorial changes to §§ 33.110, 33.209 and 33.331—33.342.

§ 33.110. Volunteer license.

In response to comments received from the HPLC and IRRC, this section has been amended to reference updated permit requirements mandated by Act 135 and to apply those requirements to dentists who hold volunteer licenses.

§ 33.209. Preparing, maintaining and retaining patient records.

Requirements for maintaining patient records related to the administration of anesthesia has been updated to include Act 135 requirements.

§ 33.331. Definitions.

In response to comments received, the definitions have been amended to delete addresses for the AAOMS and the AAPD, which are subject to change. In addition, a definition for the term "authorized agent" has been added. The definition of "communications equipment" has been amended in the interest of clarity and examples were added. The definition of "peer evaluation organization" was amended to cross reference § 33.336b. The definitions for "clinical evaluation" and "office inspection" were amended to clarify that OMSs will be inspected and evaluated in accordance with the AAOMS Manual and

Guidelines and that general dentists will be inspected and evaluated in accordance with the ADA Guidelines (for adult patients) and the AAPD Guidelines (for pediatric patients). Finally, the definition of physician was amended as recommended by the PSA.

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

This section clarifies that a permit is required to administer deep sedation in a dental office.

§ 33.333. Types of permits.

This section clarifies that an unrestricted permit is required to administer deep sedation and would create a new type of permit, a temporary permit, which is limited to 1 year, as required by Act 135.

§ 33.334. Application for permit.

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

§ 33.335. Requirements for unrestricted permit.

As proposed, this section removes 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 5 years prior to January 1, 1986. The 1985 "grandfathering" clause of section 11.2(b) of the act tracked in the regulation is no longer necessary.

This section also increases the time required in a postgraduate program for advanced training in anesthesiology from 1 to 2 years to conform to the ADA's Guidelines.

§ 33.336. Requirements for restricted permit I.

This section removes 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 5 years prior to January 1, 1986. As described previously, that requirement is no longer necessary.

This section also reduces the number of hours of undergraduate or postgraduate didactic instruction and clinical experience in a program conforming to Part I or III of the ADA Guidelines.

§ 33.336a. Requirements for unrestricted permit and restricted permit I.

Subsection (a) requires all initial unrestricted and restricted I permit applicants to have satisfactorily completed an office inspection and clinical evaluation conducted by an approved peer evaluation organization. Beginning April 1, 2005, all renewal applicants shall complete an office inspection and clinical evaluation for permit renewal. If an applicant can demonstrate satisfactory completion of an office inspection and clinical evaluation within the 6 years preceding April 1, 2005, the office inspection and clinical evaluation may be waived.

This subsection requires all renewal applicants to satisfactorily complete an office inspection and clinical evaluation every 6 years. Subsection (a)(4) has been amended based on comments received to require that applications for initial or renewal permits must contain "documentation" from the peer review organization that conducted the office inspection and clinical evaluation evidencing the applicant's satisfactory completion of the office inspection and clinical evaluation.

Subsection (b) requires an OMS applicant to attest that the administration of anesthesia to adult and pediatric patients will be conducted in conformance with standards outlined in the AAOMS Guidelines and Manual. It requires a general dentist applicant to attest that the administration of anesthesia to adult patients would be conducted in accordance with the ADA Guidelines and that the administration of anesthesia to pediatric patients would be conducted in conformance with the AAPD Guidelines.

Under subsection (c), applicants are required to have successfully completed and maintained current certification in ACLS prior to the administration of anesthesia to an adult patient, and certification in PALS prior to the administration of anesthesia to a pediatric patient.

Subsection (d) provides that as of April 1, 2005, applicants for unrestricted permits are required to complete 15 hours of Board approved courses related to general anesthesia and deep sedation, and restricted permit I applicants would have to complete 15 hours of Board approved courses related to conscious sedation. These continuing anesthesia education hours are credited toward the permitholder's regular continuing education requirement.

§ 33.336b. Approved peer evaluation organizations for administering clinical evaluations and office inspections.

This section specifies peer evaluation organizations approved by the Board for conducting clinical evaluations and office inspections. The Board initially has approved the AAOMS and the PSOMS. Other organizations may apply to the Board for approval to serve as an organization that conducts clinical evaluations and office inspections. Based on comments received, this section has been amended to include restricted permit I holders as potential peer evaluators. However, the Board has determined that a restricted permit I holder may only conduct office inspections and clinical evaluations of restricted permit I holders and applicants when part of a team including at least one unrestricted permitholder.

Subsection (b) outlines factors the Board will consider in approving an organization. This subsection has been amended to require that approved peer evaluation organizations agree to maintain records of office inspections and clinical evaluations for at least 5 years. It has also been amended to require peer evaluation organizations to utilize teams of two inspectors for conducting office inspections and clinical evaluations.

§ 33.336c. Standards for office inspections and clinical evaluations.

This section has been amended to clarify that office inspections and clinical evaluations will be conducted in accordance with the AAOMS Manual and Guidelines for OMSs and the ADA Guidelines and AAPD Guidelines for general dentists.

§ 33.336d. Qualifications of peer evaluators conducting office inspections and clinical evaluations.

This section requires peer evaluators to be licensed dentists and be independent from, and have no conflict of interest with, the dentist or dental practice being reviewed. This section has been amended to include restricted permit I holders as peer evaluators, but only when part of a team consisting of at least one unrestricted permitholder.

§ 33.336e. Confidentiality of peer review reports.

This section provides that office inspection and clinical evaluation reports and related information remain confi-

dential except when included in the permit application to the Board. Subsection (b) has been amended to clarify that the peer evaluation organization must submit a written report of the results of all inspections and evaluations and notify the Board within 30 days to document whether the applicant has successfully completed the office inspection and clinical evaluation. Subsection (c) has been added to include a requirement that the peer evaluation organization immediately notify the Bureau if a clinical evaluation or office inspection reveals that the noncompliance of a dentist or dental office presents an immediate and clear danger to the public health and safety.

§ 33.337. Requirements for restricted permit II.

This section removes 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 5 or more years prior to January 1, 1986, for the reasons set forth previously. Also, the number of required hours of undergraduate or postgraduate didactic instruction and clinical experience in a conforming program is reduced from 40 to 14 to comply with changes to the ADA's *Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry*.

Subsections (b) and (c) have been amended based on comments received to require initial permit applicants to certify and renewal permit applicants to provide an attestation that the equipment used to administer nitrous oxide/oxygen analgesia is properly calibrated and maintained, contains a fail-safe system and is in working order.

§ 33.337a. Requirements for temporary permit.

This section requires an applicant for a temporary permit of any type to include with the application proof that the applicant possesses the qualifications for the permit requested. Temporary permits expire in 1 year and are not renewable.

§ 33.338. Expiration and renewal of permits.

Renewal requirements have been amended to include proof of current certification in ACLS or PALS or both for unrestricted and restricted I permits; an attestation that any equipment used to administer general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia has been installed, calibrated and maintained according to the equipment manufacturer's guidelines and contains a failsafe system; proof of compliance with anesthesia continuing education requirements; and proof of compliance with office inspection and clinical evaluation requirements.

§ 33.339. Fees for issuance of permits.

Permit fees have been amended as follows: initial unrestricted permits and restricted permit I fees is $100 and the initial restricted permit II fee remains $15. The renewal unrestricted permit and restricted permit I fee is $200. The Board proposed to increase the renewal restricted permit II fee from $15 to $50 in proposed rulemaking published at 34 Pa.B. 5596. In response to comments received, the Board has incorporated that increase in this final rulemaking package.

