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INDEPENDENT REGULATORY REVIEW COMMISSION
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

February 7, 2002

Norbert O. Gannon, D.D.S., Chairman
State Board of Dentistry
116 Pine Street
Harrisburg, PA 17105

Re: Regulation #16A-4610 (IRRC #2233)
State Board of Dentistry
Administration of General Anesthesia, Deep Sedation, Conscious Sedation
and Nitrous Oxide/Oxygen Analgesia

Dear Chairman Gannon:

Enclosed are our Comments. They will soon be available on our website at www.irrc.state.pa.us.

Our Comments list objections and suggestions for consideration when you prepare the final version of this regulation. We have also specified the regulatory criteria which have not been met. These Comments are not a formal approval or disapproval of the proposed version of this regulation.

If you would like to discuss these Comments, please contact my office at 783-5417.

Sincerely,

Robert E. Nyce
Executive Director

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Enclosure

cc: Honorable Mario J. Civera, Jr., Majority Chairman, House Professional Licensure Committee
Honorable William W. Rieger, Democratic Chairman, House Professional Licensure Committee
Honorable Clarence D. Bell, Chairman, Senate Consumer Protection and Professional
Licensure Committee
Honorable Lisa M. Boscola, Minority Chairman, Senate Consumer Protection and Professional
Licensure Committee

Comments of the Independent Regulatory Review Commission

on

State Board of Dentistry Regulation No. 16A-4610

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

February 7, 2002

We submit for your consideration the following objections and recommendations regarding this regulation. Each objection or recommendation includes a reference to the criteria in the Regulatory Review Act (71 P.S. § 745.5a(h) and (i)) which have not been met. The State Board of Dentistry (Board) must respond to these Comments when it submits the final-form regulation. If the final-form regulation is not delivered by January 7, 2004, the regulation will be deemed withdrawn.

1. Section 33.335(a). Requirements for unrestricted permit. - Protection of Public Health, Safety and Welfare; Clarity; Reasonableness.

Subsection (a)(1)

This subsection requires a dentist to have “Successfully completed at least 1 year in a postgraduate program for advanced training in anesthesiology and related academic subjects that conforms to Part II of the American Dental Association’s (ADA) *Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry...*” In order to be consistent with the current Part II of the ADA’s guidelines, the Board should change this phrase to “successful completion of at least two years.” (Emphasis added).

Subsection (a)(2)

Commentators have indicated the organization referenced in subsection (a)(2) should read, “Fellow of the American Dental Society of Anesthesiology,” rather than, “Fellow of the American Society of Dental Anesthesiology.” We suggest that the Board consider their concern.

Commentators also have indicated that one certification option was not included. Did the Board consider adding, “be certified as a Diplomat of the American Dental Board of Anesthesiology”?

2. Section 33.335(c). Administration of Anesthesia to Children. - Clarity.

This subsection requires an applicant to attest to conformance with the American Academy of Pediatric Dentistry’s (AAPD) *Guidelines for the Elective Use of Conscious Sedation, Deep Sedation and General Anesthesia in Pediatric Dental Patients* when treating “children age 10 and under.” How did the Board determine age 10 as the cutoff for conforming with the AAPD guidelines?

3. Section 33.335(d) and Section 33.336(d). Office Inspection Requirements. - Protection of Public Health, Safety and Welfare; Clarity.

Subsection (d)(1)

This subsection, along with Section 33.336(d)(1), states, “at least every 6 years, or more frequently, as necessary.” It appears that the phrase, “or more frequently, as necessary” is not necessary and could be deleted.

Subsections (d)(1) and (d)(2)

First, the House Professional Licensure Committee commented that it is unclear whether the office inspections and clinical evaluations in Subsections (d)(1) and (d)(2), as well as Sections 33.336(d)(1) and (d)(2), apply to current permit holders or just to first-time applicants. The Committee recommends that these requirements apply to current permit holders, as well as new applicants. The Committee further recommends that the regulation include dates by which current permit holders must complete office inspections and clinical evaluations as a condition of permit renewal.

We agree with the Committee that the regulation is unclear. Is it the Board’s intent to apply the office inspection and clinical evaluation requirements to both current permit holders and first-time applicants? If so, what are the time frames for compliance? The final-form regulation should be amended to clearly reflect the Board’s intent.

Second, these two subsections, as well as other sections, use the term “authorized agents.” Commentators suggest that the “authorized agents” should be dental professionals holding permits in the same specialty as the person subject to the office inspection and clinical evaluation. The final-form regulation should identify the “authorized agents” of the Board and their qualifications, and clarify whether the same “authorized agents” perform the office inspections and the clinical evaluations.

Third, we question whether the Board intends to require a dentist, who does not perform general anesthesia or conscious sedation, to undergo a clinical evaluation. Would the clinical evaluation of the itinerant anesthesiologist be sufficient? In either case, when will the clinical evaluation occur? The Board should clarify these points in the final-form regulation.

Finally, it is unclear if the inspections and the clinical evaluations are completed prior to the receipt of a permit by a dentist. This should be clarified in the final-form regulation.

