### Regulatory Analysis Form

**1) Agency**

Department of State, Bureau of Professional and Occupational Affairs, State Board of Dentistry

**2) I.D. Number (Governor's Office Use)**

16A-4614

**3) Short Title**

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

**4) PA Code Cite**

49 Pa. Code Chapter 33, Subchapter E

**5) Agency Contacts & Telephone Numbers**

| Primary Contact: Cynthia K. Montgomery, Counsel | Secondary Contact: Joyce McKeever, Deputy Chief Counsel, Department of State |
| State Board of Dentistry (717) 783-7200 | Department of State (717) 783-7200 |

**6) Type of Rulemaking (check one)**

- [ ] Proposed Rulemaking
- [X] Final Order Adopting Regulation
- [ ] Final Order, Proposed Rulemaking
- [ ] Omitted

**7) Is a 120-Day Emergency Certification Attached?**

- [X] No
- [ ] Yes: By the Attorney General
- [ ] Yes: By the Governor

**8) Briefly explain the regulation in clear and nontechnical language.**

These amendments enhance requirements for permit holders who administer general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia, specifically with reference to "appropriate monitoring equipment," in response to Watkins v. State Board of Dentistry, and implement the legislative mandate of Act 135 of 2002.

**9) State the statutory authority for the regulation and any relevant state or federal court decisions.**

The Board is authorized to adopt regulations concerning anesthesia under Sections 3(o) and 11.2(a) of the Dental Law (63 P.S. §§122(o), 130c(a)).
Regulatory Analysis Form

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

The regulations are mandated by Act 135 of 2002.

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

The existing anesthesia regulations were adopted in 1988. In 1999, the Commonwealth Court invalidated a provision of the regulations which required the use of “appropriate monitoring equipment” when administering anesthesia to a patient in a dental office as unconstitutionally vague in Watkins v. State Board of Dentistry, 740 A.2d 760 (Pa. Cmwlth. 1999). The Watkins case involved the death of a 3½ year-old child during the administration of anesthesia in a dental office. Thereafter, the Board undertook a comprehensive review of all regulations dealing with the administration of anesthesia in order to update them based on the current state of the art in the use of anesthesia in the practice of dentistry. Proposed regulations were published at 31 Pa.B. 6691 on December 8, 2001. The Board entertained public comment on the proposal and considered those comments and suggestions throughout the following year. However, before the Board was able to adopt final regulations, the legislature responded to the Watkins case by adopting Act 135 of 2002 on November 25, 2002, which required the Board to revisit the proposed regulations. This final rulemaking package implements the legislative mandates of Act 135.

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

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

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

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

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

Permit holders may perceive that they will be adversely affected by permit renewal fee increases and fees for office inspections and clinical evaluations.

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

Permit holding dentists who administer general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia in dental offices will be required to comply with the regulations.

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

In accordance with Executive Order 1996-1, the Board sent a draft of the first proposed rulemaking on April 28, 2000 to 138 dental associations, schools and interested individuals for predraft comment. Subsequent drafts, including a draft of the second proposed rulemaking, were made available to these persons and organizations. Proposed changes were discussed extensively at regularly scheduled Board meetings. The Board considered all comments received.

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

The Board estimates that 466 unrestricted permit holders, 477 restricted permit I holders and 2,389 restricted permit II holders will seek permit renewals every two years, resulting in $244,750 additional cost for this part of the regulated community. In addition, unrestricted and restricted permit I holders will be required to incur costs estimated at $700 - $900 every 6 years for the required office inspection/clinical evaluations, or an average of $125,734 per year. The number of temporary permit applications is not known, however an increase is anticipated during the initial year of Act 135 implementation.
(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

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

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

There should be no additional costs or savings to state government since the cost of implementing the regulation will be born by permit holders.
(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

<table>
<thead>
<tr>
<th></th>
<th>Current FY</th>
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<th>FY +2</th>
<th>FY +3</th>
<th>FY +4</th>
<th>FY +5</th>
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<td><strong>Total Savings</strong></td>
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</tr>
</tbody>
</table>

| **COSTS:**       |            |       |       |       |       |       |
| Regulated Community | $370,484  | $125,734 | $370,484 | $125,734 | $370,484 | $125,734 |
| Local Government  | $N/A       | $N/A  | $N/A  | $N/A  | $N/A  | $N/A  |
| State Government  | $N/A       | $N/A  | $N/A  | $N/A  | $N/A  | $N/A  |
| **Total Costs**   | $370,484  | $125,734 | $370,484 | $125,734 | $224,750 | $125,734 |

| **REVENUE LOSSES:** |            |       |       |       |       |       |
| Regulated Community | N/A        | N/A   | N/A   | N/A   | N/A   | N/A   |
| Local Government    | N/A        | N/A   | N/A   | N/A   | N/A   | N/A   |
| State Government    | N/A        | N/A   | N/A   | N/A   | N/A   | N/A   |
| **Total Revenue Losses** | N/A        | N/A   | N/A   | N/A   | N/A   | N/A   |

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

While it is impossible to anticipate how many initial permits will be issued, the regulation increases anesthesia permit renewal fees for unrestricted and restricted permit I holders by $175 (from $25 to $200) and restricted permit II holders by $25 (from $25 to $50). Therefore, the regulated community will incur increased costs in the amount of $244,750 biennially, calculated as follows:

- 466 unrestricted permit holders X $175(increase) = $81,550
- 477 restricted permit I holders X $175(increase) = $83,475
- 2,389 restricted permit II holders X $25(increase) = $59,725

In addition, the Board anticipates that the cost of the office inspection/clinical evaluation could be as high as $700 to $900 every 6 years. This would result in an average annual cost of approximately $125,734, calculated as follows:

- 943 permit holders X $800 (average cost) = $754,400 ÷ 6 = $125,733.33
(20b) Provide the past three year expenditure history for programs affected by the regulation.

<table>
<thead>
<tr>
<th>Program</th>
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<th>FY -2</th>
<th>FY -1</th>
<th>Current FY</th>
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<td>FY 03-04 Projected</td>
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<td>$1,018,724.64</td>
<td>$1,020,169.72</td>
<td>$1,124,000</td>
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</table>

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

The benefits of tightly regulating the administration of general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia will outweigh the costs if even one life is saved. All citizens who need to have anesthesia administered in a dental office will benefit by the improved standards and more stringent permitting requirements.

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

Nonregulatory alternatives were not considered because the decision in Watkins made it clear that regulatory changes would be needed and Act 135 of 2002 mandates that the Board adopt regulations.

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

No alternate regulatory schemes were considered because these regulations implement the legislative mandates of Act 135.
### Regulatory Analysis Form

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

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

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

This rulemaking should put Pennsylvania in the forefront of public health and safety measures related to anesthesia/analgesia provided to children and adults in dental offices. No competitive disadvantage with other states should occur. See attached chart, which compares these requirements with those of surrounding states.

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

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

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

The Board reviews regulatory proposals at regularly scheduled public meetings. However, in light of the statutory mandate, the Board has not scheduled public hearings or informational meetings regarding this regulation.
(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

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

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

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

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

Because of the public health and safety issues involved and the direction of Commonwealth Court in Watkins, as well as the legislative mandates of Act 135 of 2002, the Board urges that these final regulations be adopted as soon as possible. The regulation will be effective upon publication as final rulemaking in the Pennsylvania Bulletin and the regulated community will be expected to comply with the continuing education requirements and office inspection/clinical evaluation requirement for permit renewals effective April 1, 2005 as mandated by the statute. All affected unrestricted and restricted permit I holders received actual notice from the Board reminding them of the mandates of Act 135 in August of 2004 and PSOMS has already begun offering the office inspections/clinical evaluations.

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

The proposed amendments have not been given a sunset date. The Board regularly evaluates the effectiveness of the proposed amendments following their adoption as final rulemaking.
NOTICE OF FINAL RULEMAKING
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF DENTISTRY
49 Pa. Code, Chapter 33

SUBCHAPTER E. ADMINISTRATION OF GENERAL ANESTHESIA, DEEP SEDATION, CONSCIOUS SEDATION AND NITROUS OXIDE/OXYGEN ANALGESIA
The State Board of Dentistry (Board) hereby 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 amendments will be effective upon publication of final-form rulemaking 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), 130c(a)).

