Form: TH- 06



Periodic Review and Notice of Intended Regulatory Action Agency Background Document

Agency Name:	Board of Dentistry
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
Date:	

This information is required pursuant to the Administrative Process Act § 9-6.14:25, Executive Order Twenty-Five (98), and Executive Order Fifty-Eight (99) which outline procedures for periodic review of regulations of agencies within the executive branch. Each existing regulation is to be reviewed at least once every three years and measured against the specific public health, safety, and welfare goals assigned by agencies during the promulgation process.

This form should be used where the agency is planning to amend or repeal an existing regulation and is required to be submitted to the Registrar of Regulations as a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B).

Summary

Please provide a brief summary of the regulation. There is no need to state each provision; instead give a general description of the regulation and alert the reader to its subject matter and intent.

Regulations governing the practice of dentistry and dental hygiene provide education and examination requirements for full licensure, as well as temporary permits and teaching licenses. Provisions also establish requirements for renewal or reinstatement of a license, including hours of continuing education and set fees to support the regulatory and disciplinary activities of the board. Regulations set forth requirements for the administration of general anesthesia and conscious sedation and for radiation certification. In addition to the responsibility for direction of patient treatment and appropriate delegation by a dentist, the regulations list those duties that may not be delegated by a dentist and those that shall only be delegated to a dental hygienist.

Finally, grounds for unprofessional conduct of a licensee and for standards of practice are established, including restrictions on advertising.

Basis

Form: TH- 06

Please identify the state and/or federal source of legal authority for the regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. Where applicable, explain where the regulation exceeds the minimum requirements of the state and/or federal mandate.

The statutory authority for this regulation is found in § 54.1-2400 and Chapter 27 of Title 54.1 of the Code of Virginia.

Section 54.1-2400 establishes the general powers and duties of health regulatory boards including the responsibility to establish qualifications for licensure, to set fees and schedules for renewal, to establish requirements for an inactive license and to promulgate regulations, in accordance with the Administrative Process Act, which are reasonable and necessary to effectively 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:

- 1. To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.
- 2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.
- 3. To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.
- 4. To establish schedules for renewals of registration, certification and licensure.
- 5. To levy and collect fees for application processing, examination, registration, certification or licensure and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.
- 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 and Chapter 25 of this title.
- 7. To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate or license which such board has authority to issue for causes enumerated in applicable law and regulations.

8. To appoint designees from their membership or immediate staff to coordinate with the Intervention Program Committee and to implement, as is necessary, the provisions of Chapter 25.1 (§ 54.1-2515 et seq.) of this title. Each health regulatory board shall appoint one such designee.

Form: TH- 06

- 9. To take appropriate disciplinary action for violations of applicable law and regulations.
- 10. To appoint a special conference committee, composed of not less than two members of a health regulatory board, to act in accordance with § 9-6.14:11 upon receipt of information that a practitioner of the appropriate board may be subject to disciplinary action. The special conference committee may (i) exonerate the practitioner; (ii) reinstate the practitioner; (iii) place the practitioner on probation with such terms as it may deem appropriate; (iv) reprimand the practitioner; (v) modify a previous order; and (vi) impose a monetary penalty pursuant to § 54.1-2401. The order of the special conference committee shall become final thirty days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the thirty-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 9-6.14:12, and the action of the committee shall be vacated. This subdivision shall not be construed to affect the authority or procedures of the Boards of Medicine and Nursing pursuant to §§ 54.1-2919 and 54.1-3010.
- 11. To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 9-6.14:12, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 9-6.14:11 shall serve on a panel conducting formal proceedings pursuant to § 9-6.14:12 to consider the same matter.
- 12. To issue inactive licenses and certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of such licenses or certificates.

Chapter 27 of Title 54.1 sets forth statutory provisions for the licensure and practice of dentists and dental hygienists. The applicable Code sections may be accessed at the website for the Department of Health Professions:

http://www.dhp.state.va.us/dentistry/dentistry_laws_regs.htm#law

Public Comment

Please summarize all public comment received as the result of the Notice of Periodic Review published in the Virginia Register and provide the agency response. Where applicable, describe critical issues or particular areas of concern in the regulation. Also please indicate if an informal advisory group was or will be formed for purposes of assisting in the periodic review or development of a proposal.

