Form: TH- 02

Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Board of Dentistry/Department of Health Professions
VAC Chapter Number:	18 VAC 60-20-10 et seq.
Regulation Title:	Regulations Governing the Practice of Dentistry and Dental Hygiene
Action Title:	Periodic review/changes in rules for anesthesia
Date:	

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form,Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The Board of Dentistry has proposed amendments for 18 VAC 60-20-10 et seq. to update certain requirements and terminology, to clarify the Board's requirements, especially related to dental education, to eliminate a jurisprudence examination and add requirements for additional training for applicants who have had multiple examination failures. Amendments also modify educational, monitoring and equipment requirements for administration of various forms of analgesia, sedation and anesthesia as minimally necessary to ensure public safety.

In response to public comment, the Board took action at its meeting on June 18, 2004 to substantially amend the proposed regulations. Therefore, it is re-submitting the proposed stage for an additional 30 days of public comment.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400 (6) provides the Board of Dentistry the authority to promulgate regulations to administer the regulatory system:

> ***§ 54.1-2400 -General powers and duties of health regulatory boards***
> *The general powers and duties of health regulatory boards shall be:*
> *…*
> *6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. …*

The legal authority to license and regulate dentists and dental hygienists may be found in Chapter 27 of Title 54.1 of the Code of Virginia.

http://leg1.state.va.us/000/lst/h3205422.HTM

The Office of the Attorney General has certified by letter that the Board has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

As a result of an extensive periodic review of its regulations, the Board has proposed amendments to clarify or simplify certain provisions for applicants and licensees and to eliminate unnecessary examinations. Educational criteria, currently applied by the Board and required by the Code of Virginia, are spelled out in regulation for a clearer understanding by applicants for licensure. With the intent of protecting the live patients on which the examination is conducted,

applicants who fail the clinical examination three times would be required to take additional clinical hours to prepare them for the specific area (s) failed.

The primary intent of amending regulations is to more clearly specify the requirements for administration of sedation or anesthesia. Dentists who administer any form of analgesia, sedation or anesthesia in a dental office must have specific knowledge and training in delivery of those agents and in the monitoring and recovery of a patient. Likewise, it is essential for the dentist to be appropriately prepared and equipped to respond to emergencies that may arise if a patient's breathing or responses are compromised. Both the dentist and the ancillary personnel should be proficient in handling related complications or emergencies. Therefore, requirements for training, emergency equipment and techniques, and monitoring are necessary to protect the health and safety of patients in dental offices.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

Definitions have been updated to reflect current terminology, particularly that pertaining to revised regulations for anesthesia and sedation and to eliminate terms that were no longer being used. Amendments to the requirements for dental education will reflect the current Board interpretation of an accredited or approved dental program, which is either a pre-doctoral dental education program or a one or two year post-doctoral dental education program.

Changes in examination requirements offer additional options for persons who took the board-approved examinations five or more years prior to applying for licensure in Virginia. In addition, there are new requirements for remediation for candidates who have failed the licensure examination three times. Rather than requiring passage of a jurisprudence examination, the Board will now require that the applicant read and understand the laws and regulations governing the practice of dentistry in Virginia.

Regulations for anesthesia, sedation and analgesia have been rewritten and reorganized to make clear the application of the rules in various settings, the educational and training qualifications of the dentist and dental assistants, the equipment and monitoring needed for each level, and the discharge criteria for ensuring the safety of the patient.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.

Advantages and disadvantages to the public:

Dentists are increasingly utilizing some form of analgesia, sedation or anesthesia to perform dental procedures with the maximum amount of comfort to their patients. In addition, some oral and maxillofacial surgeons are performing cosmetic surgery in an office-based setting. While the Board currently has regulations for anesthesia and sedation, there has been a growing concern that the practitioner qualifications, equipment and monitoring standards were not sufficient to ensure the safety of patients in a dental practice. Most dentists practice with an accepted standard of care, utilizing trained anesthesia providers, equipping their offices with essential rescue and monitoring equipment, and carefully selecting the appropriate anesthesia and informing the patient in advance. These regulations, however, will provide a clearer standard by which dentists are expected to practice and give patients a higher degree of safety when receiving office-based anesthesia. As insurers and practitioners encourage more procedures to be performed in an office-based practice or surgi-center rather than a hospital, these regulations will provide a definite advantage to patients, who typically do not have sufficient knowledge to judge whether the dentist and the facility are appropriately equipped and trained and whether adequate care is being taken to prepare and monitor their recovery. Since the regulations generally do not apply to the administration of local anesthesia, there should be little effect on the majority of general dentists and no disadvantages to the public in terms of limiting access or increasing cost.

Advantages and disadvantages to the agency:

There are no specific advantages or disadvantages to the agency. Regulations that set standards for practice may create an opportunity for complaints for non-compliance, but under current laws and regulations, failure to appropriately provide and monitor anesthesia could be considered substandard care and subject the licensee to disciplinary action. The advantage of these regulations is derived from having more specific, objective standards on which to base such a decision or make findings in a disciplinary case involving sedation or anesthesia. However, with more complete and objective rules to follow, practitioners who are conscientious about their practice and protecting their patients should be able to avoid incidents of unprofessional conduct related to delivery of anesthesia.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

Projected cost to the state to implement and enforce:

(i) Fund source: As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation.

(ii) Budget activity by program or subprogram: There is no change required in the budget of the Commonwealth as a result of this program.

(iii) One-time versus ongoing expenditures: The agency will incur some one-time costs (less than $2,000) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending copies of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled.

Projected cost on localities:

There are no projected costs to localities.

Description of entities that are likely to be affected by regulation:

The entities that are likely to be affected by these regulations would be licensed dentists and dental hygienists.

Estimate of number of entities to be affected:

Currently, there are 3,825 dental hygienists and 5,332 dentists who hold a license in Virginia.

Projected costs to the affected entities:

All applicants for licensure, whether by examination or endorsement, will be required to submit a current report from HIPDB at a cost of $8.50 in order to gain independent information on possible disciplinary actions in other states.

For those dentists and dental hygienist who do not have training in cardiopulmonary resuscitation, there will be some additional cost to be incurred within one year of the effective date of these regulations. A CPR course with certification in the use of an automated external defibrillator (AED) takes 5 hours (always taught in the evening or on a Saturday) and costs $55; the course with AED takes 4 hours and costs $50.

