



townhall.virginia.gov

Final Regulation Agency Background Document

Agency name	Board of Dentistry, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC60-21-10 et seq. 18VAC60-25-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Dentistry Regulations Governing the Practice of Dental Hygiene
Action title	Conforming regulations to ADA Guidelines on Sedation in Dentistry
Date this document prepared	3/9/18

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

A revision of the American Dental Association (ADA) *Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry* was published in October of 2016. Currently, Board regulations specify that education and training for conscious/moderate sedation must be consistent with the ADA Guidelines. With the revision, certain training requirements and uses of terminology are now inconsistent with the Guidelines, now entitled *Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students*.

Consequently, the Board has: 1) amended the use of the term *conscious/moderate* sedation throughout the chapter to refer to *moderate* sedation; 2) changed the name of the Guidelines consistent with the 2016 title; and 3) eliminated the training for dentist to administer moderate

sedation by the enteral method only, as the Guidelines no longer make a distinction for enteral administration and specify the same training for all who administer moderate sedation.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

ADA = American Dental Association

Statement of final agency action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On March 9, 2018, the Board of Dentistry adopted final amendments to 18VAC60-21-10 et seq., Regulations Governing the Practice of Dentistry and 18VAC60-25-10 et seq., Regulations Governing the Practice of Dental Hygiene.

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and (2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which 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 (§ 2.2-4000 et seq.) that 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.).

The statutory authority for the Board to promulgate regulations to determine required equipment standards for safe administration and monitoring of sedation and anesthesia is found in Chapter 27 of Title 54.1:

§ 54.1-2709.5. Permits for sedation and anesthesia required.

A. Except as provided in subsection C, the Board shall require any dentist who provides or administers sedation or anesthesia in a dental office to obtain either a conscious/moderate sedation permit or a deep sedation/general anesthesia permit issued by the Board. The Board shall establish by regulation reasonable education, training, and equipment standards for safe administration and monitoring of sedation and anesthesia to patients in a dental office.

B. A permit for conscious/moderate sedation shall not be required if a permit has been issued for the administration of deep sedation/general anesthesia.

C. This section shall not apply to:

1. An oral and maxillofacial surgeon who maintains membership in the American Association of Oral and Maxillofacial Surgeons (AAOMS) and who provides the Board with reports which result from the periodic office examinations required by AAOMS; or

2. Any dentist who administers or prescribes medication or administers nitrous oxide/oxygen or a combination of a medication and nitrous oxide/oxygen for the purpose of inducing anxiolysis or minimal sedation consistent with the Board's regulations.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

As stated in the ADA Guidelines, “because sedation and general anesthesia are a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to diagnose and manage the physiologic consequences (rescue) for patients whose level of sedation becomes deeper than initially intended.” Therefore, the Guidelines no longer specify a lesser amount of training for dentists who only intend to administer by the enteral route. The Guidelines now specify training in moderate sedation adequate to prepare a dentist for an unintended loss of consciousness or greater alteration of the state of consciousness than is the intent of the dentist. Accordingly, regulations of the Board of Dentistry are amended to ensure the same level of training and experience as specified in the ADA Guidelines that are necessary to protect the health and safety of patients in the Commonwealth.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

For consistency with the revised *Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students* (October 2016), the Board has: 1) amended the use of the term *conscious/moderate* sedation throughout the chapters to refer to *moderate* sedation; 2) changed

the name of the Guidelines consistent with the 2016 title; and 3) eliminated the training for dentist to administer moderate sedation by the enteral method only, as the Guidelines no longer make a distinction for enteral administration and specify the same training for all who administer moderate sedation.

Issues

Please identify the issues associated with the proposed regulatory action, including: 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 indicate.

- 1) The primary advantage to the public is the greater protection for the citizens of the Commonwealth who receive moderate sedation in dental offices. Adequate training for dentists who administer or supervise administration of moderate sedation is essential for health and safety of patients. There are no disadvantages.
- 2) There are no advantages or disadvantages to the agency or the Commonwealth.
- 3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under 54.1-2400 “*To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system...*” As stated in the Purpose section, general dentists who are administering moderate sedation must be adequately trained in all aspects of patient evaluation, drug dosing, administration and monitoring must be thoroughly knowledgeable about sedation drugs, techniques, equipment and emergency management in order to protect patients who are receiving sedation in a dental office. Therefore, the proposed amendments are a foreseeable result of the statute requiring the Board to protect the safety and health of patients in the Commonwealth. Any restraint on competition that results from this regulation is in accord with the General Assembly’s policy as articulated in § 54.1-100 and is necessary for the preservation of the health, safety, and welfare of the public.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent 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.

There is no impact on the family.

Changes made since the proposed stage

*Please list all changes that made to the text since the proposed regulation was published in the Virginia Register of Regulations and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

There have been no changes made since the proposed regulation was published.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

Commenter	Comment	Agency response
Va. Association of Nurse Anesthetists	Commented that the delegation of administration to an anesthesiologist in section 18VAC60-21-291 exceeds the statutory authority for delegation. Requested that the Board eliminate the term “medical direction” in section 291.	The Board will consider the comment in its regulatory action in which all requirements for sedation and anesthesia are being reviewed. This comment is not directly related to the conformity of moderate sedation permits to the ADA guidelines. Same response as above.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation.

Throughout the chapters, the term “conscious/moderate sedation” is amended to “moderate sedation” for consistency with terminology used in the October 2016 version of the ADA Guidelines. The term “conscious/moderate sedation” is deleted in the definition section with the same definition now applied to the definition of “moderate sedation.”

Additionally, the title of the ADA Guidelines is amended from *Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry* to *Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students*.

The only other change is:

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
290	Sets out the types of moderate sedation permits and the training required for each.	<p>Subsection C is amended to eliminate the permit allowed for enteral administration only. The reference to a temporary permit is also eliminated because it is no longer applicable.</p> <p>Subsection D is amended to:</p> <ol style="list-style-type: none"> 1) Revise the name of the ADA Guidelines for consistency with the current name; and 2) Eliminate option to obtain an “enteral administration only” permit that only requires 18 hours of didactic instruction. <p><i>Currently, regulations specify that the course content for enteral administration only “shall be consistent with the ADA’s Guidelines...” The 2016 ADA Guidelines are consistent with the current requirements for moderate sedation administration by any method. They no longer allow for reduced course content for enteral administration but specify didactic instruction and clinical training for moderate sedation by any method. Therefore, it is impossible for any enteral-only course to be consistent with ADA Guidelines, and regulations of the Board are amended accordingly.</i></p>