C. Background and Purpose

The amendments are in response to Act 135 of 2002 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 permit holders) is unconstitutionally vague. Shortly after the decision, the Board constituted an Anesthesia Committee. This Committee was tasked with reviewing state of the art equipment, procedures and protocols for safe and effective delivery of anesthesia and analgesia in dental offices. Several drafts of the proposed rulemaking were developed. On March 23, 2001 the State Board of Dentistry approved the final draft for promulgation as proposed rulemaking. Proposed rulemaking was published December 8, 2001 at 31 Pa.B. 6691.

Following the comment period, the State Board of Dentistry and its Anesthesia Committee reviewed the comments received. The Anesthesia Committee met on March 14, 2002 to consider the suggestions and prepare responses. Just prior to that meeting, the Anesthesia Committee learned that Dr. Robert S. Muscalus, Physician General, had several concerns regarding the proposed regulations. 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 regulation package approved by the State Board of Dentistry, was under internal Departmental review on November 25, 2002, when Act 135 of 2002 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 Board’s Anesthesia 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 permit holders. 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 or unrestricted permit holders 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 PSOMS conducting the clinical evaluations and office inspections for nonmember permit holders. 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 Society’s insurance carrier.

4. Legislative amendment to Dental Law to grant limited immunity to evaluators/inspectors.

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 regulation 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, 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.


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 Pennsylvania Society of Oral and Maxillofacial Surgeons (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. The Board did not receive comments from the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC).

Following the comment period, the State Board of Dentistry and its Anesthesia 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 Anesthesia Committee to review all comments and to determine initial responses for this final regulation package. The Anesthesia Committee met via teleconference on July 26, 2004. After considering all of the public comments, this final rulemaking was drafted and presented to the Board at its October 22, 2004, meeting. The Board subsequently voted to adopt the final rulemaking at its December 3, 2004, meeting.

D. Comment and Regulatory Review of Proposed Rulemaking

Volunteer Regulations

The House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC) both 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 has amended §33.110 (relating to volunteer license) 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 the Volunteer Health Services Act at 35 P.S. §449.43 (relating to definitions), 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 3 active volunteer dentist licensees and that none of these licensees hold an anesthesia permit.

Compliance with Act 135 of 2002

The HPLC noted that Act 135 of 2002 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 11.2(b)(1) 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 permit holders seeking renewal for the biennial period beginning April 1, 2005, must have a clinical evaluation and office inspection. The Board intends 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 the Act 135 requirements regarding office inspection and clinical evaluations. The Board notes that section 11.2(b)(6) 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 permit holder 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 permit holders and 477 restricted I permit holders. According to the Pennsylvania Society of Oral and Maxillofacial Surgeons (PSOMS), most of the 466 unrestricted permit holders are members of the PSOMS and many have satisfactorily undergone both a clinical evaluation and office inspection within the previous six years. In addition, PSOMS is now offering inspections and clinical evaluations to nonmembers. The Board anticipates that a majority of these permit holders will have complied with the requirement prior to April 1, 2005.

The HPLC also noted that the proposed regulation was delivered to the Committee on March 31, 2004, one day before the statutorily imposed deadline. The Board acknowledges that unresolved issues and uncertainty regarding implementation of this 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 regulation from inception of the first proposed rulemaking through this final rulemaking. Given the technical nature of the regulation and the varying opinions of the various organizations and other interested parties, the Board sought to assure that the regulation safeguards the public’s health and safety, while not unduly restricting access to care for the citizens of the 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 regulation 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 Dental Law 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. Additionally, under the direction of the Commissioner of Professional and Occupational Affairs, the Board is also, in addition to publishing these final regulations, 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 Dental Law, 63 P.S. §130c(c) to initial applicants until April 1, 2005.

Moreover, none of the three dental schools in Pennsylvania 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 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 PSOMS has been able to obtain the necessary liability coverage in order 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 permit holders in August of 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 permit holders could apply to conduct peer evaluations. Section 11.2(b)(1) the act (63 P.S. § 130c(b)(2)) 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 Pennsylvania Dental Association (PDA) and Dr. Walter Laverick, DMD, 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. PDA commented that restricting the pool of potential peer evaluators to only those who hold an unrestricted permit places an undue burden on those permit holders, who make up approximately half of the affected permit holders. 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 permit holder.

**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) relating to 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 discussed above. 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 permit holders and requested the Board’s rationale for this reduction. Act 135, and 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; non-permit holders allowing anesthesia in offices – 5 hours) and crediting the continuing anesthesia education toward the permit holder’s 30 hours of continuing education required for licensure under Section 3(j.2)(2) of the Dental Law (63 P.S. §122(j.2)(2)). The Board had recommended that anesthesia permit holders 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 (relating to requirements for restricted permit II). These reductions were done to comply with changes to the ADA’s Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry.

BLS/ACLS/PALS

The HPLC noted that the requirement contained in Act 135 of 2002 that assistants be certified in CPR. The committee sought clarification that Basic Life Support (BLS) includes CPR. Basic Life Support 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 (FBAO) and the use of automatic external defibrillators (AEDs).

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 ACLS or 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 these regulations are 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 regulation was silent with respect to this requirement. IRRC also noted that the regulation is silent regarding recordkeeping requirements for peer review organizations. The Board’s current regulation at §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 regulations 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, 33.340a and 33.340b (relating to duties of dentists who are unrestricted permit holders; 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 regulation 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 the Pennsylvania Association of Nurse Anesthetists (PANA) suggested that the Board include language in §33.331 recognizing the successor volumes for each of the documents (AAOMS Guidelines, AAOMS Manual, AAPD Guidelines, 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 permit holders, 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. The Pennsylvania Society of Anesthesiologists (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 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 administering, 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 revision of §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 regulation 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 (see 63 P.S. § 11.2(b)(1)(emphasis added)). 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 Subsection (b) of 33.336e (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.” The 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 oral and maxillofacial surgeon (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. Where 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 permit holders and applicants.

IRRC requested the reason a separate attestation for unrestricted permit holders and restricted permit I holders was necessary under §33.336a(b) (relating to requirements for unrestricted permit and restricted permit I). 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 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) and 33.340(a)(9) (relating to expiration and renewal of permits; and duties of dentists who are unrestricted permit holders). PDA recommends that §33.338(b)(4) be amended by the words “and maintained” after “…properly calibrated.” PDA believes that periodic preventive maintenance as well as calibration is an accepted standard of practice and should apply to such 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, non-permit holders must 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 permit holders) as proposed merely requires the nonpermit holder to verify with the permit holder that the equipment meets the statutory standards regarding safety. This section requires that a nonpermit holder 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 nonpermit holder to obtain written certification from the permit holder that all monitoring equipment and equipment used to administer general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia is present in the nonpermit holder’s office, is properly installed, maintained and calibrated, and that monitoring equipment is being used during the administration of general anesthesia. The nonpermit holder must also receive a written certification that the permit holder has satisfactorily completed a clinical evaluation and the equipment transported to the nonpermit holder’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) (relating to duties of dentists who are unrestricted permit holders) be amended to specify that the permit holder must take the medical history and conduct the physical evaluation, subsection (a)(12) should be deleted, and the same clarification made in §33.340(a)(1) and 33.340b(a)(1) (relating to duties of dentists who are restricted permit I holders; and duties of dentists who are restricted permit II holders). PSA also commented regarding §11.2 of
Act 135 of 2002, which requires permit holders to conduct the physical evaluation. 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 the regulations be amended at §3340(a)(12) by adding "or a physician" and deleting the CRNA. The Board agrees with IRRC that Act 135 requires the permit holder who administers the anesthesia to take the medical history and conduct the physical evaluation. Therefore, the regulations have been amended to so require. The scope of these regulations does not extend to hospitals or ambulatory surgical facilities, therefore, the Board has declined to adopt 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 regulations to make it clear that auxiliary personnel assist the permit holder 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. Mr. Warfel suggested that true anesthesia, where the patient is actually paralyzed and cannot breathe on his own, requires a separate anesthetist from the provider. The Pennsylvania Society of Anesthesiologists (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 permit holders 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. 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 nonpermit holders’ offices and equipment transported to the nonpermit holder’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 nonpermit holder’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 nonpermit holder’s office is not necessary. All believe that the inspection of the permit holder’s equipment is sufficient, and note that Act 135 does not require inspections of nonpermit holders’ offices. IRRC and PDA opined that the permit holder should be responsible for ensuring that all appropriate equipment and facility requirements are met. Both IRRC and the PDA suggest that the provision in §33.341(a)(5) requiring the nonpermit holder to verify with the permit holder that the equipment is installed properly and calibrated, should be deleted as only permit holders should be responsible for verifying that the standards are met. The 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 where itinerant anesthesia providers are evaluated and their equipment is inspected and certified before they visit multiple nonpermit holders’ offices, and that the nonpermit holder’s office is not inspected. The PDA suggests that to subsequently coordinate an inspection and evaluation simultaneously with each nonpermit holders’ 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 nonpermit holder’s offices would also be too costly for the nonpermit holder and it would be more cost-effective to have the unrestricted permit holder submit verification for each nonpermit holder’s office that equipment standards are met, and that auxiliary office personnel have been trained appropriately by the permit holder. This process will not disrupt the patient’s ability to access dental care in a timely manner. Non-itinerant permit holders are not required to be re-inspected each time they experience turnover of staff that assist in the administration of anesthesia. In a similar fashion the permit holder is charged with training the new staff. The PDA also recommends deletion of §33.341(a)(5), which requires the nonpermit holder to verify with the permit holder that all monitoring equipment is properly installed and calibrated, because only permit holders should have to verify that the standards for equipment are met.

