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MARY S. WYATTE, CHIEF COUNSEL

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

irrc@irrc.state.pa.us
http://www.irrc.state.pa.us
(717) 783-5417
Fax (717) 783-2664

June 9, 2004

Veasey B. Cullen, Jr., D.M.D., Chairman
State Board of Dentistry
2601 North 3rd Street
Harrisburg, PA 17110

Re: Regulation #16A-4614 (IRRC #2396)
State Board of Dentistry
Administration of General Anesthesia, Deep Sedation, Conscious Sedation and Nitrous Oxide/Oxygen Analgesia

Dear Chairman Cullen:

Enclosed are the Commission's comments for consideration when you prepare the final version of this regulation. These comments are not a formal approval or disapproval of the regulation. However, they specify the regulatory review criteria that have not been met.

The comments will be available on our website at www.irrc.state.pa.us. If you would like to discuss them, please contact my office at 783-5417.

Sincerely,

Robert E. Nyce
Executive Director
evp
Enclosure
cc: Honorable Robert M. Tomlinson, Chairman, Senate Consumer Protection and Professional Licensure Committee
Honorable Lisa M. Boscola, Minority Chairman, Senate Consumer Protection and Professional Licensure Committee
Honorable Thomas P. Gannon, Majority Chairman, House Professional Licensure Committee
Honorable William W. Rieger, Democratic Chairman, House Professional Licensure Committee
Honorable Pedro A. Cortes, Secretary, Department of State

Comments of the Independent Regulatory Review Commission
on
State Board of Dentistry Regulation #16A-4614 (IRRC #2396)
Administration of General Anesthesia, Deep Sedation, Conscious Sedation and Nitrous Oxide/Oxygen Analgesia
June 9, 2004

We submit for your consideration the following comments that include references to the criteria in the Regulatory Review Act (71 P.S. § 745.5b) which have not been met. The State Board of Dentistry (Board) must respond to these comments when it submits the final-form regulation. The public comment period for this regulation closed on May 10, 2004. If the final-form regulation is not delivered within two years of the close of the public comment period, the regulation will be deemed withdrawn.

Act 135 of 2002 (Act) amended The Dental Law to provide additional safeguards related to the administration of anesthesia. Included in the Act are requirements for office inspections and clinical evaluations prior to the issuance of permits to administer general anesthesia, deep sedation or conscious sedation. These requirements, as well as requirements related to nitrous oxide/oxygen analgesia equipment, were to take effect on April 1, 2004.

Section 2 of the Act mandates the Board to promulgate regulations "within one year of the effective date" of the Act. The Act became effective on December 25, 2002. In its May 11, 2004 comments, the House Professional Licensure Committee expressed concern that the Board did not comply with the April 1, 2004 statutory deadline. Additionally, the Committee stated, "...that, as a consequence, the statutorily imposed deadline concerning these safety measures cannot be implemented as the law directs." We agree with the Committee that the Board has not met the legislative intent of the Act and as a result, the protection of the public health could be endangered. Therefore, we urge the Board to prepare and submit the final-form regulation as soon as possible.

1. Existing volunteer license regulations. – Conflict with existing regulations.

Section 33.110(c)(4) of the Board's existing volunteer license regulations addresses the requirements for a volunteer license applicant who wants to administer various types of anesthesia. This section, however, does not refer to "deep sedation." Additionally, the cross-references to education requirements do not correspond with the section numbers in the proposed regulation, and do not include the new requirements for office inspections and clinical evaluations. In the final-form regulation, we suggest the Board amend Section 33.110(c)(4) to update the terminology and cross-references, and add a cross-reference to the office inspection and clinical evaluation requirements.

2. Recordkeeping requirements. – Clarity.

Section 11.2(e) of the Act requires permit holders to keep records of a patient's "physical evaluation, medical history and anesthesia procedures utilized." The proposed regulation requires the permit holder's office to retain the results of the medical history and physical evaluation (Sections 33.340(a)(2)(xvii), Section 33.340a(a)(2)(xvii) and Section 33.340b(a)(2)(x)). It does not specify how long records must be maintained and in what form.

Section 33.209 of the Board's existing regulations addresses patient records but does not include deep sedation as a type of anesthesia for which records must be kept.