For those dentists and ancillary personnel who may not meet the stated qualifications for administration of anesthesia or sedation, there would be some additional cost for compliance. Advanced cardiac life support certification typically requires 16 hours of class at a cost of $250 to $300; basic cardiac life support certification requires 8 hours of class at a cost of $150 to $200. Both courses are available on weekends and do not require any disruption of a work schedule.

Dentists who do not meet the current educational requirements for use of enteral conscious sedation may be able to become qualified under the proposed regulation by completing a 18 hours of didactic instruction plus 20 clinically-oriented experiences in enteral and/or combination inhalation-enteral conscious sedation techniques. To do so generally necessitates attendance at a weekend seminar or course at a cost of less than $1,000. Becoming qualified to administer

conscious sedation is not necessary to a general dentistry practice; it would be a choice based on a practitioner's decision that it would be beneficial to his practice and his patients to have that option available. Therefore, any cost incurred for completion of the required hours of training would be more than offset by additional fees that could be charged for that service.

The redrafted proposed regulation requires additional equipment required for a dental office where general anesthesia is administered, including pharmacologic antagonist agents, an external defibrillator and, for intubated patients, an End-Tidal CO monitor. According to testimony from oral and maxillofacial surgeons, who administer general anesthesia, such equipment is standard in offices where out-patient surgery is performed. If a dentist was required to purchase equipment to meet the new regulations, an automatic external defibrillator would cost approximately $1,100 and an End-Tidal CO monitor approximately $850.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

18 VAC 60-20-10. Definitions.

- The Board recommends deleting several definitions and adding others in order to provide clarity for terms used in the regulation of anesthesia and sedation. The terms "conscious sedation" and "local anesthesia" are amended to update the term as used in practice and in regulation. A definition of "general anesthesia" is given in conjunction with the term "deep sedation" since the state of consciousness and response can easily flow from one state to the other, and the old definition of "general anesthesia" is eliminated. Terms that are no longer used in regulation have also been eliminated.

- The definitions for "monitoring general anesthesia and conscious sedation" and "monitoring nitrous oxide oxygen inhalation analgesia" are deleted from this section and the requirements contained therein included in monitoring requirements in Part IV.

Changes in the resubmission of the proposed regulation:

- The definition of "direction" is amended to clarify that the responsibility of the dentist for providing direction includes an evaluation of the patient, not merely being present during the evaluation.

- A new definition for "parental" was amended to more accurately define the term as used in provision of sedation to a patient.

18 VAC 60-20-16. Address of record.

Amendments delete a prohibition on the use of a post office box number in providing an address to the Board and the requirement that a dental hygienist provide a residential address. Since licensee information is currently posted on the departmental website or available via a FOIA request, some licensees have expressed safety concerns about having their resident address listed.

18 VAC 60-20-20. License renewal and reinstatement.

The regulation for reinstatement of a lapsed license currently authorizes the executive director of the Board to reinstate a license provided the applicant can "demonstrate continuing competence;" no specific requirement was established. To provide a clear standard by which the applicant's competency can be measured, the Board proposes requiring evidence of continuing education and possibly active practice in another state or current board specialty.

Changes in the resubmission of the proposed regulation:

- Changes in subsection C 3 will: 1) identify the regulation in which CE requirements for reinstatement of a license are specified; and 2) include dental practice in federal service as acceptable evidence of active practice in another jurisdiction.

18 VAC 60-20-50. Requirements for continuing education.

In number 14 of subsection C, the Board has the authority to approve other continuing education sponsors in addition to those listed in regulation. By Board action, the MCV Orthodontic and Research Foundation and the Dental Assisting National Board have been approved, so for clarity and consistency, the Board proposes to add those entities to the list.

The Board has also reduced the burden of compliance for persons who have allowed their license to lapse by requiring no more than 3 years' worth (45 hours) of continuing education regardless of the number of years out of active practice.

Changes in the resubmission of the proposed regulation to subsection A:

- The Board has added to the section on continuing education a requirement for all licensed dentists and dental hygienist to have training in basic cardiopulmonary resuscitation (CPR). In discussion of the proposed regulations on sedation and anesthesia, it was agreed that all licensees should have knowledge about resuscitative techniques as a basic patient safety measure. The administration of local anesthesia or performance of a dental or hygiene procedure can trigger a cardiopulmonary event, to which the licensee must be able to respond. Since hygienists are now permitted to practice under general supervision (without the physical presence of a dentist), they may be the only licensee available when such an event occurs.
- Additionally, the Board determined that all dentists who administer or hygienists who monitor patients under general anesthesia, deep sedation or conscious sedation should complete 4 hours of approved continuing education directly related to administration or monitoring every 2 years. The 4 hours could be obtained by taking a course to recertify in resuscitation techniques and would be counted in the 15 hours required for renewal of licensure.

- Legislation passed by the 2004 General Assembly removed the statutory requirement that dental hygienist obtain 15 hours of continuing education annually. Since no such language was in the Code for dentists, the current regulation allows them to carry over up to 15 hours. The amendment will make the regulation consistent for dentists and hygienists.

Changes in the resubmission of the proposed regulation to subsection C:

- Number 8 was amended to appropriately identify the accrediting bodies for colleges and universities and for hospital and health care institutions.
- Number 9 was amended to add the American Safety and Health Institute, an approved continuing education provider that offers continuing education in resuscitative techniques.
- Number 10 was amended to add accredited dental schools or specialty residency programs as approved CE providers.
- Number 15 was amended to eliminate "any other board approved program" and add a regional testing agency when a licensee is serving as an examiner in a clinical exam. The Board proposes to eliminate board-approval of continuing education programs because it is a costly process for which there is no fee to the providers, the review and approval process is time-consuming for staff and board members, and there is a wide array of approved organizations and entities through which a provider can get a course offered.

Changes in the resubmission of the proposed regulation to subsection H & I:

- In subsection H, a requirement is added to specify that at least 15 of the continuing education hours required for reinstatement must be in the most recent 12 months and the remainder within the most recent 36 months preceding application. In order to ensure that the practitioner is competent to return to active practice, the Board is requiring continuing education, the validity of which is partially based on whether the hours of CE are relatively current.
- In subsection I, the terminology for an order is clarified, and it is specified that completion of CE under a board order in a disciplinary case does not meet the requirement for CE for renewal or reinstatement.

18 VAC 60-20-60. Education.

- The Board proposes to amend the educational requirement to specify that an applicant must be a graduate of an accredited or approved program which consists of a pre-doctoral dental education program or at least a one year post-doctoral clinical program in general dentistry or a post-doctoral program in any specialty recognized by the Commission on Dental Accreditation of the American Dental Association. Current language states that the applicant must be a graduate of a school recognized by the Commission; however, the Commission only recognizes dental programs, not dental schools. The amendment is consistent with current Board policy.