The Board has amended these sections to require itinerant permit holders to satisfactorily complete a clinical evaluation, and to require the equipment transported to nonpermit holders’ offices be inspected. As part of the clinical evaluation, the permit holder 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 permit holder provides services. In addition, the regulations have been amended to require the nonpermit holder to receive a written certification from the permit holder that the equipment used to administer general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia and all monitoring equipment is present, is properly installed, maintained and calibrated, and in proper working order. In addition the nonpermit holder
must receive a written certification from the permit holder that the permit holder has satisfactorily completed a clinical evaluation and the equipment transported to the nonpermit holder’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 permit-holder, 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 49 Pa. Code §21.17(3) and (4) (relating to anesthesia). IRRC suggested that the Board amend these sections to cross-reference the supervision requirements for CRNAs. The Pennsylvania Association of Nurse Anesthetists (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).

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 permit holder, who assumes full responsibility for the performance, and do not perform duties beyond the scope of the permit holder’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 that was published on October 9, 2004 at 34 Pa.B. 5596, in which they proposed an increase in the renewal fee for restricted permit II’s to $50. That increase is also incorporated in this final rulemaking.

General Impact of Regulations

Dr. Bennett commented that the proposed regulations, with the emphasis on sophisticated monitors, are unduly restrictive, confusing and will not contribute to patient safety. Dr. Laverick suggested that the regulations would limit access to dental care to groups with the greatest need, that
is, the "dental phobic," individuals with special physical and mental needs and fearful pediatric patients. He opined that the regulations would allow these patients unfettered access to care in offices of oral and maxillofacial surgeons, 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 oral and maxillofacial surgeon, the dental treatment most often provided will be extraction.

In response, the Board notes that the regulations have 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 of 2002. 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 revisions to Subchapters B, C and 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 House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (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 American Association of Oral and Maxillofacial Surgeons (AAOMS) and the American Academy of Pediatric Dentistry (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 (relating to approved peer evaluation organizations for administering clinical evaluations). The definitions for "clinical evaluation" and "office inspection" were amended to clarify that oral and maxillofacial surgeons 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 Pennsylvania Society of Anesthesiologists (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 one 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 "grandparenting" clause of Section 11.2(b) of the law, (63 P.S. §130c(d)), tracked in the regulation is no longer necessary.

The 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 must 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 the AAOMS 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 Advanced Cardiac Life Support (ACLS) prior to the administration of anesthesia to an adult patient, and certification in Pediatric Advanced Life Support (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 permit holder’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 Pennsylvania Society of Oral and Maxillofacial Surgeons (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 permit holder.

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 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.

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 permit holder.

§ 33.336e. Confidentiality of peer review reports.

This section provides that office inspection and clinical evaluation reports and related information remain confidential 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 would be $100, and the initial restricted permit II fee would remain $15. The renewal unrestricted permit and restricted permit I fee would be $200. The Board proposed to increase the renewal restricted permit II fee from $15 to $50 in proposed rulemaking published on October 9, 2004 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 permit holders.

This section establishes the standards for the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia by unrestricted permit holders. It lists the equipment and supplies that are required in the office and requires that auxiliary personnel who assist the permit holder must be currently certified in Basic Life Support (BLS). The section has been amended based on comments received by the Board to clarify auxiliary personnel may assist the permit holder so long as they are trained to perform the duties that the permit holder 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 permit holders, that is, those permit holders who travel to the offices of non-permit holders for the purpose of administering general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia, have been amended to require itinerant permit holders to complete a clinical evaluation and the equipment they transport to non-permit holders’ offices must be inspected. As part of the clinical evaluation and inspection, the permit holder 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 permit holder must conduct the patient medical history and patient physical evaluation as required by Act 135 and to provide a cross-reference to §33.209 (relating to preparing, maintaining and retaining patient records).

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

§ 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 (relating to preparing, maintaining and retaining patient records) has been added.

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

This section establishes the duties of dentists who are not permit holders, but who allow permit holders 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 nonpermit holder to certify that the dental office meets the equipment and facility requirements prescribed in this subchapter. In addition, rather than verify with the permit holder that the equipment used by a permit holder is properly installed, maintained and calibrated, the regulations now require that a nonpermit holder receive a certification from the permit holder 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 nonpermit holder must obtain a certification from the permit holder that the permit holder has successfully completed a clinical evaluation and that the equipment transported to the nonpermit holder’s office has been inspected as required. A cross-reference to the definition of “physician” in §33.331 (relating to definitions) has been inserted.

§ 33.342. Inspection of dental offices.

This section allows inspections of dental offices by Board authorized agents as now defined in §33.331 (relating to definitions) to determine if the equipment and facilities requirements have been met. This section anticipates that the Board may, through its authorized agents, conduct inspections where a death or injury related to the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia has occurred; where a complaint has been filed alleging that a dentist or dental office is not in compliance with this subchapter; or where 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. Compliance With Executive Order 1996-1

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

G. Fiscal Impact and Paperwork Requirements

Some of the provisions of this proposed rulemaking will have a fiscal impact upon permit holders. 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 permit holders 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 permit holders is being increased to $50. In addition, requirements for current certification in Advanced Cardiac Life Support (ACLS) and some additional required monitoring equipment may entail increased costs to permit holders. 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.

H. Sunset Date

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

I. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), the Board submitted copies of the notice of proposed rulemaking, published at 34 Pa.B. 1949, (April 10, 2004) to IRRC and the Chairpersons of the House Professional Licensure Committee (HPLC) and the Senate Consumer Protection and Professional Licensure Committee (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 Board/Commission 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 ________, the final-form rulemaking was approved by the HPLC. On ________________, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on ________________, and approved the final-form rulemaking.

J. Contact Person

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

K. Findings

The State Board of Dentistry finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the Commonwealth Documents Law (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 amendment does not enlarge the purpose of proposed rulemaking published at 34 Pa.B. 1949.

(4) This amendment is necessary and appropriate for administering and enforcing the authorizing act identified in Part B of this Preamble.

L. Order

The State Board of Dentistry, acting under its authorizing statutes, orders that:

(a) The regulations of the Board at 49 Pa. Code §§ 33.110 and 33.209 and 33.331-333.342 are amended to read 33.110 and 33.209 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.
§33.110. Volunteer license.

* * *

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

* * *

(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 complete a refresher course in advanced training in anesthesiology and related subjects, or in conscious sedation (whichever is applicable) as approved by the Board, that conforms to the American Dental Association guidelines of either §33.335(a)(1) (relating to requirements for unrestricted permit) or §33.336(a)(1) relating to requirements for restricted permit I) 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 also apply for reissuance of the permit, but shall be required to complete a refresher course in nitrous oxide/oxygen analgesia approved by the Board that conforms to §33.337(a)(1) (relating to requirements for restricted permit II) 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(a)(1) or §33.337(a)(1) (RELATING TO REQUIREMENTS FOR UNRESTRICTED PERMIT; REQUIREMENTS FOR RESTRICTED PERMIT I; AND REQUIREMENTS FOR RESTRICTED PERMIT II), AS APPLICABLE.
Subchapter C. MINIMUM STANDARDS OF CONDUCT.

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:

(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 PRE-ANESTHESIA PHYSICAL EVALUATION, MEDICAL HISTORY AND ANESTHESIA PROCEDURES UTILIZED.

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, with principal offices at 9700 W. Bryn Mawr Avenue, Rosemont, IL 60018.


AAPD – American Academy of Pediatric Dentistry, with principal offices at 211 East Chicago Avenue, Suite 700, Chicago, IL 60611-2663.


