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Final Regulation
Agency Background Document

Agency name	Board of Dentistry, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC60-21-10
Regulation title(s)	Regulations Governing the Practice of Dentistry
Action title	Requirement for capnography
Date this document prepared	12/19/16

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 of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 during a dental procedure and further that the patient's end-tidal carbon dioxide be monitored during administration of moderate sedation or deep sedation/general anesthesia.

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 December 9, 2016, the Board of Dentistry amended 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 (§ 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.

Substance

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

Section 291 sets out the requirements for administration of conscious/moderate sedation; subsection B would be amended to include a capnograph/end tidal CO_2 monitor as required equipment and to require the dentist to monitor end-tidal carbon dioxide during administration. Currently, subsection C section 301 requires a capnograph/end tidal CO_2 monitor as equipment for use for intubated patients; the amendment would require it for all patients receiving deep

sedation or general anesthesia and to require the dentist to monitor end-tidal carbon dioxide during administration.

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) 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, 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.
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 of the proposed regulation 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.*

Section number	Requirement at proposed stage	What has changed	Rationale for change
291	The patient's blood pressure, oxygen saturation, and pulse are required to be monitored.	Addition of end-tidal carbon dioxide to the requirement for monitoring	By adding an end-tidal carbon dioxide monitor to required equipment, it is presumed that it is required to be used to monitor the patient during administration of moderate sedation. The change is a clarification of that intent.
301	The patient's vital signs and EKG readings are required to be monitored.	Addition of end-tidal carbon dioxide to the requirement for monitoring	By adding an end-tidal carbon dioxide monitor to required equipment, it is presumed that it is required to be used to monitor the patient during administration of deep sedation or general anesthesia. The change is a clarification of that intent.

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
Dr. Jonathan Wong	Strongly supports use of end Tidal CO2 monitoring or capnography. Recommends requiring use of end tidal CO2 monitoring, not just requiring the presence of the equipment.	The Board concurred with the comment and clarified the monitoring requirements accordingly.

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

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
291	Sets out the requirements for administration of conscious/moderation sedation	Subsection B is amended to include a capnograph/end tidal CO2 monitor as required equipment for all patients receiving moderate sedation. *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.* **Subsection D is amended to clarify that the patient's end-tidal carbon dioxide is to be monitored during administration of sedation.**
301	Sets out the requirements for administration of deep sedation/general anesthesia	Subsection C 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. *See rationale as stated above.* **Subsection E is amended to clarify that the patient's end-tidal carbon dioxide is to be monitored during administration of sedation. The phrase "and recovery" was deleted in subdivision 2 because**

		monitoring in recovery is specified in subdivision 3.