Subsection (d)(2)

The House Committee notes that the language in Subsection (d)(2), as well as Section 33.336(d)(2), seems to exempt permit holders, who do not maintain their own offices, from clinical evaluations. The Committee recommends that the regulation be clarified to require all permit holders to undergo clinical evaluations. We agree that the Committee’s recommendation would enhance protection of the public health, safety and welfare.

Finally, as printed in the *Pennsylvania Bulletin*, this subsection states, “through its authorized agents be in accordance....” It appears that the word “be” is unnecessary and could be deleted.

4. Section 33.337. Requirements for restricted permit II. - Reasonableness.

Under Subsection (a)(1), a dentist must complete 20 hours of undergraduate or postgraduate instruction and clinical experience as a requirement for obtaining a restricted permit II. The existing regulation requires 40 hours of instruction and clinical experience. What is the basis for reducing the hours of instruction and clinical experience from 40 to 20?

5. Section 33.338. Expiration and renewal of permits. - Clarity.

Subsection (b)(2) requires a dentist, who wants to renew a permit, to submit "The permit renewal fee." However, the regulation does not list the permit renewal fees. For clarity, these fees should be included in the final-form regulation.

6. Section 33.340. Duties of dentists who are unrestricted permit holders. - Reasonableness; Need; Protection of the Public Health, Safety and Welfare; Economic Impact; Clarity.

Subsection (a)(1)

Paragraph (1) requires a "history" to be taken prior to the administration of anesthesia. Paragraph (2)(xvii) refers to "patient history." It appears that both terms refer to the patient's *medical* history. If so, Paragraphs (1) and (2)(xvii) should be revised to use the term "patient medical history." The same change should be made in Sections 33.340a(a)(1) and (a)(2)(xvii) and 33.340b(a)(1) and (a)(2)(xi).

Subsection (a)(2)

First, paragraph (2)(iv) refers to "appropriate oropharyngeal suction." The term "appropriate" is vague and open to interpretation. For improved clarity, the Board should specify the factors used to determine "appropriate oropharyngeal suction," such as the patient's age, size and medical condition. The same clarification should be added to Sections 33.340a(2)(iv) and 33.340b(2)(iv).

Second, paragraph (2)(xii) requires monitoring equipment, procedures and documentation to conform to certain guidelines established by the American Association of Oral and Maxillofacial Surgeons and AAPD. However, the ADA *Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia for Dentists* is not included as a standard. Why are the ADA guidelines excluded from Paragraph (2)(xii) and Sections 33.340a(a)(2)(xii) and 33.340b(a)(2)(x)?

Third, Paragraphs (2)(xiii) through (xvi) list specific monitoring equipment that is required in the permit holder's dental office. Monitoring of expired carbon dioxide concentration is not included in the requirements. However, the AAPD guidelines specify monitoring of expired carbon dioxide when deep sedation or general anesthesia is administered. The Board should include this requirement in the final-form regulation, or explain why it is unnecessary.

Fourth, Paragraph (2)(xvi) (and Section 33.340a(a)(2)(xvi)) require the dental office to have an automatic external defibrillation (AED) device. Commentators have noted that AEDs are not recommended for children, and suggest that the regulation simply require a "defibrillator." The Board should consider adopting the commentators' suggestion to ensure that appropriate equipment is present for the type of patient being treated.

Section 33.340 (cont'd.)

Finally, paragraph (2)(xviii) requires “Signed patient consent” prior to administration of anesthesia. The House Committee recommended that this requirement be changed to “written informed consent of a patient.” The Committee further recommended that when the patient is a minor, consent should be obtained from the parent or guardian. We agree that the Committee’s suggested language would add clarity, as well as health and safety protections for the patient and liability protections for the permit holder. The Board should consider adopting the Committee’s recommendation in Paragraph (2)(xviii) and in Sections 33.340a(a)(2)(xviii) and 33.340b(a)(2)(xii).

Subsection (a)(3)

Paragraph (3)(iv) requires auxiliary personnel to maintain current certification in Advanced Cardiac Life Support (ACLS). This requirement is also contained in Section 33.340a(a)(3)(iv). Commentators object to this requirement as unnecessary, and note that ACLS training includes instruction on administration of certain medications that auxiliary personnel are not licensed to administer. They suggest that auxiliary personnel be required to maintain Basic Life Support (BLS) certification. We request the Board explain the process for obtaining BLS and ACLS certification. We further request the Board provide the rationale for requiring ACLS certification for auxiliary staff.

Additionally, some commentators have suggested that pediatric dentists be given the option of maintaining certification in Pediatric Advanced Life Support (PALS). Has the Board considered allowing PALS certification as an option?

Subsection (a)(8)

Under this subsection, general anesthesia requiring intubation must be administered by a qualified person, other than the person performing the dental work. Why is this requirement limited to general anesthesia provided with intubation? Will the public health be adequately protected if the person performing the dental work is simultaneously monitoring the provision of anesthesia?