ACLS – Advanced Cardiac Life Support.

ADA – American Dental Association.

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

AUTHORIZED AGENT – ANY 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 DENTAL LAW, OR THIS CHAPTER.

BLS – Basic Life Support.

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 49 Pa. Code § 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 eliciting 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.
**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, including deep sedation, that is produced by a pharmacologic method, a nonpharmacologic method, or a combination of both, and that is accompanied by a complete or partial loss of protective reflexes that include the patient’s inability to maintain an airway independently and to respond purposefully to physical stimulation or verbal command.

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

* * *

**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 340b(a)(2)(relating to duties of dentists who are unrestricted permit holders; 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, with principal offices at 2700 North Broad Street, Suite 106, Lansdale, PA 19644.

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 with unrestricted permits 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. [Effective January 9, 1990, a] A dentist shall possess a current permit issued by the Board under this subchapter before administering, or supervising the administration of, general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia in a dental office.

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

* * *

§ 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.

* * *

(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.

* * *

§ 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 [1 year] 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) [Be certified] 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 Surgeons Surgery or a Fellow of the American Dental Society of Dental Anesthesiology, or be eligible for examination by the American Board of Oral and Maxillofacial Surgery.

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

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

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

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

§ 33.336. Requirements for restricted permit I.

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

(1) Successfully completed a course on conscious sedation comprising at least 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 [American Dental Association’s] ADA’s Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry.

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

(i) Is competent to administer conscious sedation.

(ii) Administers conscious sedation in a properly equipped dental office as prescribed in § 33.340(a)(2) (relating to duties of dentists who are permit holders).
(b) To determine whether the requirements of subsection (a)(2) are satisfied, the Board will require the applicant to undergo a clinical evaluation and office inspection conducted by the Board through its authorized agents. The clinical evaluation and office inspection will be conducted in accordance with the American Association of Oral and Maxillofacial Surgeons' *Office Anesthesia Evaluation Manual*.

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

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

(a) Office inspections and clinical evaluations.

1. *Initial permits. Beginning April 1, 2004,* all 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 after BEGINNING April 1, 2005.* Beginning April 1, 2005, all 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, all 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 [an original letter] 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 permit holder’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:


(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 PERMIT HOLDERS) 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 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 State Board of Dentistry 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 permit holders 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 PERMIT HOLDERS AS FOLLOWS:

   (i) FOR OFFICE INSPECTIONS AND CLINICAL EVALUATIONS OF UNRESTRICTED PERMIT HOLDERS AND APPLICANTS, A TEAM OF AT LEAST TWO UNRESTRICTED PERMIT HOLDERS.

   (ii) FOR OFFICE INSPECTIONS AND CLINICAL EVALUATIONS OF RESTRICTED PERMIT I HOLDERS AND APPLICANTS, A TEAM CONSISTING OF AT LEAST TWO UNRESTRICTED PERMIT HOLDERS, OR A TEAM CONSISTING
OF AT LEAST ONE UNRESTRICTED PERMIT HOLDER 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 PERMIT HOLDERS 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
PERMIT HOLDER.

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

(e)(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 must notify 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 conducted as to whether the office inspection and clinical evaluation report has been accepted or rejected by the peer evaluation organization. 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 OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS.
§ 33.337. Requirements for restricted permit II.

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

(1) 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 American Dental Association’s ADA’s Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry.

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

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

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

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

Initial permits. Beginning April 1, 2004, all 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 he 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.

* * * *

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

(1) A renewal application on a form provided by the Board [and pay the].

(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 equipment utilized 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) [Issuance under § 33.335(a)(1) or (2)] Initial.................................$ [15] 100

(ii) [Issuance under § 33.335(a)(3)] Renewal.................................$[300] 200

(iii) Temporary...........................................................................$100

(2) Restricted permit I.

(i) [Issuance under § 33.336(a)(1)] Initial.................................$ [15] 100

(ii) [Issuance under § 33.336(a)(2)] Renewal.................................$[300] 200

(ii) Temporary...........................................................................$100
§ 33.340. Duties of dentists who are unrestricted permit holders.

(a) A dentist who possesses [a] 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 PERMIT HOLDER TAKES OR UPDATES a patient medical history is taken or updated and GIVES the patient is given a physical evaluation sufficient to determine the patient’s suitability to receive general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia.

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

* * * *

(iv) Suction equipment commensurate with the patient’s age, size and condition.

* * * *

(xii) [Appropriate monitoring] 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 permit holder in the administration of general anesthesia, deep sedation or conscious sedation [or nitrous oxide/oxygen analgesia]:

(i) Are trained to perform the duties that the permit holder delegates to them, if the duties do not require the professional judgment and skill of the permit holder and do not involve the ACTUAL administration of general anesthesia, deep sedation or conscious sedation [or nitrous oxide/oxygen analgesia].
(iv) Are currently certified in BLS.

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

(iii) Are currently certified in ACLS.

(5) [He] The dentist possesses a current certification [to administer cardiopulmonary resuscitation (CPR)] in ACLS for adult patients and PALS for pediatric patients.

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

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

(8) 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) The non-permit holder dentist’s office and IF THE PERMIT HOLDER TRAVELS TO THE OFFICES OF NON-PERMIT HOLDERS FOR THE PURPOSE OF ADMINISTERING GENERAL ANESTHESIA, DEEP SEDATION, CONSCIOUS SEDATION OR NITROUS OXIDE/OXYGEN ANALGESIA, THE PERMIT HOLDER SHALL SATISFACTORILY COMPLETE A CLINICAL EVALUATION AND THE equipment transported to the non-permit holder dentist’s office for the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia by a permit holder shall satisfactorily complete an office-inspection conducted by an approved peer evaluation organization under § 33.336b(a) in accordance with the requirements of the AAOMS Manual and AAOMS Guidelines (OMS). AS PART OF THAT CLINICAL EVALUATION AND INSPECTION, THE PERMIT HOLDER SHALL CERTIFY THAT EACH OFFICE LOCATION IN WHICH GENERAL ANESTHESIA, DEEP SEDATION, CONSCIOUS SEDATION OR NITROUS OXIDE/OXYGEN ANALGESIA IS ADMINISTERED BY THE PERMIT HOLDER 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) The patient medical history and patient physical evaluation are conducted by the permit holder, physician or CRNA.

(13)—PATIENT RECORDS ARE PREPARED, MAINTAINED AND RETAINED IN ACCORDANCE WITH §33.209 (RELATING TO PREPARING, MAINTAINING AND RETAINING PATIENT RECORDS).

* * *

§ 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 PERMIT HOLDER TAKES OR UPDATES a patient medical history is taken or updated and GIVES the patient is given a physical evaluation sufficient to determine the patient’s suitability to receive conscious sedation or nitrous oxide/oxygen analgesia.

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

(i) An operating room.

(ii) An operating table or chair.

(iii) A lighting system.

(iv) Suction equipment 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 permit holder in the administration of conscious sedation:

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

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

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

(iv) Are currently certified in BLS.

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

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

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

(iii) Are currently certified in 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 permit holder or by a certified registered nurse anesthetist working under the supervision of the permit holder. The permit holder shall submit the report within 30 days of the death or incident.

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

(8) 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) The non-permit holder dentist’s office and **if the permit holder travels to the offices of non-permit holders for the purpose of administering conscious sedation or nitrous oxide/oxygen analgesia, the permit holder shall satisfactorily complete a clinical evaluation and the equipment transported to the non-permit holder dentist’s office for the administration of conscious sedation or nitrous oxide oxygen analgesia by a permit holder must satisfactorily complete an office inspection conducted by an approved peer evaluation organization under § 33.336b(a) 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 PERMIT HOLDER 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) The patient medical history and patient physical evaluation are conducted by the permit holder, physician or CRNA.

(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).

§ 33.340b. 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 PERMIT HOLDER TAKES OR UPDATES a patient medical history is taken or updated and GIVES the patient
is given a physical evaluation sufficient to determine the patient's suitability to receive nitrous oxide/oxygen analgesia.

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

(i) An operating room.
(ii) An operating table or chair.
(iii) A lighting system.
(iv) 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 permit holders.

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

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

2. The dental office has been inspected and meets the appropriate equipment and facility requirements prescribed in § 33.340(a)(2), or § 33.340a(a)(2) or § 33.340b(a)(2) (relating to duties of dentists who are unrestricted permit holders; 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 Pennsylvania licensed medical or osteopathic physician who is currently credentialed to administer anesthesia in a hospital licensed by the Department of Health AS DEFINED IN §33.331 (RELATING TO DEFINITIONS).