Changes in the resubmission of the proposed regulation:

- Terminology is amended to clarify the accreditation of dental and dental hygiene programs.

18 VAC 60-20-70. Licensure examinations.

- If the practitioner has taken the licensure examination more than five years prior to applying for licensure in Virginia, current regulations require continuous active practice during that entire period. The Board has adopted a somewhat less restrictive rule that would continue to require evidence of active practice (48 out of the last 60 months) to permit short gaps in practice or hours of continuing education could also indicate continued competency.

- Board members who have participated in testing of candidates have concerns about those that have failed in multiple attempts. Since the testing is performed on live patients, this is an issue of public safety, so the Board adopted a requirement for additional training after three failed attempts at passage. For dentists, the requirement is 14 hours of additional clinical training in each treatment section to be retested, and for dental hygienists, the requirement is 7 hours of each treatment section.

- Current regulations require passage of an examination on the applicable Virginia dental and dental hygiene laws and regulations. Other boards within the Department have adopted requirements for the candidates to attest that they have read and understand the applicable rules. The Board proposes to accept a signed statement attesting to a review and understanding of the laws and regulations.

18 VAC 60-20-80. Licensure by endorsement for dental hygienists.

- For dental hygienists who are seeking licensure by endorsement, the Board proposes to add a requirement for submission of a HIPDB report, which would notify the Board of disciplinary action in another state. As with the dentists, a change would also propose to accept a signed statement attesting to a review and understanding of the laws and regulations.

Changes in the resubmission of the proposed regulation:
- A change in subsection D adds a requirement to "remain current" to the attestation by an applicant that he has read and understands the applicable laws and regulations.
- The Board decided that a HIPDB report should be obtained for all applicants for licensure, so that requirement was eliminated in section 80 and added to section 100.

18 VAC 60-20-90. Temporary permit, teacher's license and full-time faculty license.

- The Board intends to clarify certain portions of this section for consistency with the Code; regulations state that a temporary permit is valid until the release of grades of the next examination, but the Code states that it is valid until the second June after issuance. That discrepancy is confusing to permit-holders and sometimes results in the regulations being more restrictive than the Code.

- The Board has also clarified that holders of a full-time faculty license are permitted to practice and accept fee for service pursuant to § 54.1-2714.1 of the Code.

- Applicants for faculty licenses or temporary permits will also be asked to attest that they have read and understand the laws and regulations rather than having to pass a jurisprudence examination.

Changes in the resubmission of the proposed regulation:

- Rather than requiring practice by a full-time faculty licensee in an intramural clinic "in" a dental school, the amended regulation would allow practice in a clinic "affiliated" with the school. Sometimes, the clinics are not physically located in the dental school but are clinics operated by the school in another location.

18 VAC 60-20-105. Inactive license.

The Board proposes to eliminate an unnecessary provision requiring someone to hold an inactive license for more than one year before he can request reactivation. There is also a clarification that the requirement for evidence of continuing education cannot exceed 45 hours (or the equivalent of 3 years).

Changes in the resubmission of the proposed regulation:

- A requirement is added to specify that at least 15 of the continuing education hours required for reactivation must be in the most recent 12 months and the remainder within the most recent 36 months preceding application. In order to ensure that the practitioner is competent to return to active practice, the Board is requiring continuing education, the validity of which is partially based on whether the hours of CE are relatively current.

Part IV. The title of this section is changed to reflect the scope of regulations for anesthesia, sedation and analgesia.

18 VAC 60-20-106. General provision.

- Subsection A is added to indicate requirements of Part IV do not apply to administration of local anesthesia in dental offices or to the administration anesthesia in hospitals or facilities directly maintained or operated by the federal government. Similar language is now in subsection D of section 130.
- Subsection B specifies that high risk patients shall not be provided anesthesia or sedation in a dental office and that patients with moderate risk should only be given anesthesia after consultation with a physician treating that patient.

Changes in the resubmission of the proposed regulation:

- Subsection B is titled, "Appropriateness of administration of general anesthesis or sedation in a dental office" and is inclusive of the rules for treating all levels of patients in risk categories determined by the American Society of Anesthesiologist (ASA). Number 1 specifies that it is acceptable to treat patients in Classes I and II, and number 2 specifies that it is not acceptable to treat patients in Classes IV and V in a dental office. Number 3 is amended at the request of the oral and maxillofacial surgeons to allow them to perform the assessment on patients to determine the risk category for patients in Class III and the need for any additional equipment.
- Subsection C is added to require that the dentist discuss with the patient prior to administration the risks, benefits and alternatives of sedation or anesthesia and obtain written informed consent. A requirement for patient communication and consent is identical to a

rule in regulations governing administration of anesthesia or sedation under the Board of Medicine.
- Subsection D is also similar to a rule in the Medicine regulations and clarifies that the determining factor for the application of regulations is the degree of sedation or consciousness level that could reasonably be expected, as documented in the patient's chart.
- Subsection E is added to give dentists who are currently authorized to use anesthesia or sedation one full year from the effective date of the regulations to comply with educational requirements for the various levels.

The next three sections set forth Board requirements for the various levels of analgesia, anesthesia or sedation. In each, requirements for education and training, equipment, and monitoring are described.

18 VAC 60-20-107. Administration of anxiolysis or inhalation analgesia.

- The administration of anxiolysis or inhalation analgesia (nitrous oxide) can be provided to patients by a dentist who understands and has had training in the medications used, the physiological effects and potential complications. No specific training is required for this level of analgesia.
- Basic equipment is required in the office to measure blood pressure and oxygen levels and to assist a patient with respiration, should that become necessary.
- In order to monitor a patient being treated with anxiolysis or inhalation analgesia, there must be an assistant with the dentist to help in monitoring the level of consciousness.
- If being discharged to his own care, the dentist must ensure that the patient exhibits normal responses.

Changes in the resubmission of the proposed regulation in section C:
- The amendments clarify that the second person on the treatment team must be in the operatory with the patient to assist, monitor and observe the patient, and that one member of the team must be with the patient at all times, once administrative has begun.
- In response to public comment, the Board has eliminated the requirement for a beginning and ending blood pressure to be taken.