An announcement of the board's review of its regulations governing the practice of dentistry and dental hygiene was posted on the Virginia Regulatory Townhall, sent to the Registrar of Regulations, and sent to persons on the Public Participation Guidelines mailing list for the board. Public comment was received from March 26, 2001until April 25, 2001. During that period, no comment was received from members of the public. However, the Regulatory Review Committee specifically consulted with other licensed dentists who have particular expertise in certain aspects of practice, and comments were received regarding regulations on general anesthesia and conscious sedation and on continuing education requirements for those that administer either. There was also comment on the need for standards and training for ancillary personnel who monitor sedated patients.

Form: TH- 06

Effectiveness

Please provide a description of the specific and measurable goals of the regulation. Detail the effectiveness of the regulation in achieving such goals and the specific reasons the agency has determined that the regulation is essential to protect the health, safety or welfare of citizens. In addition, please indicate whether the regulation is clearly written and easily understandable by the individuals and entities affected.

1) Achieve positive ratings on the Customer Service Satisfaction Survey for application process and renewal of licensure.

The Board reviewed the responses of recent licensees on the Customer Service Satisfaction Surveys and determined that the application process and renewal of licensure was effective in that instructions for making application are clear and easy to understand and complete. Of those that responded, 92.6 % of the dentists and 85.6% of the dental hygienists agreed or strongly agreed that the instructions were easy to understand. Asked if the application was processed promptly, 94.5 % of the dentists and 89.4% of the dental hygienists agreed or strongly agreed. Asked if the forms were easy to complete, 95.4 % of the dentists and 88.2% of the dental hygienists agreed or strongly agreed. Therefore, no changes in regulations are being considered in the application process. There are, however, certain recommendations regarding the accreditation of dental programs and qualifying examinations.

2) Achieve a reduction in the number of cases of unprofessional conduct for advertising by guidelines on permissible practices.

To address the increase experienced in the number of complaints and disciplinary actions related to violations of statutes and regulations on advertising, the Board has attempted to provide additional guidance to its licensees. In January 1998, the Board adopted a guidance document that set out the applicable sections of the law and regulations and then gave specific examples of advertising or professional listings that are considered permissible and in conformity. All licensees of the Board were sent that information.

Disciplinary cases that were adjudicated by the Board during the past five fiscal years indicate the effectiveness of communication with licensees and guidance on permissible and prohibited

practices in advertising. In fiscal year '96-'97, there were 90 cases in which the category or subcategory of the complaint was advertising. In '97-'98, there were 32 cases; in '98-'99, there were 23 cases; in '99-'00, there were 15 cases. This past year ('00-'01) that number was back up to 21 cases, but the overall trend demonstrates a significant reduction in the number of advertising cases since the 1996-97 fiscal year.

Form: TH- 06

Following a March 20, 2000 decision by the Fairfax Circuit Court involving a challenge to the Board's enforcement of Va. Code § 54.1-2718, the Board, in accordance with the circuit court's decision, adopted the following interpretive guidance for the use of a trade name in advertising:

"In accordance with Va. Code § 54.1-2718, as well as the Board's advertising regulations, no dentist may practice dentistry under a name other than his own if such name is either false, misleading or deceptive or where such name is promotional and/or conveys no relevant information to consumers regarding either the geographic location or type of dentistry practiced therein."

Again that guidance was provided in a special notice mailed to all licensees. Unless the Code sections and regulations on advertising or practicing under a trade name are modified, the Board has few options other than communication with licensees on permissible practices and if that fails, docketing cases of unprofessional conduct.

Alternatives

Please describe the specific alternatives for achieving the purpose of the existing regulation that have been considered as a part of the periodic review process. This description should include an explanation of why such alternatives were rejected and this regulation reflects the least burdensome alternative available for achieving the purpose of the regulation.

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 several practicing dentists with extensive knowledge and experience. 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 needs to occur 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 some regulations may need to be amended to assure safe delivery of services and appropriate preparation for emergencies.

• The need for continuing education specified in conscious/deep sedation and/or general anesthesia for those dentists who use them in practice.