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

(5) The nonpermit holder dentist verifies with RECEIVES A WRITTEN CERTIFICATION FROM the permit holder that all monitoring equipment and equipment used to administer general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia is present in the nonpermit holder'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 nonpermit holder dentist's office and RECEIVES A WRITTEN CERTIFICATION FROM THE PERMIT HOLDER THAT THE PERMIT HOLDER HAS SATISFACTORILY COMPLETED A CLINICAL EVALUATION AND THE equipment transported to the nonpermit holder dentist's office for the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia by a permit holder shall--HAS satisfactorily complete COMPLETED an office inspection conducted by an approved peer evaluation organization under § 33.336b(a), 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 [unusual] an incident requiring medical care and resulting in physical or mental injury that directly resulted from the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia in his dental office. The report shall be submitted within 30 days of the death or [unusual] incident.
(d) *Continuing anesthesia education.* Beginning April 1, 2005, and for all subsequent renewal periods, nonpermit holder 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 nonpermit holder licensee’s continuing education requirement under § 33.401(a)(1).

§ 33.342. Inspection of dental offices.

(a) *[Routine inspections]* Inspections. [No more than once a year during regular business hours, the] The Board, through its authorized agents, may conduct [a routine inspection] 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 permit holders; duties of dentists who are restricted permit I holders; and duties of dentists who are restricted permit II holders)[.] or as follows:

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

(1) Upon a death or injury related to the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia in the office.

[(4) As a follow-up to a previous inspection that revealed the office’s non-compliance with the equipment and facility requirements prescribed in § 33.340(a)(2).]
(c) (b) **Notice of inspection.** Prior to the start of [a routine or special] 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.

[(d) (c)] **Access during inspection.** [For purposes of a routine or special inspection, a] 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.

* * *


[(f) (e)] **Inspection showing noncompliance.**

If [a routine or special] an inspection reveals that a dental office is not in compliance with the equipment and facility requirements prescribed in §§ 3.340(a)(2), 33.340(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.
<table>
<thead>
<tr>
<th>State</th>
<th>General Anesthesia Permit</th>
<th>Deep Sedation Permit</th>
<th>Conscious Sedation Permit</th>
<th>Nitrous Oxide/Oxygen Analgesia Permit</th>
<th>CLS or ACLS</th>
<th>AAMS Standards</th>
<th>American Academy of Pediatric Dentistry Standards</th>
<th>Office Inspection</th>
<th>Specified Monitoring or Equipment</th>
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Safe proprietorship—A business in which an architect licensed in this Commonwealth owns all the assets and operates in his personal capacity.

§ 9.3. Fees.

Annual renewal fee for registered [architecture firms] partnerships, professional associations, professional corporations, business corporations, limited liability companies and limited liability partnerships ($100 fee shall be assessed biennially) .................. $ 50

[Pa.B. Doc. No. 04-596. Filed for public inspection April 9, 2004, 9:00 a.m.]

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) proposes to amend Subchapter E (relating to administration of general anesthesia, conscious sedation and nitrous oxide/oxygen analgesia) to read as set forth in Annex A.

A. Effective Date

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

B. Statutory Authority

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

C. Background and Purpose

In 1986, the act was amended to establish standards for the administration of general anesthesia and conscious sedation in a dental office. Subchapter E was adopted to implement the amendments to the act at 18 Pa.B. 3045 (July 9, 1989). In 1999, the Commonwealth Court in Watkins v. State Board of Dentistry, 740 A.2d 760 (Pa. Cmwlth. 1999) invalidated a provision of § 33.340 (relating to duties of dentists who are permit holders) concerning “appropriate monitoring equipment” required for the administration of general anesthesia as unconstitutionally vague.

In response to the Watkins decision, the Board undertook a comprehensive review of all regulations dealing with the administration of general anesthesia, conscious sedation and nitrous oxide adopted under the 1985 amendments to the act. While the Board focused its attention primarily upon clarifying necessary monitoring equipment, it considered the need to update and improve other requirements of the regulations to conform to current standards of safe dental practice.

The Board empanelled an Anesthesia Committee (Committee) which was tasked with reviewing state-of-the-art equipment, procedures and protocols for safe and effective delivery of anesthesia and analgesia in dental offices. The Committee sought input from 138 dental associations, schools and interested licensees. From the discussions, the Board published a proposed rulemaking at 31 Pa.B. 6691 (December 6, 2001). The Board entertained public comment on the proposal and considered comments and suggestions on regulatory review throughout the following year. On November 25, 2002, the act of November 25, 2002 (P.L. 1109, No. 135) (Act 135) was enacted which amended section 11.2 of the act, further regulating the administration of anesthesia and sedation in dental offices. Section 2 of Act 135 required the Board to promulgate regulations necessary to implement the amendments within 1 year of the effective date, December 26, 2002.

Act 135 amended section 11.2 of the act as follows:

1. Section 11.2(a)(1) of the act requires the Board to establish minimal training and education for general anesthesia on an outpatient basis and requires a minimum of 1 year of advanced training in anesthesiology beyond graduation from dental school.

2. Section 11.2(a)(2) of the act requires the Board to establish further requirements for use of general anesthesia including equipment standards and conducting workplace inspections, permit fees, temporary permit fees, biennial renewal fees, office inspection fees and clinical evaluation fees.

3. Section 11.2(a)(3) of the act requires the Board to establish minimal training and education for conscious sedation permits and directs the Board to require a minimum period of didactic instruction/clinical experience in an accredited program.

4. Section 11.2(a)(4) of the act requires the Board to establish further requirements for use of conscious sedation including equipment standards, conducting workplace inspections and collection of permit fees, temporary permit fees, biennial renewal fees, office inspection fees and clinical evaluation fees.

5. Section 11.2(a)(5) of the act requires the Board to establish minimal training and education for nitrous oxide/oxygen analgesia including equipment standards, conducting workplace inspections and collection of permit fees.

6. Section 11.2(a)(6) of the act requires the Board to establish further requirements for use of nitrous oxide/oxygen analgesia including equipment standards, conducting workplace inspections and collection of permit fees.

7. Under section 11.2(b)(1) of the act, beginning April 1, 2004, prior to issuing initial permits to administer general anesthesia, deep sedation or conscious sedation, the Board is to require applicants to satisfactorily undergo clinical evaluations and office inspections. The Board may contract with dental schools, organizations or individuals with expertise in dental outpatient anesthesia to perform office inspections and clinical evaluations and requires written reports of all inspections and evaluations to be provided to the Board. If the results of an evaluation or inspection are deemed unsatisfactory, subsequent evaluations or inspections may be conducted upon written request of the applicant, and no permit may be issued until the applicant satisfactorily completes a clinical evaluation and office inspection.

8. Under section 11.2(b) of the act, beginning April 1, 2004, prior to issuing initial nitrous permits, the Board must require applicants to provide the make, model and...
serial number of all nitrous equipment and certify that the equipment is in proper working order. Thereafter, permit holders must provide evidence that equipment is properly calibrated, at least once every 6 years.

9. Under section 11.2(b)(3) of the act, the Board must establish standards and procedures necessary to perform clinical evaluations and office inspections to include the requirement that equipment be maintained in good working order and in accordance with manufacturer’s specifications. Equipment standards must be updated periodically and all staff assisting in the administration of anesthesia must maintain, at a minimum, current CPR certification.

10. Under section 11.2(b)(4) of the act, itinerate permit holders must ensure that the office location they are working in has the required equipment and staff properly trained to handle anesthesia-related emergencies.

11. Under section 11.2(b)(5) of the act, nonpermit holders who allow itinerate permit holders to administer anesthesia in their offices must meet the same requirements pertaining to equipment and staffing.

12. Under section 11.2(b)(6) of the act, beginning April 1, 2005, as a condition for permit renewal, the Board must require unrestricted and restricted permit I holders to have satisfactorily passed a clinical evaluation and office inspection. This requirement may be waived if the permit holder can satisfactorily demonstrate a successful clinical evaluation administered by an organization acceptable to the Board, within 6 years preceding the effective date of section 11.2(b)(6) of the act. Thereafter, clinical evaluations and office inspections must be done at least once every 6 years.

13. Under section 11.2(c) of the act, beginning April 1, 2004, the Board may issue temporary permits, valid for 1 year which are not renewable.

