Virginia Regulatory Town Hall

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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Dentistry, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC60-20-10 et seq.
Regulation title	Regulations Governing Dental Practice
Action title	Permits for Administration of Conscious/Moderate Sedation or Deep Sedation/General Anesthesia
Date this document prepared	9/12/11

Preamble

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006.

1) Please explain why this is an emergency situation as described above.
2) Summarize the key provisions of the new regulation or substantive changes to an existing regulation.

Chapter 526 (Senate Bill 1146) of the 2011 Acts of the Assembly requires the Board of Dentistry to revise its regulations to provide for permits for dentists who provide or administer conscious/moderate sedation or deep sedation/general anesthesia in a dental office. The legislation, which was introduced at the request of the Board and the Department, further requires that the Board promulgate regulations to implement the provisions of the act to be effective within 280 days of its enactment. Therefore, there is an "emergency situation" as defined in § 2.2-4011 of the Administrative Process Act. **The statutory deadline for regulations to be in effect is December 30, 2011.**

The key provisions of the regulations are: 1) establishment of definitions for words and terms used in sedation and anesthesia regulations; 2) general provisions for administration, including record keeping and requirements for emergency management; 3) requirements for deep

sedation/general anesthesia permits including training, delegation of administration emergency equipment, monitoring and discharge of patients; and 4) requirements for conscious/moderate sedation permits including training, delegation of administration emergency equipment, monitoring and discharge of patients.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary. Please include a citation to the emergency language.

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:

…

5. To levy and collect fees for application processing, examination, registration, certification or licensure and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory Boards.

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 specific mandate to promulgate regulations for sedation and anesthesia permits is found in:

§ 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.

(2011, c. 526.)

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The intent of the regulatory action in the adoption of emergency regulations is compliance with the statutory mandate of Chapter 526 of the 2011 Acts of the Assembly to "*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"* and to "*establish by regulation reasonable education, training, and equipment standards for safe administration and monitoring of sedation and anesthesia to patients in a dental office*."

Dentists who meet current qualifications of education and training will be qualified for permits under the emergency regulations. The intent is to have some accountability for such qualifications to ensure that patients are being treated by dentists who are appropriately trained and experienced in sedation or anesthesia. Dentists who were "self-certified" (no formal education or training required) prior to January 1989 will be allowed to hold a temporary permit for two years to allow adequate time to obtain the appropriate qualifications for administration of conscious/moderate sedation.

Additionally, regulatory provisions relating to sedation and anesthesia previously adopted by the Board during the periodic review of Chapter 20 are included in this action to set standards for safe administration and monitoring of sedation and anesthesia in a dental office. Those standards include essential emergency equipment, recordkeeping, emergency management, monitoring and sedation of pediatric patients. The goal of the amended regulation is to allow persons currently qualified to administer sedation and anesthesia in dental offices to continue to do so, provided they administer or delegate administration in a safe environment with appropriate personnel and equipment to monitor and to handle emergency situations. Once dentists have obtained sedation or anesthesia permits, the Board will be able to periodically inspect dental offices to ensure there are qualified personnel and essential equipment and practices in place as necessary for patient health and safety.

Need

Please detail 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, delineate any potential issues that may need to be addressed as the regulation is developed.

To protect the health and safety of patients who receive conscious/moderate sedation or deep sedation/general anesthesia, the Board of Dentistry and the Department of Health Professions sought legislative action in the 2011 General Assembly to authorize the issuance of permits for provision or administration of sedation or anesthesia in dental offices.

In recent years, the use of sedation and anesthesia in dental practices has increased significantly and the offer of "sedation dentistry" is frequently used in advertising to attract patients. Sedation and anesthesia are provided by dentists to reduce patient anxiety about undergoing dental treatment and to eliminate pain during the procedure. The use of such controlled substances brings with it the risks of adverse reactions and even death. Current regulations require dentists to have appropriate training, trained auxiliary personnel and patient monitoring equipment in order to administer sedation and anesthesia. Dentists are also required to report adverse patient reactions to such administration. Based on the current legal authority of the Board of Dentistry, compliance with these requirements to ensure patient safety is only checked by the Board after a complaint or an adverse reaction report is received.