Form: TH- 06

The Board has looked at the possibility of requiring courses that would be considered "anesthesia courses" as a requirement for relicensure for those who use sedation or general anesthesia in their practice. While it may be difficult to ascertain compliance since the subject of anesthesia is often embedded in other subject matter, the Board concluded that the benefit of additional public protection did outweigh the potential burden to licensees. It was recommended no additional hours of continuing education be required but that some of those hours should be devoted to the administration, monitoring and potential consequences of sedation or anesthesia.

• 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 inhalation analgesia, 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 may be unavoidable to adequately protect the public. Also recommended and considered were requirements for written emergency protocols including transfer to a hospital, annual inspection of anesthesia equipment, prohibition on conscious sedation in dental offices for children under the age of 12, and availability of EKG monitoring as standard equipment. Based on the comments on this issue and the concern about patient safety, the Board will consider some modest additions to the requirements for equipment and trained personnel available in the treatment area during the dental procedure.

• The need for additional qualifications or standards for dentists who administer general anesthesia, conscious or deep sedation.

Recommendations on additional qualifications included: a permit to provide general anesthesia and conscious sedation to be renewed annually; Advanced Cardiac Life Support certification;

current DEA registration; and training to the level of competency in enteral and/or conscious sedation consistent with Part I and Part III of the ADA guidelines. At this time, it believes that those additional qualifications may be necessary for those who administer deep/conscious sedation, and that training in Basic Cardiac Life Support is essential for those who administer inhalation or combination inhalation-enteral conscious sedation. The Board has considered these recommendations and will consider additional comment during the NOIRA period.

Form: TH- 06

Recommendation

Please state whether the agency is recommending the regulation be amended or terminated and the reasons such a recommendation is being made.

The Board of Dentistry is recommending that consideration be given to amendments for 18 VAC 60-20-10 et seq. to update certain requirements and terminology, to clarify the Board's requirements, and to expand accessibility to Virginia licensure for persons who are licensed in other states and hold board certification in a specialty area of dentistry approved by the American Dental Association Commission on Dental Accreditation. The Board will consider modifying and adding requirements for administration of various forms of analgesia, sedation and ane sthesia as minimally necessary to ensure public safety. It will also consider an amendment to specify that dental education must be in an accredited program of at least 24 months in duration. During the development of regulations, the Board will also consider any other issues raised during public comment on the Notice of Intended Regulatory Action.

Substance

Please detail any changes that would be implemented.

18 VAC 60-20-10. Definitions.

- The Board recommends amending the definition of "general anesthesia" to include the term and definition for deep sedation, since the state of consciousness and response can easily flow from one state to the other. Additional definitions for "combination inhalation-enteral conscious sedation," "enteral" and "inhalation" are recommended to further define terms used in the regulations for anesthesia or sedation.
- The definitions for "monitoring general anesthesia and conscious sedation" and "monitoring nitrous oxide oxygen inhalation analgesia" may be deleted from this section and the requirements contained therein included in section 130 on "Minimal equipment and monitoring requirements."
- The definition of "nitrous oxide oxygen inhalation analgesia" may need to be amended to reflect current terminology and amendments to Part IV of these regulations.

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

Amendments will 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 now posted on the departmental website, some licensees have expressed safety concerns about having their resident address listed.

Form: TH- 06

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

- The regulation for reinstatement of a lapsed license currently permits the executive director of the Board to reinstate a license provided the applicant can "demonstrate continuing competence;" no specific requirement, such as information about active practice in another jurisdiction, is established. The Board will consider adopting a more specific requirement in order to provide a clear standard by which the applicant's competency can be measured.
- The Principles for Fee Development adopted by the Department in 1999 distinguish between a lapsed license (not renewed within one renewal cycle) and an expired license (beyond one renewal cycle). Typically, the licensee is allowed to renew a lapsed license by payment of the renewal fee and a late fee; renewal of an expired license requires reinstatement with an application and additional information provided. The Board will examine the terms and conditions for renewal, reinstatement or reactivation and may consider offering to those who have been lapsed or out of practice for a period of years the option of taking a refresher clinical course or repeating the licensure examination.
- The Board will consider deleting the requirement that it immediately notify a licensee whose license has expired. That is not the policy of other health regulatory boards, so the Board would like to receive comment on that practice.