18 VAC 60-20-110. Requirements to administer deep sedation/general anesthesia.
- The Board proposes to include in this section the requirements to administer deep sedation or general anesthesia, since by definition they are the same. Training requirements do not differ from current rules in subsection A, but a new subsection B adds requirements for additional training in advanced resuscitation techniques and a current DEA registration.
- Subsection C clarifies the exceptions to the requirements for training.
- Subsection D is similar to the current language in section 130 B, which has been repealed.
- Subsection E states the emergency equipment and techniques that must be employed. Currently, equipment requirements for all forms of sedation and anesthesia are listed in section 130 A. In the proposed regulation, the Board has added pulse oximetry, blood pressure monitoring equipment, appropriate emergency drugs, EKG monitoring equipment

and temperature measuring devices as basic equipment essential for safe administration of deep sedation or general anesthesia.

- Subsection F sets out the requirements for monitoring and discharge. Current regulations (section 130 C) for the anesthesia team and discharge are restated in subdivision 1. In addition, there is more specificity about monitoring the patient beginning immediately after anesthesia or sedation has been induced and continuously throughout the procedure.

Changes in the resubmission of the proposed regulation:

- Amendments to subsection A 2 more accurately state the training in anesthesia and related subjects received in an approved residency in a dental specialty. Within the one year of training in clinical anesthesia would be included related medical subjects.
- Amendments modify the requirement for ACLS or PCLS by making it generic and eliminating the specific reference to the American Heart Association.
- Amendments to subsection D will add 3 requirements for monitoring patients under anesthesia. The additions are in response to comment from dentists who testified that the 3 additions should be the standard of care for administration of general anesthesia or deep sedation.
- Amendments to subsection E will: 1) change the term from "anesthesia" team to "treatment" team since all 3 are not involved with the anesthesia; 2) clarify that all members of the team must be in the operatory during the procedure; 3) specify what is meant by "monitoring" to include direct, visual observation of the patient by a member of the team; 4) specify that monitoring begins prior to induction of anesthesia and must take place continuously through the patient's recovery; and 5) specify that another qualified practitioner may remain on the premises until the patient has recovered and been discharged.

18 VAC 60-20-120. Conscious sedation.

- There are currently two methods by which a licensee can be qualified to administer conscious sedation: 1) completion of training in this treatment modality while enrolled in an accredited dental program or a post-doctoral program; or 2) self-certification issued by the Board to dentists who were using anesthesia or conscious sedation prior to January 1989 before the time dental programs included education in sedation. Subsection B of section130 currently requires posting a certification of education or the certificate issued by the Board. In the proposed regulation, the Board proposes to require those who were not qualified by an educational program to obtain 12 hours of approved CE directly related to administration of conscious sedation by March of 2005. In addition, the Board proposes a third method by which a dentist, who does not meet the current requirements, could become qualified to administer conscious sedation. That would consist of a program of at least 40 hours of clinical training in the treatment modality.
- A requirement is proposed to ensure that all dentists who administer conscious sedation or general anesthesia would have to have certification in Advanced Cardiac Life Support, current DEA registration.
- Subsection D specifies the emergency equipment and techniques required for conscious sedation, which are identical to those currently stated in subsection A of section 130 with the addition of #7, requiring the dentists to have on hand appropriate emergency drugs for patient resuscitation.

- Subsection E sets out the requirements for the treatment team in monitoring the patient until discharge and requires that the person who administers the sedation remain on the premises until the patient is responsive and ready for discharge.

Changes in the resubmission of the proposed regulation:

- Another option is added to the educational credential required to administer conscious sedation by any means, allowing a dentist to complete an approved continuing education course of 60 hours of didactic instruction, plus the management of at least 20 patients, in parenteral conscious sedation. The course must be consistent with guidelines of the ADA on teaching the comprehensive control of anxiety and pain in dentistry. Acceptance of such a credential will enable the practicing dentist who wants to expand his ability to administer sedation the opportunity to obtain the necessary training without having to return to school for an advanced dental education program.
- Amendments to subsection B eliminated the specific requirement for 12 hours of continuing education related to administration of conscious sedation for those dentists who were self-certified prior to 1989. The Board concluded that some continuing education hours for all dentists who administer sedation or general anesthesia was necessary for public health and safety, so the requirement was generally added in section 50.
- Amendments to subsection C modified the continuing education requirement for dentist who want training in the administration of conscious sedation by the enteral method. The proposed rule required 40 hours, and that was reduced to 18 hours plus 20 clinically-oriented experiences. The amended credential, which must be offered as an approved continuing education course, is currently the program that is frequently used to train dentists in such a method.
- Amendments to subsection D will give dentists one year from the effective date of the regulations to obtain certification in advanced resuscitation techniques and eliminates the specific reference to the American Heart Association.
- Amendments to subsection E: 1) offer an alternative to the requirement for a laryngoscope and endotracheal tubes; and 2) add requirements for pulse oximetry, blood pressure monitoring equipment, and pharmacologic antagonist agents to reverse the effect of the drugs if the patient is not appropriately responding.
- Amendments to subsection F: 1) specify what is meant by "monitoring" to include direct, visual observation of the patient by a member of the team; 2) specify that monitoring begins prior to induction of anesthesia and must take place continuously through the patient's recovery; and 3) specify that another qualified practitioner may remain on the premises until the patient has recovered and been discharged.

18 VAC 60-20-130. General information. (This section would be repealed, and all requirements placed in other sections of the regulation.)

18 VAC 60-20-135. Training for ancillary personnel. (new section)

The Board proposes to require dentists who employ ancillary personnel to assist in the administration and monitoring of sedation and anesthesia to document that such personnel have had minimal training and certification. The minimal requirement for ancillary personnel include certification in Basic Cardiac Life Support and a clinically-oriented course approved by the

Board devoted primarily to responding to clinical emergencies. Certification as a certified anesthesia assistant (CAA) by the American Academy of Oral and Maxillofacial Surgeons would be acceptable evidence of competency and training.

Changes in the resubmission of the proposed regulation:

- An amendment will allow one year from the effective date of the regulation to ancillary personnel used to assist in sedation or anesthesia to obtain the required credential in basic cardiac life support. An amendment also states the requirement generically and eliminates the specific reference to the American Heart Association.

18VAC60-20-190. Nondelegable duties; dentists

In the re-adoption of proposed regulations, the Board has amended section 190 to clarify that, as provided in sections on administration of sedation and anesthesia, a dentist can delegate to a non-dentist the monitoring of patients.

18 VAC 60-20-195. Radiation certification.

There are currently four methods by which a dental assistant can be qualified to expose dental x-ray film, including passage of an examination offered by the Board. The Board intends to eliminate that examination and add a provision that allows someone to be qualified by completion of a radiation course and examination offered by the Dental Assisting National Board.