§ 33.340. Duties of dentists who are unrestricted permitholders.

This section establishes the standards for the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia by unrestricted permitholders. It lists the equipment and supplies that are required in the office and requires that auxiliary personnel who assist the permitholder must be currently certified in BLS. The section has been amended based on comments received by the Board to clarify auxiliary personnel may assist the permitholder so long as they are trained to perform the duties that the permitholder delegates to them, but are not permitted to actually administer the anesthesia. This section has also been amended to clarify that monitoring equipment and the equipment used to administer general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia is installed, maintained, calibrated and in proper working condition.

The requirements for itinerant permitholders, that is, permitholders who travel to the offices of nonpermitholders for the purpose of administering general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia, have been amended to require itinerant permitholders to complete a clinical evaluation and the equipment they transport to nonpermitholders' offices must be inspected. As part of the clinical evaluation and inspection, the permitholder is expected to certify that each office in which general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia is administered meets the equipment requirements of this subchapter and that the staff is properly trained to handle anesthesia-related emergencies.

Finally, this section was amended to clarify that the permitholder shall conduct the patient medical history and patient physical evaluation as required by Act 135 and to provide a cross-reference to § 33.209.

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

This section establishes the standards for the administration of conscious sedation or nitrous oxide/oxygen analgesia for restricted permit I holders. It has been amended in substantially the same manner as § 33.340.

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

The requirements for restricted permit II holders have been amended to require that monitoring equipment and equipment used to administer nitrous oxide/oxygen analgesia be installed, maintained and calibrated according to the equipment manufacturers' guidelines, contain a fail-safe system and be in proper working condition. In addition, a cross-reference to § 33.209 has been added.

§ 33.341. Duties of dentists who are not permitholders.

This section establishes the duties of dentists who are not permitholders, but who allow permitholders to administer general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia in their offices. In response to comments to the proposed rulemaking, this section has been amended to require the nonpermitholder to certify that the dental office meets the equipment and facility requirements prescribed in this subchapter. In addition, rather than verify with the permitholder that the equipment used by a permitholder is properly installed, maintained and calibrated, the regulations now require that a nonpermitholder receive a certification from the permitholder to that effect prior to allowing the administration of anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia in the office. In addition, the nonpermitholder shall obtain a certification from the permitholder that the permitholder has successfully completed a clinical evaluation and that the equipment transported to the non-permitholder's of-

fice has been inspected as required. A cross-reference to the definition of "physician" in § 33.331 has been added.

§ 33.342. Inspection of dental offices.

This section allows inspections of dental offices by Board authorized agents as defined in § 33.331 to determine if the equipment and facilities requirements have been met. This section anticipates that the Board may, through its authorized agents, conduct inspections when a death or injury related to the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia has occurred; when a complaint has been filed alleging that a dentist or dental office is not in compliance with this subchapter; or when a reasonable belief exists that conditions exist in the office that pose a danger to the health or safety of the public. It also allows for a reinspection to take place within 30 days of an inspection finding deficiencies.

F. *Fiscal Impact and Paperwork Requirements*

Some of the provisions of this final-form rulemaking will have a fiscal impact upon permitholders. Fees for an office inspection and clinical evaluation will be set by the approved peer evaluation organizations. Although the fee amounts are not known at this time, the Board upon information provided to it estimates that the combined fee for the office inspection and clinical evaluation will be in the $700 to $900 range. The one-time initial permit fee for these permitholders is increased from $15 to $100. The permit renewal fees for both unrestricted and restricted permit I holders will be $200. The initial permit fee for restricted permit II holders remains the same ($15), while the renewal fee for these permitholders is being increased to $50. In addition, requirements for current certification in ACLS and some additional required monitoring equipment may entail increased costs to permitholders. Act 135 permits the Board to "grandfather" the successful clinical evaluation and office inspection of an applicant within the last 6 years, and thereafter a clinical evaluation and office inspection is required once every 6 years. This will lessen the initial fiscal impact upon permit applicants. If the cost of a clinical evaluation and office inspection is an average of $800, the cost per year is $133, which the Board believes is a reasonable amount. At this stage, it is not possible to estimate the fiscal impact with precision.

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 (71 P. S. § 745.5(a)), on March 30, 2004, the Board submitted a copy of the notice of proposed rulemaking, published at 34 Pa.B. 1949, to IRRC and the Chairpersons of the HPLC and the SCP/PLC for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC, the HPLC and the SCP/PLC were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Department has considered all comments from IRRC, the HPLC, the SCP/PLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on March 30, 2005, the final-form rulemaking was approved by the HPLC. On April 13, 2005, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on April 14, 2005, and approved the final-form rulemaking.

I. *Contact Person*

Additional information can be obtained by contacting Cynthia K. Montgomery, State Board of Dentistry, P. O. Box 2649, Harrisburg, PA 17105-2649, (717) 783-7200.

J. *Findings*

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and the regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) This final-form rulemaking does not enlarge the purpose of proposed rulemaking published at 34 Pa.B. 1949.

(4) This final-form rulemaking is necessary and appropriate for administering and enforcing the authorizing act identified in Part B of this preamble.

K. *Order*

The Board, acting under its authorizing statutes, orders that:

(a) The regulations of the Board, 49 Pa. Code Chapter 33, are amended by amending §§ 33.110, 33.209, 33.331—33.336, 33.337, 33.338—33.340, 33.341 and 33.342 and by adding §§ 33.336a—33.336e, 33.337a, 33.340a and 33.340b to read as set forth in Annex A.

(b) The Board shall submit this order and Annex A to the Office of General Counsel and to the Office of Attorney General as required by law.

(c) The Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(d) This order shall take effect on publication in the *Pennsylvania Bulletin*.

VEASEY B. CULLEN, Jr., D.M.D.,
Chairperson

(*Editor's Note:* For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 35 Pa.B. 2073 (April 30, 2005).)

Fiscal Note: Fiscal Note 16A-4614 remains valid for the final adoption of the subject regulations.

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 B. LICENSURE OF DENTISTS AND DENTAL HYGIENISTS

§ 33.110. Volunteer license.

(a) *Purpose and definitions.*

(1) The following subsections implement the Volunteer Health Services Act (35 P. S. §§ 449.41—449.50) and provide for the issuance of a volunteer license to a qualified individual who retires from active practice and seeks to provide professional services as a volunteer. A

volunteer license authorizes the holder to practice only in an organized community-based clinic without remuneration.

(2) The following words and terms, when used in this section, have the following meanings, unless the context clearly indicates otherwise:

Approved clinic—

(i) An organized community-based clinic offering primary health care services to individuals and families who cannot pay for their care, to Medical Assistance clients or to residents of medically underserved areas or health professionals shortage areas.

(ii) The term includes a State health center, nonprofit community-based clinic and Federally qualified health center, as designated by Federal rulemaking or as approved by the Department of Health or the Department of Public Welfare.

Unrestricted license—A license which is not restricted or limited by order of the Board under its disciplinary power.

(b) *License.* A volunteer license may be issued to a licensee or certificateholder of the Board who documents to the satisfaction of the Board that the licensee will practice without personal remuneration in approved clinics and meets one of the following conditions:

(1) Holds a currently renewed, active, unrestricted license, registration or certificate in this Commonwealth and retires from active practice at the time the licensee applies for a volunteer license.

(2) Retires from the active practice of dentistry, or as a dental hygienist or as an expanded function dental assistant in this Commonwealth in possession of an unrestricted license, registration or certificate which was allowed to lapse by not renewing it. A retired licensee, registrant or certificateholder shall meet any requirements of the act or the regulations pertaining to continued education or continued competency to be eligible for renewal.