14. Beginning April 1, 2005, as a condition of permit renewal, unrestricted permit holders must have completed 15 hours of Board-approved courses related to general anesthesia and deep sedation and restricted I permit holders must have completed 15 hours of Board-approved courses related to conscious sedation. Nonpermit holder dentists who maintain offices where general anesthesia, deep sedation or conscious sedation is administered must have completed 5 hours of Board-approved courses related to anesthesia. Continuing anesthesia education will be credited toward the licensee’s continuing education requirement.

15. Permit holders are required under section 11.2(e) of the act to conduct a physical evaluation and take a medical history prior to the administration of general anesthesia, deep sedation, conscious sedation or nitrous, and maintain records.

16. Written informed consent is required under section 11.2(f) of the act prior to administration of general anesthesia, deep sedation, conscious sedation or nitrous to include the description of the procedure, risks and alternatives.

The Committee and the Department of State (Department) discussed problems with implementing the provisions of Act 35 within the time parameters specified in the act. The most difficult area has been implementing provisions that require clinical evaluations and office inspections as a condition of the issuance or renewal of a permit. Although current § 33.342 (relating to inspection of dental offices) authorizes the Board to make office inspections, none have been conducted due to difficulties encountered in obtaining qualified inspectors. The proposed rulemaking is designed to address these issues.

On September 5, 2003, the Board approved a new proposed rulemaking in response to the mandate of Act 135. In its proposal, the Board incorporates many proposed amendments from the proposed rulemaking published at 51 Pa.B. 6691.

D. Description of Proposed rulemaking

The proposed rulemaking to Subchapter E makes substantive and editorial changes to §§ 33.331—333.342.

§ 33.331 (relating to definitions)

The Board proposes to add a definition for “deep sedation” derived from the American Academy of Pediatric Dentistry’s (AAPD) Guidelines for the Effective Use of Conscious Sedation, Deep Sedation and General Anesthesia in Pediatric Dental Patients (Guidelines). In so doing, the proposed rulemaking recognizes that even though sedation is on a continuum, deep sedation is a defined stage between general anesthesia and conscious sedation. The AAPD, the American Association of Oral and Maxillofacial Surgeons (AAOMS) and the American Dental Association (ADA) all recognize distinctions between general anesthesia and deep sedation.

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

The Board also proposes to add definitions for “AAOMS,” “AAOMS Guidelines,” “AAOMS Manual,” “AAPD,” “AAPD Guidelines,” “ADA” and “ADA Guidelines.”

The following acronyms and terms have also been defined in this proposed rulemaking: “ACLS,” “adult patient,” “BLS,” “CRNA,” “clinical evaluation,” “communications equipment,” “general dentist,” “PALS,” “patient physical evaluation,” “pediatric patient,” “peer evaluation organization,” “peer evaluator,” “physician,” “OMS” and “office inspection.”

§ 33.332 (relating to requirement of permit to administer general anesthesia, conscious sedation or nitrous oxide/oxygen analgesia)

The proposed rulemaking clarifies that a permit is required to administer deep sedation in a dental office.

§ 33.333 (relating to types of permits)

The proposed rulemaking clarifies that an unrestricted permit is required to administer deep sedation and creates a new type of permit, a temporary permit, which is limited to 1 year, as required by Act 135.

§ 33.334 (relating to application for permit)

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

§ 33.335 (relating to requirements for unrestricted permit)

The proposed rulemaking 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 3 years prior to January 1, 1986. The 1985 "grandparenting" clause of section 11.2(b) of the act, tracked in the regulation, is no longer necessary.

The proposed rulemaking increases the time required in a postgraduate program for advanced training in anesthesia from 1 year to 2 years to conform to the ADA's Guidelines.

§ 33.336 (relating to requirements for restricted permit I)

The proposed rulemaking 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.

The proposed rulemaking 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 (relating to 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, 2004. After April 1, 2005, all renewal applicants must 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 also requires all renewal applicants to satisfactorily complete an office inspection and clinical evaluation every 6 years. Applications for initial or renewal permits must contain an original letter from the peer evaluation organization that conducted the office inspection/clinical evaluation evidencing the applicant's satisfactory completion of the office inspection/clinical evaluation.

Subsection (b) requires an oral and maxillofacial surgeon (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 for the Elective Use of Conscious Sedation, Deep Sedation and General Anesthesia in Pediatric Dental Patients (Guidelines) and the AAOMS Office Anesthesia Manual (Manual). It would require 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 advanced cardiac life support (ACLS) prior to the administration of anesthesia to an adult patient, and certification in pediatric advanced life support (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 have to complete 15 hours of Board-approved courses related to conscious sedation. These continuing anesthesia education hours would be credited toward the permit holder's regular continuing education requirement.

§ 33.336b (relating to 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 proposes to initially approve the AAOMS and the Pennsylvania Society of Oral and Maxillofacial Surgeons. Other organizations may apply to the Board for approval to serve as an organization that conducts clinical evaluations and office inspections. Subsection (b) outlines factors the Board will consider in approving an organization.

§ 33.336c (relating to standards for office inspections and clinical evaluations)

This section proposes to conduct office inspections and clinical evaluations in accordance with the AAOMS Manual and the AAOMS Guidelines. This continues the current policy in § 33.342(e) of utilizing the AAOMS materials as they represent the most current and comprehensive standards, and should apply to any permit holder. In addition, the AAOMS Manual is the only office inspection manual of this caliber.

§ 33.336d (relating to qualifications of peer evaluators conducting office inspections and clinical evaluations)

This section proposes that peer evaluators must be licensed dentists holding a current unrestricted permit and be independent from, and have no conflict of interest with, the dentist or dental practice being reviewed.

§ 33.336e (relating to confidentiality of peer review evaluation reports)

Office inspection and clinical evaluation reports and related information would remain confidential except when included in the permit application to the Board and upon Board inquiry of the peer evaluation organization as to whether an applicant's office inspection or clinical evaluation reports have been accepted by the peer evaluation organization.

§ 33.337 (relating to 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 previous reasons. Also, the Board proposes to reduce the number of required hours of undergraduate or postgraduate didactic instruction and clinical experience in a conforming program from 40 to 14.

As of April 1, 2004, all initial restricted II applicants must provide to the Board the make, model and serial number of any nitrous equipment utilized; certify that the equipment is properly calibrated, contains a fail-safe system and is in working order; and attest 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.

After the initial permit renewal, applicants would provide an attestation to the Board every 6 years that the nitrous equipment that the applicant uses is properly calibrated.
§ 33.337a (relating to requirements for temporary permit)

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

§ 33.338 (relating to expiration and renewal of permits)

Under the proposed rulemaking, 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 nitrous oxide/oxygen analgesia equipment has been installed and calibrated according to the equipment manufacturer's guidelines and contains a fail-safe system; and proof of compliance with anesthesia continuing education requirements and proof of compliance with office inspection and clinical evaluation requirements.

§ 33.339 (relating to fees for issuance of permits)

Permit fees are proposed to be amended as follows: initial unrestricted permits and restricted I permit fees would be $100 and the initial restricted permit II fee would remain $15. The renewal unrestricted permit and restricted permit I fee would be $200 and the renewal restricted permit II fee would remain $15.

As a general rule, the establishment of a fee authorized by a licensing board in the Department is determined after an analysis by the Department's Budget Office of staff requirements to prepare forms and process applications. In the case of office inspections and clinical evaluations, however, the fees will be determined by dental professionals of the peer evaluation organizations approved by the Board to administer office inspections and clinical evaluations. The permit applicant will then select an approved peer evaluation organization to conduct the office inspection and clinical evaluation. The permit applicant will pay the fee charged by the approved peer evaluation organization to have the office inspection and clinical evaluation conducted. This is similar to what already occurs with the continuing education requirement (that is, an applicant selects an approved continuing education provider and pays the required course fee directly to the provider).

The Board proposes to lower the renewal permit fees for unrestricted permits and restricted permit based upon the Board's understanding that the clinical evaluation/office inspection fee would be in the range of $400 to $600, and the Board's understanding of the work performed by these dentist evaluators and the necessary and reasonable costs performed by dentists in the private sector.

The Board proposes to increase the one-time initial permit fee for those permit holders from $15 to $100 to cover additional administrative costs entailed in verifying compliance with new requirements. The Board had initially intended to promulgate regulations containing substantive anesthesia requirements, and to promulgate fee regulations at a later date when data became available upon which to base the new fees. However, Act 135 mandates promulgation of fee regulations by December 26, 2003, thus necessitating this approach.