Alternatives

Please describe the specific alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

To ensure minimal competency for licensure, the Board considered several revisions to requirements for education and examination that would more clearly state criteria acceptable for licensure or reinstatement of a lapsed license. Initially, the Board recommended that an applicant for licensure have evidence of completion of an accredited dental program that consisted of a pre-doctoral dental education or a 24-month post-doctoral program. Our review of Accreditation Standards for Advanced Education Programs in General Dentistry from the Commission on Dental Accreditation indicated that 12-month advanced programs are accredited in general dentistry, so the proposal that was adopted modified the regulation accordingly. Accredited post-doctoral programs in a specialty consist of a minimum of two years with programs in oral and maxillofacial surgery consisting of four years.

Further, the Board addressed the problem of repeated failures on the licensure examination by a small number of applicants. The Southern Regional Testing Agency (SRTA) provided the examination approved by the Virginia Board for licensure. It is their policy to require any candidate who has failed a section of the examination three times to meet the requirements of the state in which he is seeking licensure prior to re-testing on that section or sections. Virginia has had no requirements for remediation, resulting in harm to patients and concerns about

responsibility of the school where the examination is given for post-operative care. According to statements from SRTA, the typical example of patient harm and consequences for post-op care would be a situation in which a candidate is testing for amalgam (filling teeth) and either overdrills and breaks a tooth, leaving the patient with the need for a crown. Board members who are testers for SRTA have observed actual harm to patients, and SRTA reports that there were 6 cases in the past 3 years in which candidates who have repeatedly failed a section of the examination were stopped during the test for poor professional judgment or excessive treatment. Initially, the Board proposed requiring completion of a one-year clinical program for persons who have failed 3 times, but determined that was overly burdensome because much of that program would likely cover areas of treatment in which the applicant had already demonstrated competency in the examination. Therefore, the Board opted for a minimal amount of remediation consisting of 14 hours of additional clinical training in each section to be retested for dentists and 7 hours of additional training for dental hygienists.

To determine whether the existing regulation was achieving the purpose of protecting the public health and safety in the delivery of anesthesia and sedation services, the Board sent a questionnaire to a group of practicing dentists with extensive knowledge and experience in the administration of anesthesia and sedation. The issues that were addressed included:

- The need to clarify the distinctions regarding the use of inhalation analgesia, conscious sedation, deep sedation and general anesthesia.

From the comments received and an examination of regulations from a number of other states, the Board concluded that some additional clarification was needed to further define the distinction and requirements for various levels of analgesia, sedation and anesthesia. Other states require a separate permit to perform general anesthesia or deep sedation, annual on-site inspection of anesthesia and monitoring equipment, and standards for the treatment and recovery areas of the facilities, but the Board has not chosen to propose that level of regulation. It does concur that additional definitions are needed and that some regulations need to be amended to assure safe delivery of services and appropriate preparation for emergencies.

- The need for standards for ancillary personnel who monitor or who are otherwise engaged in general anesthesia/conscious sedation.

It was agreed by all commenters and members of the Board that some specified standards and training are necessary for ancillary personnel – or as one dentist wrote, “standards for ancillary personnel who monitor sedated patients are critical.” Certification in radiation safety is required for those who do dental x-rays, so it is logical to conclude that a similar standard should be created for those who are involved with anesthesia and sedation and may have the responsibility for monitoring a patient and handling a medical emergency. At the least, those persons need to be certified in Basic Life Support or its equivalent. The Board is working with the dental school at the Medical College of Virginia and other organizations to develop a course that would be reasonable, accessible, and effective. Comments on this issue will be important in the consideration and promulgation of a regulation for anesthesia personnel.

- The methods and equipment that are necessary for a dental office using conscious sedation, general anesthesia and deep sedation.

In addition to the equipment and requirements for monitoring that are in existing regulation, the Board has received comment that more precautions need to be established depending on the level of sedation. Comment from practitioners indicated that the standard should parallel outpatient ambulatory surgery centers. For a dentist who routinely performs light conscious sedation on healthy patients, the complete armamentarium for general anesthesia may seem burdensome, but mostly unavoidable to adequately protect the public. In proposed regulations, the emergency equipment necessary for conscious sedation is the same as is found in current regulations with the addition of appropriate emergency drugs for patient resuscitation. In addition to that equipment, dentists who utilize general anesthesia in office-based surgery would be required to have EKG monitoring equipment and temperature measuring devices. In addition, the proposed regulations require the treatment team for conscious sedation to consist of the operating dentist and a second person to monitor and assist. The requirement for the operating team for general anesthesia is the same as in the current regulations.
Also considered, but not adopted were requirements for written emergency protocols including transfer to a hospital, annual inspection of anesthesia equipment, and a prohibition on conscious sedation in dental offices for children under the age of 12. It was clearly stated that administration of local anesthesia or administration of anesthesia in a licensed hospital does not fall under these regulations. There are also limitations placed on who is eligible for anesthesia in a dental office, and it may not include patients in high risk categories (Class IV and V) and may only include patients in Class III after consultation with a physician who treats that patient.

- The need for additional qualifications or standards for dentists who administer general anesthesia or conscious sedation.

Recommendations for additional qualifications that were considered included: 1) requiring a permit to provide general anesthesia and conscious sedation to be renewed annually; 2) requiring Advanced Cardiac Life Support (ACLS) certification and current DEA registration; and 3) training to the level of competency consistent with Part I and Part III of the ADA guidelines.
The Board did not adopt a requirement for an annual permit, but it did accept a recommendation for requiring ACLS or PALS (pediatric). No cardiac life support course is required for dentists who only administer anxiolysis or inhalation analgesia.
The Board also heard testimony from a few dentists who are not currently qualified to administer conscious sedation but would like to include such a practice. Before anesthesia was incorporated into the dental school curriculum, dentists could be issued a certificate qualifying them to administer conscious sedation; those certificates are no longer issued. Under the current rules, the only educational pathway was completion of training while enrolled at an accredited dental program. To provide a means for practicing dentists to become qualified, the Board adopted an option requiring 18 hours of clinical training for this treatment modality.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

Prior to initiating a periodic review of this regulation, the Board published a notice of the review and solicited comment from March 26, 2001 to April 25, 2001. Comment was requested on whether the existing regulation was essential to protect the health, safety and welfare of the public in providing assurance that licensees are competent to practice and on alternatives or suggestions for clarification that could make the regulation less burdensome. Based on comment and review of rules governing the use of sedation and anesthesia in the practice of dentistry in other states, the Board began the process of developing draft amendments for consideration and comment by licensees.