(c) *Applications.* An applicant for a volunteer license shall complete an application obtained from the Board. In addition to providing information requested by the Board, the applicant shall provide:

(1) An executed verification on forms provided by the Board certifying that the applicant intends to practice exclusively:

(i) Without personal remuneration for professional services.

(ii) In an approved clinic.

(2) A letter signed by the director or chief operating officer of an approved clinic that the applicant has been authorized to provide volunteer services in the named clinic by the governing body or responsible officer of the clinic.

(d) *Validity of license.* A volunteer license shall be valid for the biennial period for which it is issued, subject to biennial renewal. During each biennial renewal period, the volunteer license holder shall notify the Board of any change in clinic or volunteer status within 30 days of the date of the change, or at the time of renewal, whichever occurs first.

(e) *Biennial renewal.* A volunteer license shall be renewed biennially on forms provided by the Board.

(1) As a condition of biennial renewal, the applicant shall satisfy the same continuing education requirements as the holder of an active, unrestricted license.

(2) The applicant shall be exempt from payment of the biennial renewal fee in § 33.3 (relating to fees).

(f) *Return to active practice.* A volunteer license holder who desires to return to active practice shall notify the Board and apply for biennial registration on forms provided by the Board.

(g) *Disciplinary provisions.* A volunteer license holder shall be subject to the disciplinary provisions of the act and this chapter. Failure of the licensee to comply with the Volunteer Health Services Act or this section may also constitute grounds for disciplinary action.

(h) *Permits to administer general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia.*

(1) A dentist who applies for a volunteer license under subsection (b) who holds a current permit to administer anesthetic modalities may also apply for reissuance of an unrestricted or restricted permit of the type issued to the dentist as an active licensee under § 33.333 (relating to types of permits).

(2) A retired dentist who applies under subsection (b)(1) and (2) for a volunteer license who, within 2 years of the date of application, held an unrestricted permit or a restricted permit I, may apply for reissuance of the permit, but shall be required to comply with § 33.336a (relating to requirements for unrestricted permit and restricted permit I) by completing:

(i) An attestation in accordance with § 33.336a(b).

(ii) ACLS/PALS certification in accordance with § 33.336a(c).

(iii) Continuing anesthesia education in accordance with § 33.336a(d).

(3) A retired dentist who applies under subsection (b)(1) and (2) for a volunteer license who, within 5 years of the date of application, held a restricted permit II may apply for reissuance of the permit, but shall be required to comply with § 33.337(b) (relating to requirements for restricted permit II) by providing:

(i) A statement containing the make, model and serial number of nitrous oxide/oxygen analgesia equipment.

(ii) A certification that the equipment is properly calibrated, maintained, contains a fail-safe system and is in working order.

(iii) An attestation that the applicant has written procedures for handling emergencies.

(4) A dentist who applies for a volunteer license who does not qualify for a permit under paragraphs (1)—(3) and who wishes to administer general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia under § 33.332(a) (relating to requirement of permit to administer general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia) shall satisfy the educational requirements of § 33.335(a)(1), § 33.336 or § 33.337(a) (relating to requirements for unrestricted permit; requirements for restricted permit I; and requirements for restricted permit II), as applicable.

(5) Volunteer license holders will not be subject to any fee for the issuance, reissuance or renewal of a permit under this subsection.

(i) *Supervision*. Volunteer dental hygienists shall meet the supervision requirements of § 33.205(c)(1) (relating to practice as a dental hygienist). Volunteer expanded function dental assistants shall meet the supervision requirements of section 2 of the act (63 P. S. § 121).

Subchapter C. MINIMUM STANDARDS OF CONDUCT AND PRACTICE

33.209. Preparing, maintaining and retaining patient records.

(a) A dentist shall maintain a dental record for each patient which accurately, legibly and completely reflects the evaluation and treatment of the patient. A patient dental record shall be prepared and maintained regardless of whether treatment is actually rendered or whether a fee is charged. The record shall include, at a minimum, the following:

(1) The name and address of the patient and, if the patient is a minor, the name of the patient's parents or legal guardian.

(2) The date of each patient visit.

(3) A description of the patient's complaint, symptoms and diagnosis.

(4) A description of the treatment or service rendered at each visit and the identity of the person rendering it.

(5) Information as required in § 33.208 (relating to prescribing, administering and dispensing medications) and this section with regard to controlled substances or other medications prescribed, administered or dispensed.

(6) The date and type of radiographs taken and orthodontic models made, as well as the radiographs and models themselves. Notwithstanding this requirement, the dentist may release orthodontic models to the patient. This transaction shall be memorialized on a form which is signed by the patient. The signed form shall become part of the patient's record.

(7) Information with regard to the administration of local anesthesia, nitrous oxide/oxygen analgesia, conscious sedation, deep sedation or general anesthesia. This shall include results of the preanesthesia physical evaluation, medical history and anesthesia procedures utilized.

(8) The date of each entry into the record and the identity of the person providing the service if not the dentist of record-for example, dental hygienist, expanded function dental assistant, dental assistant, and the like.

(b) A patient dental record shall be retained by a dentist for a minimum of 5 years from the date of the last dental entry.

(c) Within 30 days of receipt of a written request from a patient or a patient's parents or legal guardian if the patient is a minor, an exact copy of the patient's written dental record, along with copies of radiographs and orthodontic models, if requested, shall be furnished to the patient or to the patient's new dentist. This service shall be provided either gratuitously or for a fee reflecting the cost of reproduction.

(d) The obligation to transfer records under subsection (c) exists irrespective of a patient's unpaid balance for dental services or for the cost of reproducing the record.

(e) Dentists shall provide for the disposition of patient records in the event of the dentist's withdrawal from practice, incapacity or death in a manner that will ensure their availability under subsection (c).

(f) The components of a patient dental record that are prepared by a dentist or an agent and retained by a health care facility regulated by the Department of Health or the Department of Public Welfare shall be considered a part of the patient dental record required to be maintained by a dentist, but shall otherwise be exempt from subsections (a)—(e). The components of a patient dental record shall contain information required by applicable Department of Health and Department of Public Welfare regulations—see, for example, 28 Pa. Code § 141.26 (relating to patient dental records)—and health care facility bylaws.

(g) This section does not restrict or limit the applicability of recordkeeping requirements in §§ 33.207 and 33.208 (relating to prescribing, administering and dispensing controlled substances; and prescribing, administering and dispensing medications).

(h) A dentist's failure to comply with this section will be considered unprofessional conduct and will subject the noncomplying dentist to disciplinary action as authorized in section 4.1(a)(8) of the act (63 P. S. § 123.1(a)(8)).

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

§ 33.331. Definitions.

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

AAOMS—American Association of Oral and Maxillofacial Surgeons.

AAOMS Guidelines—AAOMS Parameters and Pathways 2000 Clinical Practice Guidelines for Oral and Maxillofacial Surgery, Anesthesia in Outpatient Facilities (AAOMS Par Path 2000), 4/15/99.

AAOMS Manual—AAOMS Office Anesthesia Manual, 6th Edition, 2000.

AAPD—American Academy of Pediatric Dentistry.

AAPD Guidelines—AAPD Guidelines for the Elective Use of Conscious Sedation, Deep Sedation and General Anesthesia in Pediatric Dental Patients (May, 1998).

ACLS—Advanced Cardiac Life Support.

ADA—American Dental Association.

ADA Guidelines—ADA Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia for Dentists (October, 2000).

Adult patient—A patient 18 years of age or older.