Authorizing the Board to require dentists in the Commonwealth to obtain a permit to administer conscious/moderate sedation and deep sedation/general anesthesia in a dental practice will advance patient safety by enabling proactive oversight by the Board through periodic inspections. The permits will enable the Board to implement a periodic inspection program of the practices where sedation and anesthesia are administered to verify that:

- the treating dentist has the necessary education and training to safely administer controlled substances and to perform life saving interventions when adverse reactions occur,
- required patient monitoring and safety equipment is present, is maintained in working order, and that personnel are properly trained in its use, and
- auxiliary personnel have the required training and are assigned duties within the parameters established in the regulations.

Based on data collected by the American Association of Dental Boards (AADB) and reported in the 2010 edition of the AADB Composite, Virginia is currently one of only four states that do not require dentists to obtain permits to administer conscious/moderate sedation and deep sedation/general anesthesia in a dental practice. The Board has determined that the emergency regulations as drafted are necessary to accord patients in Virginia the level of protection provided by the vast majority of other states.

Substance

Please detail any changes that will be proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate.

Current section number	Current requirement	Proposed change and rationale
10	Establishes definitions for words and terms used in	Definitions are added or revised for words and terms used in regulations for sedation and anesthesia.

	regulations	Definitions for "Conscious/moderate sedation," "Deep sedation," General anesthesia" and "Minimal sedation" are taken from the *Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students (2007)* of the American Dental Association. The definition of "immediate supervision" is intended to ensure that the dentist is present in the operatory to supervise the administration of sedation or provision of treatment. The definition of "monitoring" is intended to fully describe the functions appropriate to the task in order to clarify that more than observation is required when monitoring a patient.
30	Sets out fees for issuance and renewal of a sedation or anesthesia permit.	Subsection J is amended to clarify that the $350 charge for an inspection of a dental office will not apply to a routine inspection of an office in which the dentist has a sedation or anesthesia permit. The fee set out in subsection J is intended for a board-ordered inspection. Renewal fees are set to be adequate to cover the cost of a routine inspection, which would be scheduled approximately every five years. Subsections K and L establish new fees as necessary for approval of a permit application and annual renewal of the permit. The initial and renewal fees are set at $100, which will minimally cover expenditures relating to review and approval of an application and a periodic routine inspection of a dental office. The renewal date is set as March 31st for consistency with renewal of a dental license.
107	Establishes general rules for application to administration of all types of sedation and anesthesia, with the exception of local anesthesia and administration in a hospital or federal facility.	Changes in section 107 are primarily intended to clarify and further specify the information relating to administration of sedation or anesthesia that should be included in a patient record. Subsection B is amended to clarify that the dentist must <u>document</u> that he has had a consultation with a medical doctor prior to administration of general anesthesia or any type of sedation to a patient in risk category Class III. Without documentation in the record, there is no assurance that consultation took place. The complete required content of the patient record is set forth in subsection E and includes all information necessary to assure that the patient has been appropriately assessed, administered and monitored. The Board used curriculum included in *Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students (2007)* to determine elements of a patient record. Some guidelines for monitoring and management specify that vital signs and physiological measures must be recorded at regular intervals. Others, such as, *Guidelines for Monitoring and Management of Pediatric Patients During*