Following a thorough review of the regulations and consultation with practitioners and educators who have expertise in anesthesia and sedation, the Board published a NOIRA on May 20, 2002 noting the substance of regulatory changes being contemplated and requesting comment until June 19, 2002. The comment received from seven persons consisted of suggested language for sedation and anesthesia, including appropriate definitions, training, and monitoring, which the Board incorporated into its working draft. Throughout the development of the regulations, the Board utilized the services of an ad hoc committee with expertise in sedation and anesthesia. The committee consisted of two oral and maxillofacial surgeons, who are qualified to administer general anesthesia as well as lesser forms of sedation or analgesia, and two professors from the VCU School of Dentistry who teach dental students in the departments of endodontics and pediatric dentistry and anesthesiology.

From January 2001through December of 2002, the Regulatory Committee and the Board have continuously worked on amendments to regulations through numerous drafts and opportunities for public comment during the course of meetings. Draft regulations were made available to licensees, some of who expressed their views to the Board in writing or in person. Accordingly, the Board adopted those regulations that were reasonable but necessary to protect patients.

Public comment received during the 60-Day Comment Period on Proposed Regulations

Amended regulations pursuant to regulatory review were published in the Virginia Register of Regulations on December 29, 2003. Public comment was requested for a 60-day period ending February 27, 2004. During that period, the following comments were received:

The Virginia Society of Oral & Maxillofacial Surgeons (VSOMS) provided written and oral comment. VSOMS, which was represented by Dr. Robert Strauss, recommended:

> 1) A revision of the proposed regulation restricting the provision of anesthesia in dental offices for patients in ASA class IV and V and requiring consultation with a treating physician for class III patients. Class III and IV patients often need supplemental sedation and is often safer than administration of local anesthesia for them. The VSOMS believes oral and maxillofacial surgeons are trained to assess a patient's physical condition and the risks of a procedure to their patients; it recommends that OM surgeons be allowed to treat class III and IV patients after appropriate evaluation.

Board response: 18VAC60-20-106 B was amended to permit oral and maxillofacial surgeons to treat a Class III patient after performing an assessment of the patient's condition and risks of the procedure. Consistent with regulations for administration of anesthesia and sedation in office-based settings by medical doctors, the restriction on administration to Class IV patients in dental offices was retained. The Board believes that dental procedures or surgery on a Class IV patient under anesthesia should only occur in a health care institution, such as a licensed hospital.

2) A clarification of the residency educational requirement for administration of deep sedation and general anesthesia to be consistent with the American Dental Association Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry.

Board response: 18VAC60-20-110 A 2 was amended accordingly.

3) Three additions to the requirements for emergency and monitoring equipment to include: pharmacologic antagonist agents, external defibrillator, and an End-Tidal CO monitor for intubated patients.

Board response: 18VAC60-20-110 D was amended accordingly.

4) A clarification of the requirement for monitoring a patient under deep sedation or general anesthesia to ensure that monitoring begin prior to induction of anesthesia and takes place continuously throughout the procedure. They also recommended that another licensed practitioner qualified to perform that level of anesthesia be allowed to remain with the patient in lieu of the person who administered the anesthesia.

Board response: 18VAC60-20-110 E 2 was amended accordingly.

5) Two additions to the emergency and monitoring equipment required for conscious sedation to include: pharmacologic antagonist agents and an external defibrillator.

Board response: 18VAC60-20-120 E was amended to include among the emergency equipment pulse oximetry, blood pressure monitoring equipment and pharmacologic antagonist agents. An external defibrillator was not required.

The American Association of Oral and Maxillofacial Surgeons (Dr. David Moyer) provided the following comments and recommendations:

1) Section 10: A definition for "parenteral" found in the American Dental Association's "Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia:

Board response: The definition for "parenteral" in 18VAC60-20-10 was amended accordingly.

2) Section 20: For reinstatement of a lapsed license, the hours of practice "in another state" should be deleted and replaced with hours of "active practice."

Board response: 18VAC60-20-20 was amended to recognize hours of active practice in another state or in federal service.

3) Section 50: Continuing education providers should be changed to recognize "hospitals and other health care institutions" accredited by JCAHO rather accredited by the U. S. Office of Education and to add a dental school accredited by the Commission on Dental Accreditation (CDA).

Board response: 18VAC60-20-50 C 8 was amended accordingly.

4) Section 60: The word "recognized" should be changed to "accredited" by the CDA.

Board response: 18VAC60-20-60 was amended accordingly.

5) Section 106: There is concern about the prohibition on administering general anesthesia in a dental office to patients in ASA class IV patients and the requirement for consultation with a primary care physician or specialist for ASA class III patients.

Board response: 18VAC60-20-106 B was amended to permit oral and maxillofacial surgeons to treat a Class III patient after performing an assessment of the patient's condition and risks of the procedure. Consistent with regulations for administration of anesthesia and sedation in office-based settings by medical doctors, the restriction on administration to Class IV patients in dental offices was retained. The Board believes that dental procedures or surgery on a Class IV patient under anesthesia should only occur in a health care institution, such as a licensed hospital.

6) Section 107: Should add an additional statement – "Nitrous oxide/oxygen when used in combination with sedative agents may produce anxiolysis, conscious or deep sedation or general anesthesia. In these cases, the requirements in 18 VAC 60-20-110 shall apply."

Board response: Instead of the language recommended by the commenter, the Board added subsection D to section 106 to make it clear that: "The determinant for the application of these rules shall be the degree of sedation or consciousness level of a patient that should reasonably be expected to result from the type and dosage of medication, the method of administration and the individual characteristics of the patient as documented in the patient's record.."

7) Section 110: For emergency equipment and techniques for deep sedation/general anesthesia, pharmacologic antagonists and a defribrillator should be added as well as establishment of an IV line. Under "Monitoring," body temperature should be added and for intubated patients, end-tidal CO^2.

Board response: 18VAC60-20-110 D was amended accordingly.

8) Section 120 D: Add to the end of the sentence on the educational requirements for enteral administration of conscious sedation, "…and certified as competent."

Board response: The Board did not believe the addition was necessary.

9) Section 120 E: In accordance with ADA guidelines, add pulse oximetry and blood pressure monitoring equipment and pharmacologic antagonists as requirements for administration of conscious sedation.