Authorized agent—An organization or individual that the Board has officially authorized to act as the Board's agent in carrying out the mandates of the Board, the act or this chapter.

BLS—Basic Life Support

Board—The State Board of Dentistry.

CRNA—A registered nurse certified as a Registered Nurse Anesthetist by the Council on Certification or Recertification of Nurse Anesthetists of the American Association of Nurse Anesthetists authorized to administer anesthesia under § 21.17 (relating to the administration of anesthesia by a registered nurse.)

Clinical evaluation—A determination of the dentist's current technical competency to safely administer general anesthesia, deep sedation or conscious sedation and to

effectively respond to anesthesia related emergencies, in accordance with the AAOMS Manual for OMSs or the ADA Guidelines (for adult patients) and the AAPD Guidelines (for pediatric patients) for general dentists.

Communications equipment—Equipment capable of being used to elicit a response in an emergency by voice, video or electronic data transmission, such as a telephone, video link, intercom, two-way radio or other similar device.

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 or respond purposefully to physical stimulation or verbal command, or both.

General anesthesia—A controlled state of unconsciousness 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.

General dentist—A dentist who is not an oral and maxillofacial surgeon.

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

OMS—Oral and Maxillofacial Surgeon who is a current member of the PSOMS or AAOMS.

Office inspection—A determination as to whether the offices where the dentist administers anesthesia is properly equipped as prescribed in § 33.340(a)(2), § 33.340a(a)(2) or § 33.340b(a)(2) (relating to duties of dentists who are unrestricted permitholders; duties of dentists who are restricted permit I holders; and duties of dentists who are restricted permit II holders), as appropriate to the type of permit, and in accordance with the AAOMS Manual for OMSs, or the ADA Guidelines (for adult patients) and the AAPD Guidelines (for pediatric patients) for general dentists.

PALS—Pediatric Advanced Life Support.

PSOMS—Pennsylvania Society of Oral and Maxillofacial Surgeons.

Patient physical evaluation—An assessment of the patient's physical and mental condition relevant to the surgery to be performed and anesthesia or anesthetic to be utilized.

Pediatric patient—A patient under 18 years of age.

Peer evaluation organization—An entity approved by the Board for administering a program whereby licensed dentists conduct office inspections and clinical evaluations for dentists seeking initial or renewal unrestricted or restricted I permits in accordance with § 33.336b (relating to approved peer evaluation organizations for administering clinical evaluations and office inspections).

Peer evaluator—A licensed dentist with a current unrestricted permit or restricted permit I who conducts an office inspection or clinical evaluation under the auspices of an approved peer evaluation organization.

Physician—A Pennsylvania licensed medical or osteopathic physician who is currently certified by the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology, or is credentialed to administer anesthesia in a hospital or ambulatory surgical facility licensed by the Department of Health.

§ 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.* 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.

(4) *Temporary permit.* A permit limited to 1 year which authorizes the applicant for an unrestricted, restricted I or restricted II permit to administer the appropriate type of anesthesia relevant to the applicant's qualifications.

§ 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, or a temporary permit, 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 done one of the following:

(1) Successfully completed at least 2 years 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*.

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

§ 33.336. Requirements for restricted permit I.

To secure a restricted permit I, a dentist shall have successfully completed a course on conscious sedation comprising at least 60 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 ADA's *Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry*.

§ 33.336a. Requirements for unrestricted permit and restricted permit I.

(a) *Office inspections and clinical evaluations.*

(1) *Initial permits.* Initial unrestricted and restricted I permit applicants shall satisfactorily complete an office inspection and clinical evaluation conducted by an approved peer evaluation organization under § 33.336b (relating to approved peer evaluation organizations for administering clinical evaluations and office inspections).

(2) *First renewal permit beginning April 1, 2005.* Beginning April 1, 2005, renewal unrestricted and restricted I permit applicants shall satisfactorily complete an office inspection and clinical evaluation as a condition for permit renewal. Completion of an office inspection and clinical evaluation may be waived if the applicant can demonstrate satisfactory completion of an office inspection and clinical evaluation, administered by an organization approved by the Board, within 6 years preceding April 1, 2005.

(3) *Subsequent renewal permit.* Following the applicant's initial permit renewal after April 1, 2005, unrestricted and restricted permit I renewal applicants shall satisfactorily complete an office inspection and clinical evaluation once every 6 years.

(4) *Report of office inspection and clinical evaluation.* An application for an initial or renewal permit shall contain documentation from the peer review organization that conducted the office inspection and clinical evaluation that evidences the applicant's satisfactory completion of an office inspection and clinical evaluation and a written report of the results of the office inspection and clinical evaluation.

(b) *Standards for anesthesia administration.*

(1) An OMS applicant for an unrestricted or restricted I permit shall attest that the administration of anesthesia to adult and pediatric patients will be conducted in conformance with the standards outlined in the AAOMS Guidelines and the AAOMS Manual.

(2) A general dentist applicant for an unrestricted or restricted I permit shall attest that the administration of anesthesia to adult patients will be conducted in conformance with the standards outlined in the ADA Guidelines and that the administration of anesthesia to pediatric patients will be conducted in conformance with the standards outlined in the AAPD Guidelines.

(c) *ACLS/PALS certification.*

(1) *Adult patients.* An applicant for an unrestricted or restricted I permit shall have successfully completed and maintained current certification in ACLS prior to the administration of anesthesia to an adult patient.

(2) *Pediatric patients.* An applicant for an unrestricted or restricted I permit shall have successfully completed and maintained current certification in PALS prior to the administration of anesthesia to a pediatric patient.

(d) *Continuing anesthesia education.*

(1) Beginning April 1, 2005, and for all subsequent renewal periods, the following hours of continuing education are required as a condition of permit renewal:

(i) *Unrestricted permit.* An applicant for an unrestricted permit shall have completed 15 hours of Board approved courses related to general anesthesia and deep sedation.

(ii) *Restricted permit I.* An applicant for a restricted permit I shall have completed 15 hours of Board approved courses related to conscious sedation.

(2) Continuing anesthesia education will be credited toward the permitholder's continuing education requirement under § 33.401(a)(1) (relating to credit-hour requirements).

§ 33.336b. Approved peer evaluation organizations for administering clinical evaluations and office inspections.

(a) The following organizations are deemed qualified to conduct clinical evaluations and office inspections and do not require prior approval from the Board:

(1) The American Association of Oral and Maxillofacial Surgeons (AAOMS).

(2) The Pennsylvania Society of Oral and Maxillofacial Surgeons (PSOMS).

(b) An organization of oral and maxillofacial surgeons or of unrestricted permit and restricted permit I holders that does not qualify as an organization to conduct clinical evaluations and office inspections under subsection (a) may apply to the Board for approval to serve as an organization to conduct clinical evaluations and office inspections. In determining whether to grant approval, the Board will consider the following factors:

(1) Whether the organization agrees to utilize peer evaluators meeting the following criteria:

(i) A minimum 5 years experience administering general anesthesia and deep sedation (for unrestricted permitholders) or conscious sedation (for restricted permit I holders) within the last 7 years.

(ii) A current unrestricted permit or restricted permit I.

(iii) Completion of a minimum 7-hour course in conducting office inspections and clinical evaluations.

(2) Whether the organization has sufficient peer evaluators that meet the criteria listed in § 33.336d (relating to qualifications of peer evaluation conducting office inspecting and clinical evaluations) to conduct office inspections and clinical evaluations.

(3) Whether the organization has the technical competence to administer office inspections and clinical evaluations to applicants for initial and renewal permits.

