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## Proposed Regulation Agency Background Document

<b>Agency name</b>	Board of Dentistry, Department of Health Professions
<b>Virginia Administrative Code (VAC) citation(s)</b>	18VAC60-21-10
<b>Regulation title(s)</b>	Regulations Governing the Practice of Dentistry
<b>Action title</b>	Requirement for capnography
<b>Date this document prepared</b>	3/11/16

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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

Amendments will require that a dentist who administers conscious/moderate sedation or deep sedation/general anesthesia maintain a capnograph/end tidal CO<sub>2</sub> 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*

## 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.*

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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<sub>2</sub>) 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. A more detailed discussion is provided in the “Detail of changes” section below.*

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Section 291 sets out the requirements for administration of conscious/moderate sedation; subsection B would be amended to include a capnograph/end tidal CO<sub>2</sub> monitor as required equipment.

Currently, subsection C section 301 requires a capnograph/end tidal CO<sub>2</sub> monitor as equipment for use for intubated patients; the amendment would require it for all patients receiving deep sedation or general anesthesia.

## Issues

*Please identify the issues associated with the proposed regulatory action.*

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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.*

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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.*

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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.*

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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](mailto: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><b>Projected cost to the state to implement and enforce the proposed regulation, including:</b>  <b>a) fund source / fund detail; and</b>  <b>b) a delineation of one-time versus on-going expenditures</b></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 expenditures.</p>
<p><b>Projected cost of the new regulations or changes to existing regulations on localities.</b></p>	<p>There are no costs for localities.</p>
<p><b>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</b></p>	<p>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.</p>
<p><b>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.</b> 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>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.</p>
<p><b>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:</b>  <b>a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and</b>  <b>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.</b></p>	<p>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.</p>

<p><b>Beneficial impact the regulation is designed to produce.</b></p>	<p>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.</p>
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### 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.

### 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 public health and safety.

### Public comment

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

There was a public comment period on the NOIRA from November 30, 2015 to December 30, 2015. No comment was received

### 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 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.*

<b>Current section number</b>	<b>Current requirement</b>	<b>Proposed change, intent, rationale, and likely impact of proposed requirements</b>
291	Sets out the requirements for administration of conscious/moderation sedation	<p>Subsection B is amended to include a capnograph/end tidal CO2 monitor as required equipment for all patients receiving moderate sedation.</p> <p><i>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.</i></p> <p><i>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.</i></p>
301	Sets out the requirements for administration of deep sedation/general anesthesia	<p>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.</p> <p><i>See rationale as stated above.</i></p>