Board response: 18VAC60-20-120 E was amended accordingly.

Virginia Association of Dentists for Intravenous Sedation (Dr. Preston Burns) provided a letter and package of documents. As dentists utilizing parenteral conscious sedation, it is their belief that the proposed regulations will have a negative impact on their patients and may deny many citizens safe and affordable dental treatment because of the significant additional cost requirements on practitioners. The proposed regulations are more burdensome than ADA guidelines, not supported by objective research, and more onerous than neighboring jurisdictions.

Board response: As evidence that educational and monitoring requirements were unnecessary and not supported by objective research, Dr. Burns provided a 2001 article from the Journal of the American Dental Association on the safety of parenteral sedation. However, the article states that "There are limitations to the direct extraction of these findings to clinical practice" for the following reasons: 1) the patient sample was from young healthy adults rather than representative of the total population of patients undergoing sedation in a dental office; 2) the monitoring used for research may exceed that usually found in dental practice settings; and 3) the results of evaluations of prototype drugs may be extrapolated to the use of similar drugs from other classes, but are not relevant to the large number of unrelated drugs and diverse combinations of drugs in clinical use. The study also reports that a study of parenteral sedation analogous to dentistry is gastrointestinal endoscopy. A large-scale study of more than 20,000 cases yielded an estimated incidence of serious cardiovascular complications of 5.4 per thousand cases and a mortality rate of 0.3 per thousand cases. The incidence of mortality was similar to estimates of mortality associated with inpatient general anesthesia: one to three deaths per 10,000 procedures.[1]

Specifically, the Association has the following comments:

1) Section 120 D – Objects to a proposed requirement for ACLS certification for dentists practicing parenteral conscious sedation because there is no objective scientific support for the additional requirement; it is not required in the ADA Guidelines; it is not relevant to the administration of parenteral conscious sedation; neighboring states do not require ACLS for parenteral sedation; and the economic analysis of the proposed rule does not take into account all relevant costs.

Board response: While ADA Guidelines for use of conscious sedation do not mandate ACLS certification, it does "encourage" completion of ACLS or its equivalent. Some

[1] Dionne, Raymond A. et al for the Collaborative Sedation Study Group, JADA, Vol. 132, June 2001, pg. 750.

neighboring states also require advanced cardiac life support or additional continuing education for dentists who administer parenteral sedation. In Tennessee, Rule 0460-2-.07 requires that in order to maintain a limited or comprehensive conscious sedation permit, a dentist must "maintain current certification in ACLS (a pediatric dentist may substitute PALS)." In Kentucky, 201 KAR 8:390, Section 3. Conscious Sedation with Parenteral Drugs requires in (3) that a dentist administering conscious sedation with a parenteral drug complete ACLS or PALS within the past 24 months or obtain 6 hours of CE every two years specifically related to anesthesia safety and emergency procedures. The CE hours required for the permit cannot be used to satisfy other continuing education requirements. In 21 NCAC 16Q .0501 (North Carolina), a condition for renewal of a parenteral conscious sedation permit is documentation of current completion of advanced cardiac life support (ACLS) or its equivalent; or completion of BCLS and 3 hours per year of continuing education in sedation, medical emergencies, etc.
Therefore, the Board believes its regulations are consistent with the Guidelines, with neighboring states and with its responsibility to protect the public

2) Section 120 B – Objects to a proposed requirement for 12 hours of continuing education for those dentists who "self-certified" that they were qualified to administer parenteral conscious sedation as unnecessary and unavailable.

Board response: The Board has eliminated the requirement in section 120, so "self-certified" dentists who administer sedation are not required to obtain hours of continuing education over and above that required for other dentists. The Board has added a provision in section 50 requiring all dentists and hygienists who administer or monitor general anesthesia, deep sedation or conscious sedation to have 4 hours every two years in continuing education related to anesthesia or sedation. The 4 hours may be included as a part of the hours currently required for renewal and do not represent an additional burden. Recertification in cardiac resuscitative techniques by an approved continuing education sponsor would qualify for the required CE. In Maryland, renewal of a parenteral sedation administration permit requires 16 hours of continuing education per year relating to administration of sedation; the proposed rule in Virginia is very minimal.

3) Section 120 E – Objects to a proposed requirement for endotracheal tubes and a laryngoscope as emergency equipment as potentially harmful without additional training and skills maintenance.

Board response: The Board has amended 18VAC60-20-120 E accordingly by offering an alternative to a requirement for endotracheal tubes and a laryngoscope.

4) Section 107 C – Objects to a proposed requirement for a beginning and ending blood pressure be taken in the administration of anxiolysis or inhalation analgesia. Nitrous oxide does not affect blood pressure.

Board response: The Board has amended 18VAC60-20-107 C accordingly by deleting the requirement.

5) Section 135 – Objects to a proposed requirement for ancillary personnel assisting in conscious sedation to have BCLS and a clinically-oriented course devoted primarily to responding to clinical emergencies. Requests removal or clarification of this requirement.

Board response: The Board has amended 18VAC60-20-135 accordingly by deleting the word "and" and replacing it with "or" so there is a choice between BCLS and another approved, clinically oriented course in responding to clinical emergencies. The Board believes strongly that persons who assist in administering and monitoring anesthesia or sedation should receive some training in responding to a patient emergency.

Dr. Brian Hoard at the University of Virginia Health Systems commented as follows:

- For mild sedation/anxiolysis, he sees no need for monitoring guidelines or ACLS certification or for blood pressure monitoring. Questions whether any dentists in Virginia, other than oral & maxillofacial surgeons, are doing moderate or deep sedation. For moderate sedation, he questions the need for ACLS and favored training that is focused on assessing general risk, assessing airways, and managing airway and respiratory emergencies.

Board response: The Board has amended 18VAC60-20-107 C accordingly by deleting the requirement for blood pressure monitoring. Other requirements for monitoring are basic standard of care for a patient who has received anxiolysis or inhalation analgesia. Dr. Hoard is mistaken in his belief that there are few dentists doing moderate sedation. While the Board does not require a sedation permit or registration, testimony given to the board during the development of regulations indicates that there are a number of dentists who administer conscious sedation and that the number is increasing. The Board amended its proposal so it does not specify that ACLS training is required but retained a requirement for completion of a course in advanced resuscitation techniques. Such a requirement is supported by the Dental Organization for Conscious Sedation (a nationally recognized group that testified before the board).

- He questions the requirement for dental assistants to receive training in emergency management in addition to BCLS.