(4) Whether the organization's fee for office inspections and clinical evaluations is based upon reasonable costs.

(5) Whether the organization has standards for satisfactory completion of an office inspection and clinical evaluation.

(6) Whether the organization has an internal appeal procedure to contest the office inspection or clinical evaluation.

(7) Whether the organization has a peer review oversight committee whose members meet the following criteria:

(i) A minimum 5 years experience administering general anesthesia and deep sedation.

(ii) A current unrestricted permit.

(8) Whether the organization has procedures to facilitate fair, unbiased and equitable office inspections and clinical evaluations.

(9) Whether the organization agrees to make records of all office inspections and clinical evaluations available to the Board upon request and agrees to maintain these records for at least 5 years.

(10) Whether the organization agrees to conduct a subsequent office inspection or clinical evaluation within a reasonable time if the results of the initial office inspection or clinical evaluation are unsatisfactory.

(11) Whether the organization agrees to conduct office inspections and clinical evaluations in conformance with the standards outlined in the AAOMS Manual and AAOMS Guidelines (for OMSs) and the ADA Guidelines or AAPD Guidelines (for general dentists), and in accordance with §§ 33.340 and 33.340a (relating to duties of dentists who are unrestricted permitholders; and duties of dentists who are restricted permit I holders).

(12) Whether the organization agrees to utilize peer evaluator teams consisting of at least two permitholders as follows:

(i) For office inspections and clinical evaluations of unrestricted permitholders and applicants, a team of at least two unrestricted permitholders.

(ii) For office inspections and clinical evaluations of restricted permit I holders and applicants, a team consisting of at least two unrestricted permitholders, or a team consisting of at least one unrestricted permitholder and one restricted permit I holder.

(c) An approved peer evaluation organization may not require a permit applicant to become a member of the organization as a precondition for the organization to conduct a clinical evaluation and office inspection for the applicant.

§ 33.336c. Standards for office inspections and clinical evaluations.

Office inspections and clinical evaluations shall be conducted in accordance with the AAOMS Manual and AAOMS Guidelines for OMSs and the ADA Guidelines and AAPD Guidelines for general dentists.

§ 33.336d. Qualifications of peer evaluators conducting office inspections and clinical evaluations.

(a) A peer evaluator conducting office inspections and clinical evaluations of unrestricted permitholders and applicants shall be a licensed dentist holding a current unrestricted permit.

(b) A peer evaluator conducting office inspections and clinical evaluations of restricted permit I holders and applicants shall be a licensed dentist holding either a current unrestricted permit or a current restricted permit I, provided that a peer evaluator holding a current restricted permit I may only conduct office inspections and clinical evaluations when part of a team consisting of at least one unrestricted permitholder.

(c) A peer evaluator shall be independent from, and have no conflict of interest with, the dentist or dental practice being reviewed.

(d) The administering approved peer evaluation organization shall ensure that its peer evaluators are qualified under this section.

§ 33.336e. Confidentiality of peer evaluation reports.

(a) Office inspection and clinical evaluation reports and related information shall remain confidential except as provided in § 33.336a(a)(4) (relating to requirements for unrestricted permit and restricted permit I) and the act of June 21, 1957 (P. L. 390, No. 212) (65 P. S. §§ 66.1—66.4), known as the Right-to-Know Law.

(b) An administering approved peer evaluation organization shall submit to the Board a written report of the results of the office inspection and clinical evaluation within 30 days from the date the office inspection and clinical evaluation was that documents whether the applicant has successfully completed the office inspection and clinical evaluation.

(c) If a clinical evaluation or office inspection reveals that the noncompliance of a dentist or dental office presents an immediate and clear danger to the public health and safety, the administering approved peer evaluation organization shall immediately notify the commissioner of the Bureau.

§ 33.337. Requirements for restricted permit II.

(a) To secure a restricted permit II, a dentist shall have successfully completed a course in nitrous oxide/oxygen analgesia comprising at least 14 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 ADA's *Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry*.

(b) Initial restricted II permit applicants shall provide the following:

(1) The make, model and serial number of any nitrous oxide/oxygen analgesia equipment utilized by the applicant.

(2) Certification that the equipment is properly calibrated and maintained, contains a fail-safe system and is in working order.

(3) An attestation that the applicant has written office procedures for administering nitrous oxide/oxygen analgesia and handling emergencies related to the administration of nitrous oxide/oxygen analgesia.

(c) *Subsequent renewal permits.* Following the applicant's initial permit renewal after April 1, 2004, for each subsequent renewal period, an applicant shall provide an attestation to the Board, in accordance with § 33.338(b)(4) (relating to expiration and renewal of permits), that the nitrous oxide/oxygen analgesia equipment that the applicant uses is properly calibrated and maintained and contains a fail-safe system.

§ 33.337a. Requirements for temporary permit.

(a) To secure a temporary unrestricted permit, restricted permit I or restricted permit II, an applicant shall include with the application proof that the applicant possesses the qualifications required for the type of permit requested.

(b) Temporary permits expire 1 year following the effective date and may not be renewed.

§ 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 permitholder'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.

(2) The permit renewal fee prescribed in § 33.339 (relating to fees for issuance of permits).

(3) Proof of current certification in ACLS (adult patients) or PALS (pediatric patients), or both (for unrestricted permits and restricted I permits).

(4) An attestation, on the renewal application, that any equipment used to administer general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia has been installed, properly calibrated and maintained according to the equipment manufacturer's guidelines and contains a fail-safe system (for all permits).

(5) Proof of compliance with the continuing anesthesia education requirement under § 33.336a(d) (relating to requirements for unrestricted permit and restricted I permit).

(6) Proof of compliance with the office inspection and clinical evaluation requirements under § 33.336a(a).

§ 33.339. Fees for issuance of permits.

The following fees are charged for the issuance of permits under this subchapter:

(1) *Unrestricted permit.*

(i) Initial..... $100

(ii) Renewal..... $200

(iii) Temporary..... $100

(2) *Restricted permit I.*

(i) Initial..... $100

(ii) Renewal..... $200

(ii) Temporary..... $100

(3) *Restricted permit II.*

(i) Initial..... $15

(ii) Renewal..... $50

(iii) Temporary..... $15

§ 33.340. Duties of dentists who are unrestricted permitholders.

(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, the permitholder takes or updates a patient medical history and gives the patient 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 permitholder 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 commensurate with the patient's age, size and condition.

(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, size and condition of the patient and the AAOMS Manual and AAOMS Guidelines for adult and pediatric patients (OMS); the ADA Guidelines for adult patients (general dentists); and the AAPD Guidelines for pediatric patients (general dentists).

(xiii) Capnograph for intubated patients and pulse oximeter.

(xiv) ECG.

(xv) Blood pressure monitoring device.

(xvi) Defibrillator.

(xvii) Results of patient medical history and patient physical evaluation, and identification of anesthesia procedures to be utilized, prior to the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia.

(xviii) Signed, written, informed patient consent, prior to the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia, which includes a description of the procedure, its risks and possible alternative treatments. Consent for a minor patient shall be obtained from the minor's parent or guardian.

(xix) Stethoscope.

(3) Auxiliary personnel who assist the permitholder in the administration of general anesthesia, deep sedation or conscious sedation:

(i) Are trained to perform the duties that the permitholder delegates to them, if the duties do not require the professional judgment and skill of the permitholder and do not involve the actual administration of general anesthesia, deep sedation or conscious sedation.

(ii) Perform their duties under the direct on-premises supervision of the permitholder, 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 permitholder's authority.

(iv) Are currently certified in BLS.

