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Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Board of Dentistry, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC60-21
Regulation title(s)	Regulations Governing the Practice of Dentistry
Action title	Rules for sedation and anesthesia
Date this document prepared	5/14/18

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.*

Subject matter and intent

Please describe briefly the subject matter, intent, and goals of the planned regulatory action.

The Board's intent is to amend regulations relating to administration of sedation or anesthesia in dental offices. The goals are greater consistency and clarity among the requirements, depending on the level of sedation and the risk to the patient, and closer alignment with the American Dental Association Guidelines for the Use of Sedation and General Anesthesia. The Board intends to amend provisions that are problematic to dentists, such as compliance with current regulations with special needs patients. When appropriate for patient safety, the Board intends to incorporate guidelines and best practices for sedation and anesthesia, such as the use of a three-person team in the operatory during administration of moderate sedation.

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:*
>
> *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.*
>
> *...*
> *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. ...*

Specific statutory reference to issuance of sedation and anesthesia permits and requirements for equipment standards in:

§ 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 describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, please explain any potential issues that may need to be addressed as the regulation is developed.

The Regulatory Advisory Panel of experts and the members of the Board heard comment on the current regulations for administration of sedation and anesthesia and reviewed current guidelines published by the American Dental Association. Accordingly, amendments are recommended to allow for exception to rules if there are extenuating circumstances in providing care to certain patients. Amendments are also recommended to address concerns about patient safety, such as a requirement for a dentist to follow the regulations for the level of sedation that has been induced and a requirement for there to be a three-person team in the administration of moderate sedation during a dental procedure.

Administration of sedation and anesthesia in a dental office requires appropriate expertise, equipment and monitoring in order to adequately and immediately address any adverse reaction or emergency situation. Rules proposed by the Board specify what is required to protect public health and safety in such administration.

Substance

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

The substantive provisions being considered include:

- Clarification of supervision of certified registered nurse anesthetists
- Clarification that the regulations address administration to patients of any age, but that the specific guidelines for pediatric patients should be consulted when practicing pediatric dentistry.
- Requirement for a focused physician examination to be included in the patient evaluation for administration of controlled substances.
- Allowances for special needs patients in the evaluation for, administration, and monitoring of sedation and anesthesia with documentation in the patient record of the extenuating circumstances when necessitate exceptions to regulatory requirements.

- Clarification of the requirements for minimal sedation and inclusion of oxygen saturation with pulse oximeter as required equipment.
- Specific requirement that the dentist must follow requirements for the level of sedation that has been induced and that administration of one drug in excess of recommended dosage or of two or more drugs, exceeds minimal sedation.
- Clarification that no sedating medication can be administered to a child 12 years or younger prior to arrival at the dental office.
- Clarification of use of the terms continuously and continually, as used in the context of the regulation.
- Permitting consideration of extenuating patient circumstances in the monitoring and discharge requirements
- Adding oxygen saturation levels to the monitoring requirements.
- Requirement for a three-person team for moderate sedation – the operating dentist, one person to monitor the patient, and one person to assist the dentist.
- Clarification that requirements for moderate sedation or deep/general anesthesia must be followed by the dentist if he administers controlled substances or if he provides it in his office with someone else doing the administration.
- Requirement for a longer period of monitoring if a pharmacological reversal agent has been administered.

A draft of the recommendations from the Regulatory Advisory Panel is posted on Townhall.

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.

In the promulgation of regulations relating to revision of American Dental Association (ADA) guidelines for the education and training of dentists who administer moderate sedation, there were comments on the NOIRA and on proposed regulations that more broadly addressed the need to revise requirements for sedation and anesthesia. Commenters noted the need for changes relating to delegation to a certified registered nurse anesthetist and the need for consistency and clarification in the levels of sedation and anesthesia. The Board responded that comments were not specific to the subject of that regulatory action, but that they would be considered in the context of an overall review of regulations for sedation and anesthesia.

To conduct such a review, the Board convened a Regulatory Advisory Panel (RAP), consisting of two board members, the Dean of the VCU School of Dentistry and Chair of the ADA committee that reviewed Guidelines for the Use of Sedation and General Anesthesia by Dentists, a pediatric dentist, and an oral and maxillofacial surgeon. The RAP held an open forum for public comment and then met on December 1, 2017 to review all comments and the ADA guidelines for regulation.

A second meeting of the RAP was held on February 2, 2018 to review draft amendments and approve recommendations to the Regulatory-Legislative Committee of the Board. At the March 8th meeting of the Committee, the proposed changes were reviewed and a motion to issue a NOIRA was forwarded to the Board for its adoption on March 9, 2018. The proposed changes address issues identified by public comment and reflect consistency with the 2016 ADA Guidelines. The Board believes they are the least restrictive requirements consistent with the safe administration of sedation and anesthesia in a dental office.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action 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.