		and After Sedation for Diagnostic and Therapeutic Procedures (2006)," specify that monitoring records should be recorded every five minutes. The Board adopted the specific standard as consistent with patient safety. Subsection F specifies that no sedating medication can be prescribed or administered to a child aged 12 and under prior to arrival at the dental office due to the risk of unobserved respiratory obstruction during transport by untrained individuals. The standard is found in the 2007 ADA Guidelines and in the 2006 pediatric guideline. Subsection G specifies that: 1. *If a patient enters a deeper level of sedation than the dentist is qualified and prepared to provide, the dentist shall stop the dental procedure until the patient returns to and is stable at the intended level of sedation*. The standard is quoted from the 2007 ADA Guidelines. 2. *A dentist in whose office sedation or anesthesia is administered shall have written basic emergency procedures established and staff trained to carry out such procedures*. ADA Guidelines and recommendations of other bodies such as the American Society of Anesthesiologists specify that the dentist must have written procedures in place to handle emergencies and staff regularly trained on such procedures.
110	Sets out the requirements for a permit to administer deep sedation/general anesthesia	Subsection A establishes the requirement for a permit within 3 months of the anticipated effective date of the regulations (deadline is 12/30/11). Since there are no new qualifications for a dentist who is currently qualified to administer, the Board established a deadline of March 31, 2012 for obtaining the necessary permit as required by law. The March 31st date was chosen because regulations will specify that permits must be renewed by March 31st of each year. The statutory exception to the requirement for a deep sedation/general anesthesia permit for oral and maxillofacial surgeons is also included in subsection A. Subsection B sets out the required submission to determine eligibility for a permit; there are <u>no new requirements</u>. Subsection C clarifies that the current education and training may qualify a dentist for an anesthesia permit. The requirement for current certification in ACLS or PALS is further specified to include hands-on simulated airway and megacode training, including basic electrocardiographic interpretation. Professional standards, as cited above, also specify the type of advanced resuscitative techniques that a dentist with an anesthesia permit should have. In order to provide patients with some evidence that a

		dentist is qualified to administer sedation or anesthesia, the Board currently requires posting of the certificate of education (along with the dental license and current DEA registration). Subsection D is amended to require posting of the Board-issued permit or certificate from AAOMS if an oral and maxillofacial surgeon is exempt from the permit requirement. Subsection E sets out the requirements for delegation of administration consistent with recommendations of the 2007 Guidelines and with current practice. Subsection F sets out the emergency equipment that must be available in the areas where patients will be sedated and will recover from sedation or anesthesia. All are currently required with the exception of suction apparatus, a throat pack and a precordial or pretracheal stethoscope, which are recommended for emergency management of patients. Subsection G sets out the monitoring requirements. Further specification about the essential functions of monitoring are included in #3 in accordance with the 2007 Guidelines and other standards for oral and maxillofacial surgeons and anesthesia providers. Subsection H sets out the specific requirements for discharge of a patient who has been under general anesthesia or deep sedation; the provisions are consistent with national standards followed by the Board in the adoption of regulations.
120	Sets out the requirements for a permit to administer conscious sedation	Subsection A establishes the requirement for a permit within 3 months of the anticipated effective date of the regulations (deadline is 12/30/11). Since there are no new qualifications for a dentist who is currently qualified to administer, the Board established a deadline of March 31, 2012 for obtaining the necessary permit as required by law. The March 31st date was chosen because regulations will specify that permits must be renewed by March 31st of each year. The statutory exception to the requirement for a deep sedation/general anesthesia permit for oral and maxillofacial surgeons is also included in subsection A. Subsection B states the automatic qualification of a dentist with an anesthesia permit to administer conscious/moderate sedation. Subsection C sets out the required submission to determine eligibility for a permit; there are no new requirements for a dentist who is qualified to administer conscious sedation by any method or by the enteral method only. The permit will indicate the extent of the dentist's qualification. For dentists

		who self-certified their qualification prior to January 1989 (the date on which specific qualifications were added to the regulations), a temporary permit may be issued, which will allow them two years in which to obtain the necessary education and training for a conscious/moderate sedation permit. (see subsection D, #2) Subsections D, E and F clarify that the current education and training may qualify a dentist for an sedation permit. The requirement for current certification in ACLS or PALS is further specified to include hands-on simulated airway and megacode training, including basic electrocardiographic interpretation. Professional standards, as cited above, specify the type of advanced resuscitative techniques that a dentist with a sedation permit should have. In order to provide patients with some evidence that a dentist is qualified to administer sedation or anesthesia, the Board currently requires posting of the certification of resuscitative technique training (along with the dental license and current DEA registration). Subsection G is amended to require posting of the Board-issued permit or certificate from AAOMS if an oral and maxillofacial surgeon is exempt from the permit requirement. Subsection H sets out the requirements for delegation of administration consistent with recommendations of the 2007 Guidelines and with current practice. Subsection I sets out the emergency equipment that must be available in the areas where patients will be sedated and will recover from sedation. All are currently required with the exception of a defibrillator, electrocardiographic monitor, suction apparatus, a temperature measuring device, throat pack and a precordial or pretracheal stethoscope, which are all recommended for emergency management of patients. Subsection J sets out the monitoring requirements. Further specification about the essential functions of monitoring are included in #3 in accordance with the 2007 Guidelines and other standards for oral and maxillofacial surgeons and anesthesia providers. Subsection K sets out the specific requirements for discharge of a patient who has been under sedation; the provisions are consistent with national standards followed by the Board in the adoption of regulations.
135	Establishes the requirements for ancillary personnel who assist in administration and	The amendment to the qualification clarifies that the BCLS training must be a course for health providers and must include hands-on airway training (Recommendation of the