(4) CRNAs who are delegated the duties of administering general anesthesia, deep sedation or conscious sedation:

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

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

(iii) Are currently certified in ACLS.

(5) The dentist possesses a current certification in ACLS for adult patients and PALS for pediatric patients.

(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 general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia by the permitholder or by a CRNA working under the supervision of the permitholder. The permitholder 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 permitholder will be used for the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia.

(8) General anesthesia or deep sedation administered to pediatric patients by or under the delegation of a general dentist is administered by a person dedicated solely to the administration and monitoring of anesthesia, and the dental procedures are performed by a dental licensee who is not involved in the administration of the general anesthesia.

(9) Monitoring equipment and equipment used to administer general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia is installed, maintained 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 monitoring equipment is being used during the administration of general anesthesia.

(10) If the permitholder travels to the offices of nonpermitholders for the purpose of administering general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia, the permitholder shall satisfactorily complete a clinical evaluation and the equipment transported to the nonpermitholder dentist's office for the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia by a permitholder shall satisfactorily complete an inspection conducted by an approved peer evaluation organization under § 33.336b(a) (relating to approved peer evaluation organizations for administering clinical evaluations and office inspections) in accordance with the requirements of the AAOMS Manual and AAOMS Guidelines (OMS). As part of that clinical evaluation and inspection, the permitholder shall certify that each office location in which general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia is administered by the permitholder has the equipment required by paragraph (2) and that the staff is properly trained to handle anesthesia-related emergencies.

(11) General anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia is administered to adult and pediatric patients in accordance with the AAOMS Guidelines and AAOMS Manual (OMSs) or to adult patients in accordance with the ADA Guidelines (general dentists) or to pediatric patients in accordance with the AAPD Guidelines (general dentists). Conflicts between the AAOMS Guidelines, the AAOMS Manual, the ADA Guidelines, or the AAPD Guidelines and this subchapter shall be resolved in favor of this subchapter.

(12) Patient records are prepared, maintained and retained in accordance with § 33.209 (relating to preparing, maintaining and retaining patient records).

(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, the permitholder takes or updates a patient medical history and gives the patient 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 permitholder 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 commensurate with the patient's age, size and condition.

(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, size and condition of the patient and the AAOMS Manual and AAOMS Guidelines for adult and pediatric patients (OMS); the ADA Guidelines for adult patients (general dentists); and the AAPD Guidelines for pediatric patients (general dentists.)

(xiii) Pulse oximeter.

(xiv) ECG.

(xv) Blood pressure monitoring device.

(xvi) Defibrillator.

(xvii) Results of patient medical history and patient physical evaluation, and identification of anesthesia procedures to be utilized, prior to the administration of conscious sedation or nitrous oxide/oxygen analgesia.

(xviii) Signed, written, informed patient consent, prior to the administration of conscious sedation or nitrous oxide/oxygen analgesia, which includes a description of the procedure, its risks and possible alternative treatments. Consent for a minor patient shall be obtained from the minor's parent or guardian.

(xix) Stethoscope.

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

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

(ii) Perform their duties under the direct on-premises supervision of the permitholder, 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 permitholder's authority.

(iv) Are currently certified in BLS.

(4) CRNA who are delegated the duties of administering conscious sedation:

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

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

(iii) Are currently certified in ACLS.

(5) The dentist possesses a current certification in ACLS for adult patients and PALS for pediatric patients.

(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 permitholder or by a CRNA working under the supervision of the permitholder. The permitholder 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 permitholder will be used for the administration of conscious sedation or nitrous oxide/oxygen analgesia.

(8) Monitoring equipment and equipment used to administer conscious sedation and nitrous oxide/oxygen analgesia is installed, maintained 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) If the permitholder travels to the offices of non-permitholders for the purpose of administering conscious sedation or nitrous oxide/oxygen analgesia, the permitholder shall satisfactorily complete a clinical evaluation and the equipment transported to a non-permitholder dentist's office for the administration of conscious sedation or nitrous/oxide oxygen analgesia by a permitholder must satisfactorily complete an inspection conducted by an approved peer evaluation organization under § 33.336b(a) (relating to approved peer evaluation organizations for administering clinical evaluations and office inspections) in accordance with the requirements of the AAOMS Manual and AAOMS Guidelines, the ADA Guidelines or the AAPD Guidelines, as applicable. As part of that clinical evaluation and inspection, the permitholder shall certify that each office location in which conscious sedation or nitrous oxide/oxygen analgesia is administered has the equipment required by paragraph (2) and that the staff is properly trained to handle anesthesia-related emergencies.

(10) Conscious sedation and nitrous oxide/oxygen analgesia is administered to adult and pediatric patients in accordance with the AAOMS Guidelines and AAOMS Manual (OMSs) or to adult patients in accordance with the ADA Guidelines (general dentists) or to pediatric patients in accordance with the AAPD Guidelines (general dentists). Conflicts between the AAOMS Guidelines, the AAOMS Manual, the ADA Guidelines, or the AAPD Guidelines and this subchapter shall be resolved in favor of this subchapter.

(11) Patient records are prepared, maintained and retained in accordance with § 33.209 (relating to preparing, maintaining and retaining patient records).

(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, the permitholder takes or updates a patient medical history and gives the patient a physical evaluation sufficient to determine the patient's suitability to receive nitrous oxide/oxygen analgesia.

(2) The dental office in which the permitholder 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) Dental office suction equipment.

(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) Communications equipment.

(ix) Monitoring equipment, procedures and documentation to conform to the age, size and condition of the patient and the AAOMS Manual and AAOMS Guidelines for adult and pediatric patients (OMS), the ADA Guidelines for adult patients (general dentists) and the AAPD Guidelines for pediatric patients (general dentists).

(x) Results of patient medical history, patient physical evaluation and identification of the nitrous oxide/oxygen analgesia procedure to be utilized, prior to the administration of nitrous oxide/oxygen analgesia.

(xi) Signed, written, informed patient consent, prior to the administration of nitrous oxide/oxygen analgesia, which includes a description of the procedure, its risks and possible alternative treatments. Consent for a minor patient shall be obtained from the minor's parent or guardian.

(xii) Stethoscope.

(3) Nitrous oxide/oxygen analgesia is administered to adult and pediatric patients in accordance with the AAOMS Guidelines and AAOMS Manual (OMS) or to adult patients in accordance with the ADA Guidelines (general dentists) or to pediatric patients in accordance with the AAPD Guidelines (general dentists). Conflicts between the AAOMS Guidelines, the AAOMS Manual, the

ADA Guidelines or the AAPD Guidelines and this subchapter shall be resolved in favor of this subchapter.

(4) Monitoring equipment and equipment used to administer nitrous oxide/oxygen analgesia is installed, maintained 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 nitrous oxide/oxygen analgesia.

(5) Patient records are prepared, maintained and retained in accordance with § 33.209 (relating to preparing, maintaining and retaining patient records).

(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 permitholders.

(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 meets the appropriate 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 unrestricted permitholders; duties of dentists who are restricted permit I holders; and duties of dentists who are restricted permit II 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 or CRNA delegatee.

(ii) A physician as defined in § 33.331 (relating to definitions).

(4) Either the dentist who performs the dental procedure or the CRNA, physician or permitholder who administers the general anesthesia, deep sedation or conscious sedation possesses a current certification in ACLS.

(5) The nonpermitholder dentist receives a written certification from the permitholder that all monitoring equipment and equipment used to administer general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia is present in the nonpermitholder's office, is properly installed, maintained 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 that monitoring equipment is being used during the administration of general anesthesia.