Board response: The Board has amended 18VAC60-20-135 accordingly by deleting the word "and" and replacing it with "or" so there is a choice between BCLS and another approved, clinically oriented course in responding to clinical emergencies.

- The requirement for 12 hours of continuing education for sedation certificate holders is too ambiguous and not specific to the needs of their practice.

Board response: The Board has eliminated the requirement in section 120, so "self-certified" dentists who administer sedation are not required to obtain hours of continuing education over and above that required for other dentists. The Board has added a provision in section 50 requiring all dentists and hygienists who administer or monitor general anesthesia, deep sedation or conscious sedation to have 4 hours every two years in continuing education related to anesthesia or sedation.

The following persons spoke before the Regulatory/Legislative Committee on February 27, 2004 and offered similar comments:
Dr. Tom Watson
Dr. Steve Tuttle
Dr. Steve Todd
Dr. Jason Goodchild
Dr. Tom Winkler

In their comments they indicated support for all proposed regulations for conscious sedation, including a requirement for ACLS certification for dentists and BCLS or CPR for staff, with the exception of the 40-hour course requirement to qualify a dentist to administer oral conscious sedation. They concurred that taking an advanced resuscitation training course increased knowledge about emergencies and what to look for and how to react. However, they requested a revision in the proposed course requirement and supported the course in oral conscious sedation offered by the Dental Organization for Conscious Sedation (DOCS), which meets the guidelines of the ADA but offers fewer hours than the proposed regulation for enteral conscious sedation in Virginia.

Board response: 18VAC60-20-120 was amended to reduce the hours required for training in enteral conscious sedation from 40 hours to 18 hours of didactic instruction plus 20 clinically-oriented experiences. As currently proposed, the requirement can be met by completion of the DOCS course, which is consistent with the ADA Guidelines and is recognized as approved continuing education.

A Public Hearing before the Board was held on January 22, 2003, at which time the following comments on proposed regulations were received:

Dr. Ed Griggs – Supports regulations for conscious sedation, addressing training requirements, emergency equipment, and patient safety; it is important to have definitive regulations that set a standard of safety. He uses only enteral/inhalation method of sedation because he was cautioned early in his career that IV (parental) sedation was beyond the scope of practice for general dentists. His training in oral conscious sedation came from courses offered by the Dental Organization for Conscious Sedation (DOCS), which also emphasizes proper monitoring and training of staff. His specific comment on proposed regulations are: 1) Separate rules for parental and enteral/inhalation sedation as they are very different; there is increased risk to patients with parental sedation, so the training and emergency equipment needed is different. Concerned that insurance companies will interpret the rules as equating the two methods since parental sedation is a rated procedure; 2) The 40-hour course requirement for enteral/inhalation sedation is beyond the comprehensive course offered by DOCS, which the commenter believes is adequate training; 3) Under emergency equipment requirements, the Board should consider substituting the combitube airway in lieu of the laryngoscope and endotracheal tube, as it is less difficult to use and less likely to cause harm to patients and the regulations should require an AED (automated electronic defibrillator), which is considered essential to the chain of survival. Respiratory arrest is a risk with sedation, and could be followed by cardiac arrest; and 4) Under monitoring, there is no mention of monitoring the patient during the time sedation is being employed and that is an oversight; patients should be monitored with pulse oximetry and blood pressure monitoring throughout the sedation procedure. It is very easy for the airway to become occluded, so monitoring of oxygen saturation levels is critical.

Board responses are as follows:

1) The regulation in section 120 is subdivided into training requirements for those who administer conscious sedation by any method (subsection B) and those who only administer by the enteral method (subsection C).
2) 18VAC60-20-120 was amended to reduce the hours required for training in enteral conscious sedation from 40 hours to 18 hours of didactic instruction plus 20 clinically-oriented experiences, consistent with the DOCS course.
3) The Board has amended 18VAC60-20-120 E accordingly by offering an alternative to a requirement for endotracheal tubes and a laryngoscope. The proposed requirement generically describes the use of a "combitube" within referencing a specific product. An AED was not added to the requirements for monitoring/emergency equipment.
4) Subsection F 2 of section 120 was amended accordingly.

Dr. Robert Keller – Did not feel regulations on nitrous oxide and IV sedation were necessary; he no longer uses IV sedation but does use nitrous. Opposes a requirement for CPR; he is unable to administer CPR because of fear of having a stroke and would have to drive to Richmond to find a course to take. Opposes any changes to rules on nitrous oxide. Opposes requiring a course from the American Heart Association as part of his license.

Board response: The Board has eliminated any specific requirement for completion of courses offered by the American Heart Association. Since AHA is an approved continuing education provider, dentists would be able to count hours in resuscitative techniques toward the 15 hours required for annual renewal. The Board has not eliminated the requirements for CPR, as it is necessary for patient health and safety for practitioners to be able to respond to a patient who has stopped breathing. The Board also believes the requirements for monitoring patients under nitrous are very basic and represent an accepted standard of care.

Dr. James Krochmal – Expressed concern about limiting the ability of oral & maxillofacial surgeon to treat patients in ASA Class 4 and 5; typically the surgeon will consult with the patient's physician about his ability to withstand sedation or anesthesia.

Board response: Consistent with regulations for administration of anesthesia and sedation in office-based settings by medical doctors, the restriction on administration to Class IV patients in dental offices was retained. The Board believes that dental procedures or surgery on a Class IV patient under anesthesia should only occur in a health care institution, such as a licensed hospital. Oral and maxillofacial surgeons will continue to be able to treat ASA Class IV and V patients, provided administration of anesthesia occurs in a hospital rather than in a dental office.

Dr. Mark Crabtree – Opposes the elimination of the jurisprudence examination on the laws and regulations affecting the practice of dentistry as a requirement for licensure.

Board response: 18VAC60-20-70 D was amended to specify that the applicant would have to attest to having read and understand the laws and regulations and promise to remain current with law and regulation governing dentistry.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

Members of the Board met in numerous open sessions to work on the proposed regulations. The public, including representatives of the Virginia Dental Hygiene Association and the Virginia Dental Association, and a number of individuals dentists participated in and commented on draft regulations during the course of those meetings. No comments have been received regarding the need for clarity in the proposed amendments. The Assistant Attorney General who provides counsel to the Board has been involved during the development and adoption of proposed regulations to ensure clarity and compliance with law and regulation.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed regulatory action would not strengthen or erode the authority and rights of parents, encourage or discourage economic self-sufficiency, strengthen or erode the marital commitment or increase or decrease disposable family income.