§ 33.340

The proposed amendments to this section require that a patient medical history be taken prior to the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia.

The equipment list for unrestricted permit holders would be amended to require suction equipment commensurate with the patient's age, size and condition; monitoring equipment, procedures and documentation conforming to the AAOMS Manual/AAPD Guidelines; a capnograph for intubated patients and a pulse oximeter; an ECG; a blood pressure monitoring device; a defibrillator; a stethoscope; and results of patient medical history and physical evaluation, anesthesia procedures to be utilized and signed written patient consent.

The proposed amendments to this section also require that auxiliary personnel assisting unrestricted permit holders in the administration of anesthesia, deep sedation or conscious sedation (delete reference to nitrous oxide/oxygen analgesia) be currently certified in basic life support. Certified registered nurse practitioners would be required to be certified in ACLS. Permit holders would be required to hold current certification in ACLS for adult patients and PALS for pediatric patients.

The Board proposes to require that general anesthesia or deep sedation administered to pediatric patients by or under the delegation of a general dentist must be administered by a person dedicated solely to the administration and monitoring of anesthesia, while the dental procedures are performed by a dental licensee not involved in the administration of the general anesthesia or deep sedation.

All monitoring equipment and equipment used to administer general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia would have to be installed and calibrated according to equipment manufacturer guidelines, be in proper working condition prior to administration and monitoring equipment must be used during the administration of general anesthesia.

The nonpermit holder dentist's office and equipment transported to his office by an itinerate permit holder must satisfactorily complete an office inspection conducted by an approved peer evaluation organization in accordance with the requirements of the AAOMS Manual and the AAOMS Guidelines for OMSs and in accordance with the ADA Guidelines and the AAPD Guidelines for general dentists.

OMS permit holders would be required to administer general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia in accordance with the AAOMS Guidelines and the AAOMS Manual. General dentists would be required to administer general anesthesia, deep sedation, conscious sedation and nitrous oxide oxygen to adult patients in accordance with the ADA Guidelines and to pediatric patients in accordance with the AAPD Guidelines.

The patient medical history and patient evaluation would be conducted by the permit holder, physician or certified registered nurse anesthetist.

§ 33.340a (relating to duties of dentists who are restricted permit I holders)

The proposed rulemaking amends this section in substantially the same manner as § 33.340 with the exceptions that a capnograph for intubated patients is not required and a separate person dedicated to the administration of anesthesia to a pediatric patient is not required.

§ 33.340b (relating to duties of dentists who are restricted permit II holders)

This section is added to require that patients be given a physical evaluation and a medical history be taken prior to the administration of nitrous oxide/oxygen analgesia.
Equipment and operating room requirements are similar to those of restrictive permit I holders, with the exception that restricted permit II holders are not required to have a recovery area, patient transport equipment, an oximeter, an ECG, a blood pressure monitoring device, and a defibrillator, as specifically enumerated items. However, the permit holder’s monitoring equipment, procedures and documentation must conform to the AAOMS Manual and the AAOMS Guidelines for adult and pediatric patients (if the permit holder is an OMS) or the ADA Guidelines for adult patients and the AAPD Guidelines for pediatric patients (if the permit holder is a general dentist).

Requirements for restricted permit II holders would be added to require that monitoring equipment and equipment used to administer nitrous oxide/oxygen analgesia be installed and calibrated according to the equipment manufacturer’s guidelines, contain a fail-safe system and be in proper working condition.

§ 33.341 (relating to duties of dentists who are not permit holders)

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

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

A nonpermit holding dentist would be required to verify with the permit holder that all monitoring equipment is present in the nonpermit holder’s office, is properly calibrated and in proper working condition and is being used during the administration of general anesthesia.

The nonpermit holder’s office and equipment transported to the nonpermit holder dentist’s office would have to satisfactorily complete an office inspection conducted by a Board approved peer evaluation organization. As of April 1, 2005, nonpermit holders who maintain offices in which general anesthesia, deep sedation and conscious sedation is administered, would be required to complete 5 hours of Board-approved courses related to anesthesia.

§ 33.342

Under the proposed rulemaking, the classifications of inspections, routine and special, are deleted. This section now allows inspections of dental offices by Board authorized agents. It also allows for a reinspections to take place within 30 days of an inspection finding deficiencies.

E. Fiscal Impact and Paperwork Requirements

Some of the provisions of this proposed rulemaking will have a fiscal impact upon permit holders. 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 believes they will be in the $400 to $600 range for an office inspection and clinical evaluation. In view of this, the Board proposes to lower the permit renewal fees for both unrestricted and restricted permit I holders from $300 to $200. The one-time initial permit fee for these permit holders would be increased from $15 to $100. Permit fees for restricted permit II holders would remain the same ($200). In addition, requirements for current certification in ACLS and some additional required monitoring equipment may entail increased costs to permit holders. At this stage, it is not possible to estimate the fiscal impact with precision; however, cost data will be available at a later date. See the explanation for § 33.359.

F. Sunset Date

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

G. 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 this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections shall specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly and the Governor of comments, recommendations or objections raised.

H. Public Comment

Interested persons are invited to submit written comments, recommendations or objections regarding this proposed rulemaking to Deborah B. Eskin, Counsel, State Board of Dentistry, P. O. Box 2649, Harrisburg, PA 17105-2649 within 30 days following publication in the Pennsylvania Bulletin. Reference No. 16A-4614 (Administration of General Anesthesia, Deep Sedation, Conscious Sedation and Nitrous Oxide/Oxygen Analgesia) when submitting comments.

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

Fiscal Note: 16A-4614. No fiscal impact; (6) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 33. STATE BOARD OF DENTISTRY

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

§ 33.331. Definitions.

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

AAOMS—American Association of Oral and Maxillofacial Surgeons, with principal offices at 9700 W. Bryn Mawr Avenue, Rosemont, Illinois 60018.


A general dentists.

**ADA**—American Dental Association.


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

**BLS**—Basic Life Support.

**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 general dentists.

**Communications equipment**—Equipment capable of eliciting a response in an emergency.

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

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

**OMS**—An 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 permit I holders; 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 general dentists.

**PALS**—Pediatric Advanced Life Support.

**PSOMS**—Pennsylvania Society of Oral and Maxillofacial Surgeons, with principal offices at 2700 North Broad Street, Suite 100, Lansdale, Pennsylvania 19444.

**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 with unrestricted permits conduct office inspections and clinical evaluations for dentists seeking initial or renewal unrestricted or restricted I permits.

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

**Physician**—A Pennsylvania licensed medical or osteopathic physician who is currently credentialed to administer anesthesia in a hospital 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. [Effective January 9, 1990, \(^\text{a}\) ] A dentist shall possess a current permit issued by the Board under this subchapter before administering, or supervising the administration of, general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia.

(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.

§ 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.

(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.
§ 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 1 year 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) Be certified 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 Surgeons Surgery or a Fellow of the American Dental Society of Anesthesiology, or be eligible for examination by the American Board of Oral and Maxillofacial Surgeons Surgery.

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

(i) Is competent to administer general anesthesia.

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

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

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

§ 33.336. Requirements for restricted permit I.

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

(1) Successfully completed a course on conscious sedation comprising at least 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 American Dental Association's ADA's *Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry*.

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

(i) Is competent to administer conscious sedation.

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

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

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

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

(a) Office inspections and clinical evaluations.

(1) Initial permits. Beginning April 1, 2004, all 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 after April 1, 2005. Beginning April 1, 2005, all 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, all unrestricted and restricted I permit renewal applicants shall satisfactorily complete an office inspection and clinical evaluation once every 6 years.

(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 AOAMS 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.
(i) 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 permit holder’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 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.

(ii) A current unrestricted permit.

(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 evaluators conducting office inspections 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 State Board of Dentistry upon request.

(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, and in accordance with §§ 33.340 and 33.340a (relating to duties of dentists who are unrestricted permit holders; and duties of dentists who are restricted permit I holders).

(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.

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

(a) A peer evaluator shall be a licensed dentist holding a current unrestricted permit.

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

(c) 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 must notify the Board within 30 days from the date the office inspection and clinical evaluation was conducted as to whether office inspection and clinical evaluation report has been accepted or rejected by the peer evaluation organization.

§ 33.337. Requirements for restricted permit II.

(a) To secure a restricted permit II, a dentist shall have

[ done one of the following:

(1) 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 American
Dental Association's] ADA's Guidelines for Treating the Comprehensive Control of Pain and Anxiety in Dentistry.