(6) The nonpermitholder receives a written certification from the permitholder that the permitholder has satisfactorily completed a clinical evaluation and the equipment transported to the nonpermitholder dentist's office for the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia by a permitholder has satisfactorily completed an inspection conducted by an approved peer evaluation organization under § 33.336b(a) (relating to approved peer evaluation organizations for administering clinical evaluations and office inspection), in accordance with the requirements of the AAOMS Manual and AAOMS Guidelines (OMS), ADA Guidelines or AAPD Guidelines, as applicable.

(b) A dentist shall submit to the Board a complete written report on a death or 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 incident.

(c) 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).

(d) Beginning April 1, 2005, and for all subsequent renewal periods, non-permitholder licensees who maintain offices in which general anesthesia, deep sedation or conscious sedation is administered, shall have completed 5 hours of Board approved courses related to anesthesia. These 5 hours shall be credited toward the nonpermitholder licensee's continuing education requirement under § 33.401(a)(1) (relating to credit hour requirements).

§ 33.342. Inspection of dental offices.

(a) *Inspections*. The Board, through its authorized agents, may conduct inspections 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 unrestricted permitholders; duties of dentists who are restricted permit I holders; and duties of dentists who are restricted permit II holders) or as follows:

(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.

(b) *Notice of inspection*. Prior to the start of an 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.

(c) *Access during 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.

(d) *Guideline for inspection*. An inspection will be conducted under provisions pertaining to office facilities

and equipment in § 33.340(a)(2), § 33.340a(a)(2), § 33.340b(a)(2) or § 33.341(2) (relating to duties of dentists who are not permitholders).

(e) *Inspection showing noncompliance.*

If an inspection reveals that a dental office is not in compliance with the equipment and facility requirements prescribed in § 3.340(a)(2), § 33.340a.(a)(2), § 33.340b.(a)(2) or § 33.341(2), the Board will give the dentist whose office was inspected written notice of the deficiencies and of the deadline for correcting the deficiencies. A reinspection shall take place within 30 days, and, if noncompliance is still shown, formal administrative charges may be initiated.

[Pa.B. Doc. No. 05-939. Filed for public inspection May 13, 2005, 9:00 a.m.]

[49 PA. CODE CH. 33]

Biennial Renewal Fees—Dentist, Restricted Anesthesia Permit II

The State Board of Dentistry (Board) amends §§ 33.3 and 33.339 (relating to fees; and fees for issuance of permits) to read as set forth in Annex A. The final-form rulemaking increases the biennial licenses renewal fee for dentists from $100 to $250 and increase the biennial renewal fee for a restricted anesthesia permit II from $25 to $50.

Effective Date

The final-form rulemaking will be effective upon publication in the *Pennsylvania Bulletin*. The new fees will apply to the biennial renewal period beginning April 1, 2005, and thereafter.

Statutory Authority

Section 4(b) of The Dental Law (act) (63 P. S. § 123(b)) provides that if existing revenues are not sufficient to meet expenditures over a 2-year period, the Board shall increase fees by regulation to meet or exceed projected expenditures. Section 11.2(6) of the act (63 P. S. § 130c(a)(6)) specifically authorizes the Board to assess biennial renewal fees for anesthesia permits.

Background and Need for the Final-Form Rulemaking

The Board's current biennial license renewal fee for dentists was established by regulation on July 1, 1995. See 25 Pa.B. 2598 (July 1, 1995). The Board's current fee schedule for renewal of anesthesia permits was established by regulation on July 9, 1988. See 18 Pa.B. 3045 (July 9, 1988). Under section 4(b) of the act, the Board must support its operations with the revenue it derives from fees, fines and civil penalties. Historically, the Board raises virtually all of its operating revenue through biennial renewal fees.

At Board meetings in November 2003 and July 2004, the Department of State's Offices of Revenue and Budget (Offices) presented a summary of the Board's revenue and expenses for Fiscal Years (FY) 2001-2002 and 2003-2004, and projected revenue and expenses through FY 2007-2008. The Offices projected a deficit of $838,225.49 in FY 2004-2005, a deficit of $1,900,225.49 in FY 2005-2006, a deficit of $1,743,225.49 in FY 2006-2007 and a deficit of $2,876,225.49 in FY 2007-2008. The Offices recommended that the Board raise fees to meet or exceed projected expenditures, in compliance with section 4(b) of the act.

The Board's review of its actual and projected expenses over the past 5 years revealed significant shortfalls in the areas of hearing expenses, Board administration and legislative and regulatory analysis. For example, despite annual budget increases, the hearing expenses were $6,225 over budget in FY 1999-2000, $3,188 over budget in FY 2000-2001, $19,954 over budget in FY 2001-2002, $11,283 over budget in FY 2002-2003. The amount budgeted for hearing expenses has risen from $3,000 in FY 1999-2000 to $26,000 in FY 2003-2004. Nevertheless, the hearing expenses are expected to be $43,310 over budget in 2003-2004. Similarly, the budgeted amounts for law enforcement have risen from $233,000 in FY 1999-2000 to $345,000 in FY 2003-2004. The Board has also experienced significant increases in actual expenses over estimated expenses in other areas of the legal office and the Professional Health Monitoring Program (PHMP), the Bureau-wide program for impaired professionals. Overall increased expenditures in these program areas have resulted from greater enforcement activity and increases in the number of disciplinary actions and in the numbers of licensees participating in the PHMP. At the same time, the Board's licensee population has declined by about 400 licensees over the past 5 years, decreasing the Board's biennial revenue. The Offices anticipate that the proposed new biennial renewal fees will enable the Board to recapture the current deficit and to maintain a stable fee structure for renewals upon which its licensees can rely for the next four renewal periods.

In considering the appropriateness of the fee, the Board also compared the proposed renewal fee to similar fees in surrounding states. The Board found that the increase to $250 would result in a renewal fee which is comparable to the renewal fees charged in the surrounding states.

The Board is also removing the anesthesia permit biennial renewal fee from § 33.3 and moving it to § 33.339. The Board finds that § 33.339 is the more appropriate place for these fees because it is within Subchapter E (relating to administration of general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia), which relates solely to anesthesia permits and standards for the administration of anesthesia in dental offices. In a proposed rulemaking published at 34 Pa.B. 1949 (April 10, 2004), the Board filed notice that it intends to amend § 33.339 to reflect new fees for anesthesia permits. Finally, the Board is adding a cross reference in § 33.3 to § 33.339.

Comment and Review of Proposed Rulemaking

Publication of proposed rulemaking at 34 Pa.B. 5596 (October 9, 2004) was followed by a 30-day public comment period during which the Board received comments from the Pennsylvania Dental Association (PDA) and one individual dentist, Thomas F. Cwalina, D.M.D. On December 8, 2004, the Board received comments from the Independent Regulatory Review Commission (IRRC) under the Regulatory Review Act (71 P. S. §§ 745.1—745.12). The Board did not receive comments from the House Professional Licensure Committee (HPLC) or the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC). The Board reviewed all of the comments and subsequently voted to adopt the final-form rulemaking at its January 14, 2005, meeting.

IRRC and the PDA noted that the increase in the biennial renewal fee for dentists from $100 to $250 was significant. The PDA opined that raising fees at the same level in future licensure cycles could have a negative impact on patients' access to dental care should dentists elect to practice in other states. The Board has reviewed

the license renewal fees for dentists in the surrounding states and finds that $250 will not place dentists in this Commonwealth at a competitive disadvantage. For example, in New Jersey, dentists pay a biennial renewal fee of $280. In Ohio, the biennial renewal fee is $245 and in Maryland it is $449. In New York, dentists pay a triennial renewal fee of $345. In Delaware, the renewal fee is assessed annually at $125. Moreover, the Board notes that the methodology it followed in establishing the fee is that employed by every licensing board in the Department of State of averaging costs over several biennial renewal cycles. It believes that this approach provides stable fees and allows the Board to operate in compliance with section 4(b) of the act.

