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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)	18VAC60-20-10 et seq.
Regulation title(s)	Regulations Governing Dental Practice
Action title	Requirement for capnograph/end tidal CO2 monitor
Date this document prepared	8/18/2015

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.

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.

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:
...
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 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 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 that are being considered, the substantive changes to existing sections that are being considered, or both.

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.

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

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.