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Fast-Track Regulation
Agency Background Document

Agency name	Board of Dentistry, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC60-21-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Dentistry
Action title	Administration of nitrous oxide
Date this document prepared	6/30/16

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

In response to requests from dentists who only administer nitrous oxide, the Board has amended its regulations to differentiate between minimal sedation, which is defined as inhalation analgesia when used in combination with any anxiolytic agent administered prior to or during a procedure, and administration of only nitrous oxide. The amended regulations eliminate some of the burdensome requirements for dentists who only administer nitrous oxide.

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 June 10, 2016, the Board of Dentistry adopted amendments to 18VAC60-21-10 et seq., Regulations Governing the Practice of Dentistry.

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, which shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services. 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.).

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.

The purpose of the amended regulation is eliminate some requirements that are not necessary for patient safety with the administration of only nitrous oxide but to retain those that are essential to protect patients, especially pediatric patients. For example, dentists report that they have had to stop procedures on children because current rules require continuous monitoring of vital signs, and the child refused to keep a blood pressure cuff on his arm. The intent is to maintain the recommended procedural, equipment, and monitoring requirements for inhalation analgesia but eliminate requirements that are not necessary for that level of sedation and represent a deterrent to provision of dental services in some situations.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

The proposed amendments represent a reduction in the regulatory burden and have been requested by the regulated dental community. They need to be expedited to allow dentists to continue providing nitrous in their practices without incurring some of the current requirements associated with minimal sedation. There should not be any controversy since they are less costly and burdensome.

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.

A new section is being promulgated for the administration of only inhalation analgesia (nitrous oxide) and minimal sedation is redefined as inhalation analgesia when used in combination with any anxiolytic agent administered prior to or during a procedure. Requirements for administration of only inhalation analgesia differ from those for minimal sedation as follows:

1) The dentist does not have to have education and training in the medications used, including dosages, complications, and interventions.
2) A dental hygienist can be delegated administration of nitrous under indirect supervision.
3) No pulse oximeter is required for continuous monitoring.
4) Baseline vital signs do not need to include respiratory rate and may be omitted if there are extenuating circumstances documented in the patient record (such as a child who refuses to keep a blood pressure cuff on his arm).
5) Continual clinical observation is required but not continuous monitoring of vital signs.

In addition, the general provisions for administration of sedation or anesthesia are amended to specify that the "current conditions" of a patient includes his weight and height, and, if appropriate the Body Mass Index (BMI).

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 advantage to the public is less burdensome regulations will facilitate the use of nitrous oxide for all patients, especially pediatric patients for whom some of the current requirements are burdensome and unnecessary. 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 (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system.*" There is no restraint on competition as a result of promulgating this regulation.

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.

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 is no alternative to the adoption of amendments if the goal is to reduce the burden of current regulations for minimal sedation.

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.

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**	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 or entities for necessary functions of regulation. All notifications will be done electronically. There are no on-going expenditures.
Projected cost of the new regulations or changes to existing regulations on localities.	None
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Dentists and dental hygienists are potentially affected.
Agency's best estimate of the number of such entities that will be affected. Please include an 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.	There are 7292 dentists and 5722 dental hygienists with current licenses. The majority of dental practices would be considered small businesses. Since dentists are not required to hold permits to administer minimal sedation, it is unknown how many entities would be positively affected.
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.**	There would be a modest reduction in costs for those dentists who only administer nitrous oxide.
Beneficial impact the regulation is designed to produce.	The beneficial impact may be an increase in the number of dentists who will be able to offer inhalation analgesia for their patients, especially for pediatric patients who often require nitrous for dental procedures.

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.

At its meeting on March 11, 2016, the Board heard testimony from pediatric dentists that some of the current requirements for minimal sedation significantly increase the cost of treatment and exceed the guidelines of the American Academy of Pediatric Dentistry. In response, the Board Chair appointed an Ad Hoc Committee to recommend changes to regulations for administration of nitrous oxide only.

The Nitrous Oxide/Minimal Sedation Ad Hoc Committee consisted of two dentists who are members of the Board, the Chair of the Pediatric Department at the VCU School of Dentistry, the Dean of the School (who is also the Anesthesia Committee Chair of the ADA Council on Dental Education and Licensure), and the Professor for oral and maxillofacial surgery at VCU. Using the expertise of the committee members, amendments were recommended to separate nitrous oxide inhalation analgesia into a new section of regulation with less restrictive rules for monitoring patients.

Public participation notice

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

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 institution of the family and family stability.

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.

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
10	Sets out definitions for terms and words used in regulation	In subsection D, a definition is added for "analgesia" and "inhalation analgesia." The definition of "minimal sedation" is amended consistent with the revised use of the term as inhalation analgesia when in combination with any anxiolytic agent. *Definitions are consisted with ADA guidelines for anesthesia and sedation.*
260	Sets out the general provisions for sedation and anesthesia	Subsection D is amended to clarify that information in the patient record should include the patient's height and weight, and, if appropriate, the Body Mass Index. *The BMI is informative for the administration and monitoring of sedating medications but may not be appropriate for some patients whose weight would indicate obesity when the patient is obviously not obese.*
280	Sets out requirements for the administration of minimal sedation	This section is amended to exclude references to inhalation analgesia or the administration of only nitrous oxide. Subsection C is amended to correct the section of Chapter 25 cited. It is also amended to specify that the administration by a dental hygienist of nitrous while a patient is minimally sedated must occur while the dentist is in the operatory. If the nitrous is the only medication involved, the qualified hygienist can administer under indirect supervision. Subsection F is amended to clarify that monitoring of vital signs must occur continuously during the procedure (the current language is "intraoperatively").
New section number – 279	Sets our requirements for the administration of only inhalation analgesia (nitrous oxide)	Currently administration of only nitrous oxide is included in the section on minimal sedation (Section 280). To eliminate unnecessary and sometimes burdensome requirements, a new section is being promulgated for administration of nitrous oxide. Subsection A on education and training is identical to subsection A in 280, except training in medications is omitted.

		Subsection B is identical to the current rule. Subsection C on delegation of administration differs from section 280 in that a qualified dental hygienist is allowed to administer nitrous under indirect supervision (when the dentist is not in the operatory). Subsection D on equipment requirements differs from 280 in the elimination of a pulse oximeter. Subsection E on required staffing does not require a second person in the operatory. Subsection F on monitoring requirements differs from section 280 in that continual clinical observation of the patient's responsiveness, color, and respiratory rate and depth of ventilation is required but not monitoring of vital signs continuously during the procedure. Subsection G on discharge requirements is identical to the current language in section 280.