The PDA also suggested that the Board consider other methods to meet its budgetary needs, such as raising the disciplinary charges or raising fees for those dentists who are licensed in this Commonwealth, but practice in a different state. The Board is limited by section 10.1 of the act (63 P. S. § 129.1) to the imposition of a civil penalty up to $1,000 on any current licensee who violates any provision of the act or any individual who practices as a dentist, dental hygienist or expanded function dental assistant without a license or certificate. Therefore, the first option suggested by the PDA is not available absent legislative action. The Board issues licenses and certificates which authorize the holders to practice their professions in this Commonwealth without regard to whether they reside or are licensed and practice in other states. The second option suggested by the PDA raises legal considerations that the Board believes makes that option untenable.

The PDA and IRRC questioned the Board's decision not to increase the biennial renewal fees for dental hygienists and expanded function dental assistants. IRRC commented that these other license groups impact program and disciplinary costs and therefore the Board should consider at least moderate increases for these groups. The PDA also requested that the Board consider increasing licensure fees for hygienists because their infractions and subsequent disciplinary hearings incur costs that should not be absorbed by dentists alone. While the Board agrees that dental hygienists and expanded function dental assistants contribute to program costs, the Board finds that the costs associated with disciplinary matters within these groups are relatively low. There are currently 362 open disciplinary matters before the Board. Of these, 333 involve dentists, 26 involve dental hygienists, 1 involves an expanded function dental assistant and 2 involve the unlicensed practice of dentistry. Therefore, over 90% of the disciplinary matters handled by the Board involve dentists. The Board believes that these costs are more equitably borne by dentists, rather than their employees.

IRRC also commented regarding the increase to the renewal fees for anesthesia permits. IRRC noted that the biennial renewal fees are twice the initial permit fee and asked for an explanation. The initial permit fee has been set by the Board at a level that covers the cost of processing the initial permit application. However, the bulk of the Board's revenue is raised through biennial renewal fees. These fees are set at a level that is sufficient to fund the Board's operations, including Board administration, enforcement and investigation, legal office costs including hearing expenses and legislative and regulatory activity. These costs are therefore borne by licensees and permitholders, rather than initial applicants.

Dr. Cwalina also commented regarding the proposed increase in the biennial renewal fee for restricted permit II holders. He suggested that the increased fees be used to pay for a program of State inspections of nitrous oxide/oxygen analgesia equipment. Dr. Cwalina's comment is related to the Board's proposed rulemaking regarding anesthesia, which was published at 34 Pa.B. 1949. That proposed rulemaking requires dentists who hold restricted II permits to install, maintain and calibrate their nitrous oxide/oxygen analgesia equipment according to the manufacturer's guidelines. Dr. Cwalina suggested that the costs associated with calibration of nitrous oxide machines would be prohibitive because the unit must be returned to the manufacturer for calibration. The increase in the renewal fee for restricted II permits is required to support the operations of the Board as previously discussed, including the costs of implementing the anesthesia regulations. The Board has no plans at this time to implement an inspection program for nitrous oxide/oxygen analgesia equipment.

Description of Final-Form Rulemaking

Based upon the expense and revenue estimates provided to the Board, the Board is amending § 33.3 to increase the fee for biennial renewal of licenses for dentists from $100 to $250. The Board is also removing the renewal fees for anesthesia permits from § 33.3 and moving them to § 33.339 and is increasing the biennial renewal fee for a restricted anesthesia permit II from $25 to $50. The biennial renewal fees for an unrestricted anesthesia permit and a restricted anesthesia permit I were previously amended in the Board's proposed rulemaking published at 34 Pa. B. 1949.

Fiscal Impact

The proposed rulemaking will increase the biennial renewal fee for dentists and will increase the biennial renewal fee a restricted anesthesia permit II. The proposed rulemaking should have no other fiscal impact on the private sector, the general public or political subdivisions.

Paperwork Requirements

The proposed rulemaking will require the Board to alter some of its forms to reflect the new biennial renewal fees; however, it should not create additional paperwork for the private sector.

Sunset Date

The act requires that the Board monitor its revenue and costs on a FY and biennial basis. Therefore, no sunset date has been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on September 29, 2004, the Board submitted a copy of the notice of proposed rulemaking, published at 34 Pa.B. 5596, to IRRC and the Chairpersons of the SCP/PLC and the HPLC for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC, the SCP/PLC and the HPLC were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Department has considered all comments from IRRC, the SCP/PLC, the HPLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on March 30, 2005, the final-form rulemaking was approved by the HPLC. On April 13, 2005, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory

Review Act, IRRC met on April 14, 2005, and approved the final-form rulemaking.

Additional Information

Individuals who need information about the final-form rulemaking should contact Lisa Burns, Administrator, State Board of Dentistry, P. O. Box 2649, Harrisburg, PA 17105-2649.

Findings

The Board finds that:

(1) Public notice of intention to adopt amendments was given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and the regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) This final-form rulemaking is necessary and appropriate for administration of the act.

Order

The Board orders that:

(a) The regulations of the Board, 49 Pa. Code, Chapter 33, are amended by amending §§ 33.3 and 33.339 to read as set forth in Annex A.

(b) The Board shall submit this order and Annex A to the Office of General Counsel and to the Office of Attorney General as required by law.

(c) The Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(d) This order shall take effect on publication in the *Pennsylvania Bulletin*.

VEASEY B. CULLEN, Jr., D.M.D.,
Chairperson

(*Editor's Note:* For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 35 Pa.B. 2073 (April 30, 2005).)

Fiscal Note: Fiscal Note 16A-4615 remains valid for the final adoption of the subject regulations.

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 A. GENERAL PROVISIONS

§ 33.3. Fees.

(a) Following is the schedule of fees charged by the Board:

Application fee—dentists, dental hygienists and expanded function dental assistants	$20
Criteria approval application fee—dentists, dental hygienists and expanded function dental assistants	$35
Fictitious name registration fee	$35
Verification of license, permit or registration fee—dentists, dental hygienists and expanded function dental assistants	$15
Certification of scores, permit or registration fee—dentists, dental hygienists and expanded function dental assistants	$25
Biennial renewal fee—dentists (for the renewal period beginning April 1, 2005, and thereafter)	$250
Biennial renewal fee—dental hygienists	$40
Biennial renewal fee—expanded function dental assistants	$25
Temporary permit—expanded dental assistants	$15
Application fee—dental radiology authorization	$20
Notification application—postgraduate training or faculty member	$25

(b) For fees related to anesthesia permits, refer to § 33.339 (relating to fees for issuance of permits).

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

§ 33.339. Fees for issuance of permits.

The following fees are charged for the issuance of permits under this subchapter:

(1) *Unrestricted permit.*	
(i) Initial	$100
(ii) Renewal	$200
(iii) Temporary	$100
(2) *Restricted permit I.*	
(i) Initial	$100
(ii) Renewal	$200
(iii) Temporary	$100
(3) *Restricted permit II.*	
(i) Initial	$15
(ii) Renewal	$50
(iii) Temporary	$15

[Pa.B. Doc. No. 05-940. Filed for public inspection May 13, 2005, 9:00 a.m.]