	monitoring of patients under conscious/moderate sedation, deep sedation or general anesthesia.	American Society of Anesthesiologists and the 2007 Guidelines)

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider, other alternatives for achieving the need in the most cost-effective manner.

Since 2007, the Board has received 10 reports of patients needing emergency or follow-up care after receiving dental treatment under sedation or anesthesia. While seven of these incidents were minor in nature, three were highly publicized critical incidents involving children. The first of these incidents occurred in January of 2005 when a three year old child stopped breathing on her own. She was stabilized while being flown by helicopter to the University of Virginia Hospital where she recovered. In March of 2007, an eight year old child died during treatment and subsequent efforts to resuscitate her failed. Most recently in May of 2010, a six year old child suffered respiratory arrest immediately following treatment and he could not be resuscitated. The Board has learned that children under the age of 12 are particularly susceptible to having extreme adverse reactions to sedation and anesthesia. Through its investigation and adjudication of two of the three critical incident cases, the Board found that the treating dentists failed to properly monitor and record vital signs and pulse oximetry readings. In at least one of these cases, it was also found that excessive medication was administered, the sedatives were administered by unlicensed personnel and the parents were left alone with their unmonitored children following administration of the pre-operative medications.

In addition, the Board has received three petitions for rulemaking advocating for regulatory changes in the area of sedation and anesthesia (one in 2008 and two in 2009) and numerous public comments made at Board meetings asking the Board to update and strengthen its regulations for administration. Two of the petitions for rulemaking specifically advocate that dentists be required to prove they have the training required to administer sedation and anesthesia through a registration or permit process and further encourage periodic inspection of dental practices using sedation and anesthesia. When these petitions were considered, the Board was advised by legal counsel that legislative authority was needed before permits could be required.

The practice of other states, the critical incidents associated with sedation and anesthesia, and the public's interest in stronger policy indicate that the Board should pursue a more proactive posture in this area of dental practice. The Board asserts that requiring permits is not only warranted but necessary to facilitate oversight of the administration of sedation and anesthesia in the practice of dentistry and thereby promote patient safety and emergency preparedness.

There is no known alternative step to take to address the public interest. The Board has a **statutory mandate** to require permits and to "*establish by regulation reasonable education,*

training, and equipment standards for safe administration and monitoring of sedation and anesthesia to patients in a dental office."

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments on this notice.

The agency/board is seeking comments on the intended regulatory action to replace the emergency regulations with permanent regulations, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency/board is also 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 may send them to Elaine Yeatts at the 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 or by posting on the Regulatory Townhall at 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 the last day of the public comment period on the Notice of Intended Regulatory Action.

At the conclusion of the NOIRA comment, the Board will adopt proposed regulations to replace the emergency regulation. A public meeting will be held and notice of the meeting will be found in the Calendar of Events section of the Virginia Register of Regulations after Executive Branch review and approval to open the regulation for 60 days of public comment. Both oral and written comments may be submitted at that time.

Participatory approach

Please indicate the extent to which an ad hoc advisory group or regulatory advisory panel will be used in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

In the development of proposed regulations for sedation and anesthesia resulting from a very thorough periodic review, conducted from 2008 to 2011, the Board informally used the participatory approach by inviting affected parties to participate in meetings of the

Regulatory/Legislative Committee and by asking for comment and recommendations on language. Groups that that have been involved include the Virginia Dental Association, the Virginia Dental Hygienist Association, the Virginia Society of Oral and Maxillofacial Surgeons and the Virginia Association of Nurse Anesthetists.

Family impact

Assess the potential impact of the proposed 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 potential impact on the institution of the family and family stability.