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

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

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

(a) To secure a temporary unrestricted permit, restricted permit I or restricted permit II, an applicant 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, 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.

(4) An attestation, on the renewal application, that any nitrous oxide/oxygen analgesia equipment utilized has been installed, properly calibrated 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 § 33.336(a)(d) (relating to requirements for unrestricted and restricted I permit).

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

(c) Subsequent renewal permits. Following the applicant's initial permit renewal after April 1, 2004, for each subsequent renewal period, an applicant's initial permit renewal after April 1, 2004, shall include with the application proof that the applicant possesses the qualifications required for the type of permitting.

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

§ 33.339. Fees for issuance of permits.

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

(1) Unrestricted permit.

(i) (a) [Issuance under § 33.335(a)(1) or

(b) Initial .......................... $[15] 100

(ii) (a) [Issuance under § 33.335(a)(3)

(b) Initial .......................... $100

(2) Restricted permit I.

(i) (a) [Issuance under § 33.336(a)(1)

(b) Initial .......................... $[15] 100

(ii) (a) [Issuance under § 33.336(a)(2)

(b) Initial .......................... $100

(3) Restricted permit II.

(i) (a) [Issuance under § 33.337(a)(1)

(b) Initial .......................... $15

(ii) [Issuance under § 33.337(a)(2)

(b) Initial .......................... $15

(iii) Temporary ...................... $15

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

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

(i) Prior to the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia, a patient medical history is taken or updated and the patient is given a physical examination sufficient to determine the patient's suitability to receive general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia.

(ii) The dental office in which the permit holder administers general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia is a properly equipped dental office as prescribed in § 33.340(a)(2) (relating to duties of dentists who are permit holders).

(iv) Suction equipment commensurate with the patient's age, size and condition.

(c) The following fees are charged for the issuance of permits:

(i) $100

(ii) $100

(iii) $15

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

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

(i) Prior to the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia, a patient medical history is taken or updated and the patient is given a physical examination sufficient to determine the patient's suitability to receive general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia.

(ii) The dental office in which the permit holder administers general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia is a properly equipped dental office as prescribed in § 33.340(a)(2) (relating to duties of dentists who are permit holders).

(iii) Suction equipment commensurate with the patient's age, size and condition.

(iv) Appropriate monitoring equipment for the patient's age, size and condition.

(c) The following fees are charged for the issuance of permits:

(i) $100

(ii) $100

(iii) $15
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, 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.

(xviii) Signed, written, informed patient consent, prior to the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia, on an outpatient basis contains the following:

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

(ii) A sterilization area.

(iii) Are currently certified in ACLS.

(iv) ECG.

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

(vi) A lighting system.

(vii) Suction equipment commensurate with the patient's age, size and condition.

(viii) Defibrillator.

(ix) Defibrillation paddles.

(x) Capnograph for intubated patients and pulse oximeter.

(xi) Monitoring equipment and equipment used to administer general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia by the permit holder or by a certified registered nurse anesthetist working under the supervision of the permit holder dentist's office and nonpermit holder dentist's office for the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia by a permit holder shall satisfactorily complete an office inspection conducted by an approved peer evaluation organization under § 33.336b(a) (relating to approved peer evaluation organizations for administering general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia; and monitoring equipment is being used during the administration of general anesthesia.

(x) The dentist possesses a current certification [to administer cardiopulmonary resuscitation (CPR)] in ACLS for adult patients and PALS for pediatric patients.

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

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

(x) 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.

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

(x) The patient medical history and patient physical evaluation are conducted by the permit holder, physician or CRNA.

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

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

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

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

(i) An operating room.

(ii) An operating table or chair.

(iii) A lighting system.

(iv) Suction equipment 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 permit holder in the administration of conscious sedation:

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

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

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

(iv) Are currently certified in BLS.

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

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

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

(iii) Are currently certified in ACLS.

(5) He 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 permit holder or by a certified registered nurse anesthetist working under the supervision of the permit holder. The permit holder shall submit the report within 30 days of the death or incident.

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

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

(9) The nonpermit holder dentist's office and equipment transported to the nonpermit holder dentist's office for the administration of conscious sedation or nitrous oxide/oxygen analgesia by a permit holder must satisfy the following:

(a) A dentist who possesses a restricted permit II shall complete an office 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.

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

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

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

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

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

(i) An operating room.

(ii) An operating table or chair.

(iii) A lighting system.

(iv) 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
§ 33.340a(a)(2) or working condition prior to the administration of nitrous oxide/oxygen analgesia procedure to be utilized, prior to the administration of nitrous oxide/oxygen analgesia

(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 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.

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

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

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

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

(2) The dental office has been inspected and meets the appropriate equipment and facility requirements prescribed in § 33.340(a)(2), § 33.340a(a)(2) or § 33.340b(a)(2) (relating to duties of dentists who are unrestricted permit holders; 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.

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

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

(6) The nonpermit holder dentist's office and equipment transported to the nonpermit holder dentist's office for the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia by a permit holder shall satisfactorily complete an office inspection conducted by an approved peer evaluation organization under § 33.336b(a), in accordance with the requirements of the AAOMS Manual and AAOMS Guidelines (OMS).

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

(d) Continuing anesthesia education. Beginning April 1, 2005, and for all subsequent renewal periods, nonpermit holder 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 nonpermit holder licensees' continuing education requirement under § 33.401(a)(1).

§ 33.342. Inspection of dental offices.

(a) [Routine inspections] Inspections. [No more than once a year during regular business hours, the] The Board, through its authorized agents, may conduct [a routine inspection] 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 permit holders; duties of dentists who are restricted permit I holders; and duties of dentists who are restricted permit II holders)[. ] or as follows:

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

(1) Upon a death or injury related to the administration of general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia in the office. * * * *

[ (4) As a follow-up to a previous inspection that revealed the office’s noncompliance with the equipment and facility requirements prescribed in § 33.340(a)(2).]

(c) (b) Notice of inspection. Prior to the start of [a routine or special ] 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. [ (d) (c) Access during inspection. [For purposes of a routine or special inspection, a ] 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. * * * *

[ (e) (d) Guideline for inspection. [A routine ] An inspection will be conducted under provisions pertaining to office facilities and equipment in [the American Association of Oral and Maxillofacial Surgeons’ Office Anesthesia Evaluation Manual] § 33.340(a)(2), § 33.340a(a)(2), § 33.340b(a)(2) or § 33.341(2).]

(f) (e) Inspection showing noncompliance. If [a routine or special ] an inspection reveals that a dental office is not in compliance with the equipment and facility requirements prescribed in § 33.340(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. 04-607. Filed for public inspection April 9, 2004, 9:00 a.m.]
The Honorable John R. McGinley, Jr., Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

March 11, 2005

Re: Final Regulation
State Board of Dentistry
16A-4614: Administration of General Anesthesia, Deep Sedation,
Conscious Sedation and Nitrous Oxide/Oxygen Analgesia

Dear Chairman McGinley:

Enclosed is a copy of a proposed rulemaking package of the State Board of Dentistry pertaining to Administration of General Anesthesia, Deep Sedation, Conscious Sedation and Nitrous Oxide/Oxygen Analgesia.

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

Sincerely,

Veasey B. Cullen, Jr., D.M.D., Chairperson
State Board of Dentistry

VBC/CKM: sb
Enclosure

c: Basil L. Merenda, Commissioner
   Bureau of Professional and Occupational Affairs
Albert H. Masland, Chief Counsel
   Department of State
Joyce McKeever, Deputy Chief Counsel
   Department of State
Cynthia Montgomery, Regulatory Counsel
   Department of State
Herbert Abramson, Senior Counsel in Charge
   Department of State
State Board of Dentistry
### TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

<table>
<thead>
<tr>
<th>I.D. NUMBER:</th>
<th>16A-4614</th>
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<tr>
<td>SUBJECT:</td>
<td>State Board of Dentistry - Administration of General Anesthesia, Deep Sedation, Conscious Sedation &amp; Nitrous Oxide/Oxygen Analgesia</td>
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<td>DEPARTMENT OF STATE</td>
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#### TYPE OF REGULATION

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

#### FILING OF REGULATION

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<tr>
<th>DATE</th>
<th>SIGNATURE</th>
<th>DESIGNATION</th>
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<td>HOUSE COMMITTEE ON PROFESSIONAL LICENSURE</td>
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<td>SENATE COMMITTEE ON CONSUMER PROTECTION &amp; PROFESSIONAL LICENSURE</td>
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February 24, 2005