Subsection (a)(10)

This subsection requires equipment transported to a nonpermit holder dentist’s office to be inspected by the Board’s “authorized agents.” Similar requirements are contained in Sections 33.340a(a)(9) and 33.341(a)(6). We have three concerns.

First, the reference to “authorized agents” is vague. The final-form regulation should identify the Board’s “authorized agents.”

Second, it is unclear when the equipment is inspected. The final-form regulation should specify whether the inspection occurs before or after transport.

Finally, the regulation does not state how often the equipment must be inspected. For example, is there an initial inspection and then a follow-up inspection after a certain amount of time? These details should be set forth in the final-form regulation.

7. Section 33.340a. Duties of dentists who are restricted permit I holders. - Clarity.

Subsection (a)(2)

Paragraph (a)(2)(x) requires the dental office to contain “communications equipment.” The same requirement is contained in Section 33.340b(a)(2)(ix). The final-form regulation should specify what type of equipment is required.

Subsection (a)(4)

Paragraph (a)(4)(i) requires certified registered nurse anesthetists (CRNAs) to “Perform their duties under the direct on-premises supervision of the permit holder, who shall assume full responsibility for the performance of the duties.” A similar provision is contained in existing Section 33.340(a)(4)(i).

The CRNA supervision requirements of this regulation are more stringent than the State Board of Nursing requirements at 49 Pa. Code Section 21.17(3) and (4) and the Department of Health requirements at 28 Pa. Code Section 123.7(c). The State Board of Nursing regulations authorize CRNAs to administer anesthesia “in cooperation with a surgeon or dentist.” These regulations further state, “In situations or health care delivery facilities where these services are not mandatory, the nurse anesthetist’s performance shall be under the overall direction of the surgeon or dentist responsible for the patient’s care.” Additionally, the CRNA “...shall have available to her by physical presence or electronic communication an anesthesiologist or consulting physician of her choice.” The State Board of Nursing regulations do not contain a requirement for “direct on-premises supervision.”

Under the Department of Health’s Health Facilities regulations at 28 Pa. Code Section 123.7(c), when a dentist and CRNA work together, without any physicians present, “...a physician shall be immediately available in case of an emergency...” That regulation also states that “immediately available may mean in the hospital or in the immediate proximity of the operative procedure area or within minutes of the operating suite.”

We request the Board explain the reason for the differences in supervision requirements.

Subsection (a)(5)

Finally, the Board should consult Section 6.10 of the *Pennsylvania Code and Bulletin Style Manual* with respect to the phrasing of Subsection (a)(5).

8. Section 33.340b. Duties of dentists who are restricted permit II holders. - Clarity.

Subsection (a)(2)(xi) requires the dental office to maintain the “Results of patient history and physical evaluation.” However, the preamble to the proposed regulation indicates that this requirement is not imposed on restricted permit II holders. This inconsistency between the preamble and the text of the regulation should be corrected in the final-form regulation.

9. Section 33.341. Duties of dentists who are not permit holders. - Clarity; Reasonableness.

Subsection (a)(2)

Subsection (a)(2) requires that the office of a nonpermit holding dentist must be inspected to meet the requirements in Sections 33.340(a)(2), 33.340a(a)(2) or 33.340b(a)(2). A commentator has indicated that he, as the itinerant anesthesiologist, supplies the monitoring and drug administration equipment. Is it the Board’s intent that the nonpermit holder will provide all

supplies and equipment required in the referenced sections? Must the items enumerated in those sections be in the nonpermit holder's office at the time of inspection? The Board should clarify this requirement in the final-form regulation.

This subsection also requires an office inspection prior to administration of anesthesia. However, there is no provision for re-inspection. Does the Board intend to require a re-inspection every six years for dentists who are not permit holders, as is required for dentists who have an unrestricted permit or restricted permit I (found in Sections 33.335(d)(1) and 33.336(d)(1))? If so, the final regulation should contain the re-inspection provision. If not, the Board should explain why re-inspection is not necessary.

Subsection (a)(4)

The House Professional Licensure Committee notes that a CRNA is not authorized to administer anesthesia in the offices of nonpermit holders under Section 33.341(a)(3). However, CRNAs are included in Section 33.341(a)(4) relating to persons required to have ACLS certification. Was it the Board's intent to include CRNAs in Subsection (a)(4)?

Additionally, we note that unlike Sections 33.340(a)(4) and 33.340a(a)(4), this subsection contains no supervision requirements for CRNAs. If it is the Board's intent to include CRNAs in Subsections (a)(3) and (a)(4), the final-form regulation should include supervision requirements consistent with 33.340(a)(4) and 33.340a(a)(4). If it is not the Board's intent to include CRNAs in Sections 33.341(a)(3) and (a)(4), the reference to CRNAs should be deleted from Subsection (a)(4).

Subsection (a)(6)

Under this subsection, the equipment transported to a nonpermit holder's office "shall pass an inspection." The final-form regulation should specify whether the inspection occurs before or after transport, and how frequently inspection occurs.