When the Board submits the final-form regulation, it should revise Section 33.209 to include deep sedation. The Board should also insert a cross-reference to Section 33.209 in Sections 33.340, 33.340a and 33.340b.

3. Section 33.331. Definitions. – Need; Clarity.

Professional manuals and guidelines

This section defines "AAOMS Guidelines," "AAOMS Manual," "AAPD Guidelines" and "ADA Guidelines." Included in these definitions are publication dates for each document. In the final-form regulation, we suggest that the Board include language recognizing the successor volumes of each of these documents so that it is not necessary to revise the regulation each time a manual or set of guidelines is updated.

Communications equipment

This term is defined as "Equipment capable of eliciting a response in an emergency." It appears that the intent is to allow for two-way communication between personnel performing anesthesia services and emergency personnel or other medical or dental providers. We suggest the Board revise this definition to more specifically identify the type of communication required.

Physician

The proposed regulation includes a definition of the term which varies from the definition of "physician" found in The Medical Practice Act (63 P.S. § 422.2). Since the term is already defined in statute, it is unnecessary and potentially confusing to establish a different definition in this regulation. The Board should revise the definition of "physician" to be consistent with the statutory definition, or explain why the proposed definition is necessary. If the Board elects to retain the proposed definition, it should clarify the meaning of "currently credentialed." It should also consider adding a reference to offices and ambulatory surgical facilities to recognize anesthesiologists who practice in these settings.

4. Section 33.332. Requirement of permit to administer general anesthesia, deep sedation, conscious sedation or nitrous oxide/oxygen analgesia. – Clarity.

Subsection (b) establishes that a permit is not required to administer anesthetic modalities "in a State- or Federally-regulated facility other than a dental office." In its comments, the Pennsylvania Society of Anesthesiologists (PSA) notes the The Dental Law establishes authority for administering anesthesia for dental procedures only and suggests that Subsection (b) be amended by inserting "for dental procedures" after "nitrous oxide/oxygen analgesia." We agree that PSA's recommendation adds clarity and suggest that the Board insert this language in the final-form regulation.

5. Section 33.336. Requirements for restricted permit I. – Reasonableness.

The proposed regulation reduces the required number of hours of undergraduate or postgraduate didactic instruction and clinical experience from 80 hours to 60 hours. Please explain the basis for reducing the required number of hours.

6. **Section 33.336a. Requirements for unrestricted permit and restricted permit I. – Need; Reasonableness.**

Subsection (a)

Paragraph (4) requires a permit applicant to submit an "original letter" from a peer review organization that establishes the applicant's satisfactory completion of an office inspection and clinical evaluation. Why is the "original letter" required rather than a copy of the letter?

This paragraph also requires "a written report of the results of the office inspection and clinical evaluation." If the applicant produces a letter demonstrating satisfactory completion of the inspection and evaluation, why is it necessary to also submit the written report? Will the Board use the report for a specific purpose?

Subsection (b)

Paragraphs (1) and (2) require applicants to attest that they will perform their duties in conformance with the AAOMS Guidelines and Manual and the ADA and AAPD Guidelines. Since compliance with these guidelines and the manual are required in various sections throughout the proposed regulation, why is a separate attestation necessary? Is the attestation part of the application form?

7. **Section 33.336b. Approved peer evaluation organizations for administering clinical evaluations and office inspections. – Consistency with the statute; Reasonableness; Clarity.**

This section identifies approved peer evaluation organizations and authorizes organizations of oral and maxillofacial surgeons or unrestricted permit holders to apply to be approved peer review organizations. Section 11.2(b)(1) of the Act authorizes the Board to contract with "dental schools, organizations or individuals" to perform office inspections and clinical evaluations. However, it does not appear that the Board has exercised the option to contract with other entities or individuals to carry out the mandates of the Act. We have the following concerns.

Subsection (a)

We request the Board explain why it has not pursued the contracting option laid out by the Act.

Subsection (a) recognizes the Pennsylvania Society of Oral and Maxillofacial Surgeons (PSOMS) and the American Society of Oral and Maxillofacial Surgeons as qualified peer evaluation organizations. Are there other organizations, such as dental schools or associations of other dental specialties, which should be recognized as qualified peer evaluation organizations in Subsection (a)?

