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Proposed 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	9/15/17

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 (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person'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. A more detailed discussion is provided in the “Detail of changes” section below.

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.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the Board of Dentistry is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the

agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so by mail, email or fax to Elaine Yeatts at elaine.yeatts@dhp.virginia.gov or at 9960 Mayland Drive, Henrico, VA 23233 or by fax at (804) 527-4434.. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: <http://www.townhall.virginia.gov>. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (<http://www.townhall.virginia.gov>) and on the Commonwealth Calendar website (<https://www.virginia.gov/connect/commonwealth-calendar>). Both oral and written comments may be submitted at that time.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

<p>Projected cost to the state to implement and enforce the proposed regulation, including: a) fund source / fund detail; and b) a delineation of one-time versus on-going expenditures</p>	<p>a) 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; b) The agency will incur no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Since most mailings to the PPG list are handled electronically, there is very little cost involved. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There are no on-going costs.</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>There are no costs to localities.</p>
<p>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</p>	<p>Dentists who want to obtain a permit for moderate sedation; if a dentist utilizes a practitioner who has administration of anesthesia/sedation in his scope of practice (anesthesiologist or CRNA), a permit is not required.</p>
<p>Agency’s best estimate of the number of such entities that will be affected. Please include an</p>	<p>There are 224 dentists who currently have a permit for moderate/conscious sedation; all will be</p>

<p>estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>allowed to maintain and continue to renew their permits. It is unknown how many dentists, if any, who want to obtain a sedation permit may be affected by elimination of reduced training for enteral administration only.</p>
<p>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	<p>Costs for a dentist who only intends to administer moderate sedation by an enteral method will increase as the hour of didactic training increases from 18 to 60 hours, which is currently the requirement for administration by any method. A weekend course that reportedly prepares a dentist for the enteral method would cost approximately \$2,800 plus travel and lodging expenses. Courses preparing a dentist for administration of moderate sedation are typically offered by CODA-accredited educational programs and could also be counted as continuing education for renewal of licensure. Those courses would vary in length and costs.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>Will ensure a training standard that is recognized nationally as necessary for patient safety in dental offices in which moderate sedation is being administered by the dentist.</p>

Alternatives

Please describe any viable 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. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

The Board has not considered other alternatives because it has specifically followed the 2016 ADA Guidelines.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

There are no alternative regulatory methods consistent with health and safety of patients receiving sedation in a dental office.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
Jonathan Wong	Dr. Wong provided extensive comment on the guidelines for administration and monitoring of moderate sedation.	The Board is convening a committee to review sedation and anesthesia requirements in its regulation; Dr. Wong’s comment will be provided to that group. His comments were not directed to the ADA guidelines for education and training of dentists to provide moderate sedation.

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.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

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	Current requirement	Proposed change, intent, rationale, and likely
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section number		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>