townhall.virginia.gov

Fast-Track Regulation
Agency Background Document

Agency name	Board of Dentistry, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC60-20-10 et seq.
Regulation title(s)	Regulations Governing Dental Practice
Action title	Requirement for capnograph/end tidal CO2 monitor
Date this document prepared	7/27/15

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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

Amendments will require that a dentist who administers conscious/moderate sedation or deep sedation/general anesthesia maintain a capnograph/end tidal CO2 monitor in working order and immediately available to areas where patients will be sedated and recover from 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.

AAOMS = American Association of Oral and Maxillofacial Surgeons
ASA = American Society of Anesthesiologists

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 12, 2015, the Board of Dentistry amended 18VAC60-20-10 et seq., Regulations Governing Dental Practice.

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 (§ 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. ...

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.

The purpose of the amendments is to include the use of capnography as a requirement for dentists who administer moderate sedation, deep sedation or general anesthesia in their offices.

Capnography is the monitoring of the concentration or partial pressure of carbon dioxide (CO_2) in the respiratory gases. According to source references used by Wikipedia, "Capnography has been shown to be more effective than clinical judgement alone in the early detection of adverse respiratory events such as hypoventilation, oesophageal intubation and circuit disconnection; thus allowing patient injury to be prevented. During procedures done under sedation, capnography provides more useful information, e.g. on the frequency and regularity of ventilation, than pulse oximetry. Capnography provides a rapid and reliable method to detect life-threatening conditions (malposition of tracheal tubes, unsuspected ventilatory failure, circulatory failure and defective breathing circuits) and to circumvent potentially irreversible patient injury. Capnography and pulse oximetry together could have helped in the prevention of 93% of avoidable anesthesia mishaps according to an ASA (American Society of Anesthesiologists) closed claim study."

Since such equipment is the national standard for monitoring patients, it should be incorporated into Virginia regulation to ensure that the health and safety of dental patients is adequately protected.

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 American Association of Oral and Maxillofacial Surgeons has set the standard for the use of capnography for patients under moderate sedation, effective January 2014. It was previously set as the standard for deep sedation, and general anesthesia. Likewise, the American Society of Anesthesiologists "Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners who are not Anesthesia Professionals" states the monitoring of physiologic variable should include the use of capnography. Therefore, the Board does not believe this proposal will

be controversial and should be fast-tracked to ensure that all patients in the Commonwealth are equally protected, regardless of whether the sedation/anesthesia is provided by an oral and maxillofacial surgeon or a dentist with a sedation or anesthesia permit.

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.

Currently, subsection F section 110 requires a capnograph/end tidal CO2 monitor as equipment for use for intubated patients; the amendment would require it for all patients receiving deep sedation or general anesthesia. Section 120 sets out the requirements for administration of conscious/moderate sedation; subsection I would be amended to include a capnograph/end tidal CO2 monitor as required equipment.

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, deep sedation or general anesthesia in dental offices. The use of capnography coupled with pulse oximetry can prevent anesthesia/sedation problems that may be avoidable if a patient is adequately monitored. There are no disadvantages.
2) There are no advantages or disadvantages to the agency or the Commonwealth.
3) There are no other pertinent matters of interest.

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 are no alternative methods for accomplishing the purpose of this action. The equipment standards for the use of sedation or anesthesia in dental offices are set in regulation; adoption of guidelines or guidance documents would not protect the public as they are not enforceable standards.

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**	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 expenditures.
Projected cost of the new regulations or changes to existing regulations on localities.	There are no costs for localities.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Dentists who hold a permit for sedation or anesthesia issued by the Board and oral/maxillofacial surgeons with certification who are not required to hold such permits.

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 51 dentists who have a permit for deep sedation/general anesthesia; 194 have a permit for moderate/conscious sedation. Of the 258 oral/maxillofacial surgeons, the majority would hold membership in the American Association of Oral and Maxillofacial Surgeons with periodic inspections by AAOMS, and therefore, are not required to obtain an anesthesia/sedation permit from the Board.
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.**	If a dentist who uses moderate or deep sedation or general anesthesia does not currently have a capnograph, there will be a cost for compliance. Prices range from approximately $2,200 to $4,500, depending on the technology and functionality of the equipment. Equipment with multi-functionality is more costly but may also serve the monitoring functions of other equipment.
Beneficial impact the regulation is designed to produce.	Will ensure a monitoring standard that is recognized nationally as necessary for patient safety in dental offices and other settings in which sedation or anesthesia is being administered.

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.

There are no alternatives to the proposal; this is the least burdensome alternative that meets the essential purpose of safety in sedation and anesthesia.

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.

This action has 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. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the **pre**-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
110	Sets out the requirements for administration of deep sedation/general anesthesia	Subsection F is amended to include a capnograph/end tidal CO2 monitor as required equipment for all patients receiving deep sedation or general anesthesia in dental offices. Currently, it is only required for intubated patients. *As noted above, the AAOMS and the ASA both include capnography as a standard for monitoring patients who have moderate sedation, deep sedation or general anesthesia administered in any settings. Use of capnography and pulse oximetry would avoid most of the anesthesia-related events that may result in patient harm and transports to emergency rooms.* *Some dentists may have to obtain a capnograph/end tidal CO2 monitor at a cost of $2,200 to $4,500, but patients will be better protected and less likely to suffer an anesthesia/sedation event.*
120	Sets out the requirements for administration of conscious/moderation sedation	Subsection I is amended to include a capnograph/end tidal CO2 monitor as required equipment for all patients receiving moderate sedation. *Same rationale as above.*