PSOMS raises concerns about the evaluation system. PSOMS comments that the system "will not work within the existing statutory and regulatory structure due to the lack of protection from liability for the dentists who will be acting essentially as volunteers when conducting the required inspections and evaluations." PSOMS suggests this problem could be solved by the Board contracting with inspectors and evaluators as provided for in the Act. We agree that without protection from liability, there may be little incentive for dentists to perform inspections and evaluations. How does the Board intend to address this issue?

Subsection (b)

Application to become a peer review organization

Under this subsection an organization of oral and maxillofacial surgeons or of unrestricted permit holders may apply to be a peer review organization. Can individual permit holders apply to conduct peer evaluations? If so, the final-form regulation should specify that individuals can apply and set forth the review criteria that would apply to an individual's application.

The Pennsylvania Dental Association (PDA) comments that restricted permit I holders should also be allowed to apply for approval to conduct evaluations and inspections. We agree. Under Section 33.336a, all unrestricted permit holders and restricted permit I holders are required to undergo an office inspection and a clinical evaluation every six years. It is reasonable to allow restricted permit I holders to conduct evaluations and inspections for other restricted permit I holders. Furthermore, by expanding the scope of who may apply to conduct peer reviews, more inspectors and evaluators may be available to perform this function. We suggest the Board consider including restricted permit I holders in the group of practitioners who can perform peer review for restricted permit I holders.

Subsection (b)

Criteria for review of a peer review organization application

Paragraphs (b)(1) through (b)(11) list criteria the Board will consider in determining whether to grant applications for approval to serve as a peer review organization. We request the Board explain how these criteria were developed. We also request the Board explain how it 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 inspection and procedures to facilitate fair, unbiased and equitable inspections and evaluations. Furthermore, the Board should specify the documentation an applicant must produce to demonstrate compliance with the criteria in Paragraphs (3), (5) and (8).

8. Section 33.336e. Confidentiality of peer evaluation reports. – Clarity.

Under Subsection (b), a peer review organization is required to notify the Board "as to whether the office inspection and clinical evaluation report has been accepted or rejected by the peer evaluation organization." This language is confusing. Based on discussions with Board staff, the intent of this provision is for the peer review organization to notify the Board that the permit holder has successfully completed the office inspection and clinical evaluation. The Board should amend this provision in the final-form regulation to clearly reflect its intent.

Additionally, we note that the regulation is silent regarding recordkeeping requirements for peer review organizations. The final-form regulation should include the recordkeeping requirements for these organizations.

9. Section 33.337. Requirements for restricted permit II. – Reasonableness.

Subsection (a) reduces the course hour requirement for a nitrous oxide/oxygen analgesia course from 40 to 14. Please explain the basis for reducing the required number of hours.

10. Section 33.338. Expiration and renewal of permits. – Reasonableness.

Subsection (b)(4) requires attestation that nitrous oxide/analgesia equipment is "properly calibrated." In its comments, PSA notes that this provision does not place any burden on the

permit renewal applicant to show that the equipment has been properly maintained. PSA suggests that the phrase "and maintained" be inserted after "calibrated." We agree and suggest that the Board incorporate this change in the final-form regulation. Also, the same revision should be made in Section 33.340(a)(9).

11. Section 33.339. Fees for issuance of permits. – Reasonableness.

Paragraphs (1)(ii) and (2)(ii) set the permit renewal fees at $200 for an unrestricted permit and a restricted permit I. Although these fees represent a $100 reduction from the renewal fees in the Board's existing regulations, the revised fee levels for renewals are still twice as much as the $100 fee for an initial unrestricted permit or restrict permit I. Why are the renewal fees twice as much as the initial issuance fees?

12. Section 33.340. Duties of dentists who are unrestricted permit holders. – Consistency with the statute; Protection of the public health, safety and welfare; Reasonableness; Clarity.

Subsection (a)(1) requires that a patient medical history "be taken or updated and the patient is given a physical evaluation...." Subsection (a)(12) requires the patient's medical history and physical evaluation be done by "the permit holder, physician or CRNA." Section 11.2(e) of The Dental Law requires "permit holders to conduct a physical examination and take a medical history of the patient...." Therefore, Subsection (a)(1) should be amended to specify that the permit holder shall take the medical history and conduct the physical evaluation. Subsection (a)(12) should be deleted. The same clarification should be made in Section 33.340a(a)(1) and Section 33.340b(a)(1).