18 VAC 60-20-60. Education.

The Board intends to submit for comment its intent to amend the educational requirement to specify that an applicant must be a graduate of an accredited or approved 24-month clinical program 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. In addition, the Board believes that a 24-month program is minimal to ensure minimal competency and readiness to sit for the examination.

18 VAC 60-20-70. Licensure examinations.

• The Code of Virginia requires that the Board may issue a dental license to an eligible applicant who has satisfactorily passed the examination. Regulations state that all applicants must complete Part I and Part II of the examination of the Joint Commission on National Dental Examinations. In addition, the board-approved dental examination is administered by SRTA (Southeast Regional Testing Agency). Board members have expressed concern about the equity and safety of requiring dental specialists who are currently practicing in other states to take the practice examination in general dentistry.

The Board will consider other requirements that may provide greater assurance of competency in the specialty area of practice.

Form: TH- 06

- 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 may consider a somewhat less restrictive rule that would continue to require evidence of active practice but would permit short gaps in practice for good cause.
- 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 would like to consider a requirement for some additional training after three failed attempts at passage.
- 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 will evaluate the current jurisprudence exam and consider whether there should be some modification, such as an open-book exam or accepting a signed statement attesting to a review and understanding of the laws and regulations.

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 that may conflict 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 would also like to clarify 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.

Part IV. General Anesthesia and Conscious Sedation.

18 VAC 60-20-105. Applicability.

A new section would be added to indicate requirements of Part IV do not apply to administration of anesthesia and sedation in hospitals and surgery centers. That language is now in subsection D of section 130.

18 VAC 60-20-110. Requirements to administer general anesthesia. (Would be renamed "Requirements to administer")

• The Board intends to include in one section the requirements to administer all forms of analgesia, sedation, or anesthesia. Those requirements would not differ from current rules in sections 110 and 120, but amendments would add deep sedation to the

requirements for general anesthesia, so a licensee who utilizes one would need to be qualified to use the other as well.

Form: TH- 06

- Amendments are also necessary to distinguish and more clearly describe the types of analgesia and sedation that may be utilized. There should be some distinction made between inhalation analgesia (nitrous oxide) and inhalation analgesia supplemented by a pharmacological agent or agents administered via the enteral route.
- A requirement is recommended to ensure that all dentists who administer any form of
 analgesia, sedation or anesthesia are certified in Basic Cardiac Life Support and are recertified every two years with evidence of that certification posted with the license. In
 addition, dentists who administer deep/conscious sedation or general anesthesia would
 have to have certification in Advanced Cardiac Life Support, current DEA registration,
 and training to the level of competency in enteral and/or conscious sedation consistent
 with Part I and Part III of the ADA guidelines.

18 VAC 60-20-120. Conscious sedation; intravenous and intramuscular. (This section would be repealed with requirements added to section 110)

The Board is concerned that there is no attestation or documentation from dentists who utilize conscious sedation in practice of their compliance with training requirements stated in regulation. An amendment to require some statement or proof of completion of an approved course will be considered.

18 VAC 60-20-130. General information. (This section would be renamed "Minimal equipment and monitoring requirements")

- In addition to equipment that must be available in the dental facility (currently subsection A of section 130), the Board intends to specify minimal equipment that must be in a treatment room where anesthesia or sedation is being administered to include at a minimum pulse oximetry and blood pressure monitoring equipment. Dentists who administer conscious/deep sedation or general anesthesia would also be required to have EKG monitoring equipment.
- The requirement to post certification of education or training for all personnel administering or monitoring patients would be moved to section 110.
- An amendment to the rules for monitoring should include an additional requirement that the patient is to be monitor continuously during the dental procedure. The Board will consider a requirement that at least one additional ancillary person be present during the entire procedure in which conscious sedation is administered. It will also consider whether to establish a maximum number of patients that a dentist may have under inhalation analgesia, conscious sedation, deep sedation or general anesthesia at the same time.

• The Board will also consider the need to require the availability of a positive pressure oxygen system suitable for patients being treated with conscious sedation and the continuous evaluation of oxygen saturation by pulse oximetry.

Form: TH- 06

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

The Board intends to develop a regulation 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 would likely 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.

Family Impact Statement

Please provide a preliminary 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.

In its preliminary analysis of the proposed regulatory action, the agency has determined that there is no potential impact on the institution of the family and family stability and no effect on family income.