Subsection (a)(3) references "auxiliary personnel who assist the permit holder in the administration of general anesthesia, deep sedation or conscious sedation." Who are the "auxiliary personnel"?

Subsection (a)(8) requires that general anesthesia or deep sedation administered to pediatric patients be "administered by a person dedicated solely to the administration and monitoring of anesthesia." Why does this requirement apply to only pediatric patients rather than any patient receiving general anesthesia or deep sedation? The Board should explain how the health and safety of the patient is protected if a separate person is not dedicated to administering and monitoring the anesthesia.

Subsection (a)(10) requires the nonpermit holder's office and equipment transported to the nonpermit holder's office to be inspected by an approved peer review organization. It is unclear when the transported equipment is to be inspected since it would not necessarily be in the nonpermit holder's office at the time of the office inspection. We request the Board clarify how this provision will be implemented.

13. Section 33.340a. Duties of dentists who are restricted permit I holders. –Need; Reasonableness; Clarity.

Subsection (a)(3) references "auxiliary personnel who assist the permit holder in the administration of conscious sedation." Who are the "auxiliary personnel"?

Subsection (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 Section 340(a)(3)(ii) of the Board's existing regulations. We question the

need for these provisions. The State Board of Nursing regulations specify the supervision requirements applicable to CRNAs (49 Pa. Code § 21.17(3) and (4)). Rather than establish separate requirements under this regulation, we suggest that the Board amend Subsection (a)(4)(i) and existing Section 340(a)(3)(ii) to cross-reference the supervision requirements for CRNAs in 49 Pa. Code § 21.17(3) and (4).

14. Section 33.341. Duties of dentists who are not permit holders. – Reasonableness; Clarity.

Subsection (a)(2)

This subsection requires that the dental office be inspected and meet appropriate standards set forth in the regulation. PDA feels that the inspection of the office of the nonpermit holder is not necessary. PDA indicates that the inspection of the equipment of the permit holder is sufficient under the law and the permit holder should be responsible for ensuring that all required equipment and facility requirements are present. We concur with this assessment. The Board should revise this requirement to state that the permit holder should be responsible for ensuring that the appropriate equipment and facility requirements are met. However, if the Board intends to maintain this provision, it should set forth the list of facility requirements for which the nonpermit holder will be held responsible. A similar concern exists in Subsection (a)(6).

Subsection (a)(5)

We have two concerns with this subsection.

First, the requirements in this subsection state that the nonpermit holder should verify with the permit holder that the equipment is installed properly and calibrated. However, PDA believes this provision should be deleted because only the permit holders should be responsible for verifying that the standards are met. We agree. The Board should delete the language that indicates that the nonpermit holder is also responsible for verification.

Second, this subsection does not specify what type of verification is required to meet the statutory standards. Should this verification be in writing? The Board should insert language that clearly delineates what kind of verification is required.

15. Section 33.342. Inspection of dental offices. – Clarity.

The term "authorized agents" is used in Subsection (a). However, this term is not defined. Whom does the Board consider an "authorized agent"? Do the organizations in Section 33.336b fall under this term? For clarity, the Board should define "authorized agent."

Facsimile Cover Sheet

Kristine M. Shomper
Administrative Officer

Phone: (717) 783-5419
Fax #: (717) 783-2664
E-mail: kriss@irrc.state.pa.us
Website: www.irrc.state.pa.us

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

To: Suzanne Hoy
Agency: Department of State
Licensing Boards and Commissions
Phone: 7-2628
Fax: 7-0251
Date: June 9, 2004
Pages: 8

Comments: We are submitting the Independent Regulatory Review Commission's comments on the State Board of Dentistry regulation #16A-4614 (IRRC #2396). Upon receipt, please sign below and return to me immediately at our fax number 783-2664. We have sent the original through interdepartmental mail. You should expect delivery in a few days. Thank you.

Accepted by: Suzanne Hoy **Date:** 6/9/04

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