

VIRGINIA BOARD OF DENTISTRY

Public Hearing

November 8, 2013 Agenda

Department of Health Professions
Perimeter Center - 9960 Mayland Drive, 2nd Floor Conference Center
Henrico, Virginia 23233

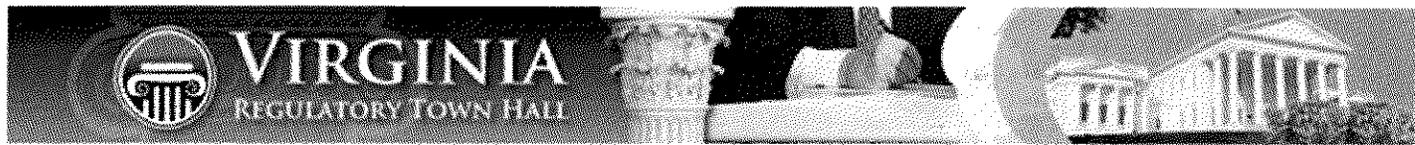
TIME

9:00 a.m. Call to Order – Jeffrey Levin, DDS, President

Evacuation Announcement – Ms. Reen

Public Hearing on Sedation and Anesthesia Regulations

Adjourn



Logged In: Huong

Agency Department of Health Professions

Board Board of Dentistry

Meeting: Public hearing

 Edit meeting
 Cancel this meeting

Meeting Details

Date / Time	11/8/2013 9:00 am
Location	Perimeter Building Conference Center 2nd floor - Board Room 2 9960 Mayland Drive Henrico VA 23233
Board Website	http://www.dhp.virginia.gov
Agenda document	Meeting Agenda 9/18/2013 (302k)

Disability Friendly? Yes Deaf interpreter available upon request? Yes

Purpose of the meeting

To receive public comment on proposed regulations for sedation and anesthesia permits

Meeting Scope	<input type="checkbox"/> General business of the board <input type="checkbox"/> Discuss particular regulations / chapters <input checked="" type="checkbox"/> Public hearing to discuss a proposed change
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This meeting is a public hearing to discuss the following proposed change(s)

Sedation and anesthesia permits for dentists

Contact Information

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Virginia
Regulatory
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Proposed Regulation 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	January 28, 2013

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

Chapter 526 (Senate Bill 1146) of the 2011 Acts of the Assembly required 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 required that the Board promulgate emergency regulations which became effective September 14, 2012. These proposed regulations are submitted to replace the emergency regulations.

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.

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:

...

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.*

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

The intent of the regulatory action 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 are qualified for permits under the proposed 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 until September 14, 2014 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.

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 proposed regulations, which replace emergency regulations, are necessary to accord patients in Virginia the level of protection provided by the vast majority of other states.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)

The substantive 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.

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 the regulatory action poses no disadvantages to the public or the Commonwealth, please indicate.

- 1) The primary advantage to the public is greater patient safety and accountability in the provision of sedation and anesthesia in dental offices. There are no disadvantages; persons who are currently qualified will be able to obtain permits or will have adequate time to obtain the required coursework and equipment for monitoring and emergency management.
- 2) There are no advantages or disadvantages to the Commonwealth; the Board set the application and renewal fee with the goal of covering expenditures related to sedation and anesthesia permits.
- 3) There are no other pertinent matters of interest.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale 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.

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.

In addition to any other comments, the board/agency 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 may do so via the Regulatory Townhall website, 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 the last date of the public comment period.

A public hearing will be held after this regulatory stage is published in the *Virginia Register of Regulations* 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 (<http://www.virginia.gov/cmsportal3/cgi-bin/calendar.cgi>). 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 requirements creates the anticipated economic impact.

<p>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.</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 should not incur costs for email notification to the Public Participation Guidelines mailing lists or for conducting a public hearing. On-going expenditures related to permits should be offset by application and renewal fees generated.</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>There is no cost on localities.</p>
<p>Description of the individuals, businesses or other entities likely to be affected by the new regulations or changes to existing regulations.</p>	<p>Persons affected by the amended regulations are dentists who administer or cause to be administered moderate sedation/conscious sedation or deep sedation/general anesthesia in dental offices.</p>
<p>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 (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>Emergency regulations that went into effect in September, 2012 require all dentists who administer moderate sedation/conscious sedation or deep sedation/general anesthesia in dental offices to obtain a permit by March, 2013. As of January 31, 2013, there were 46 moderate/conscious permits issued and 12 deep sedation/general anesthesia permits. Oral and maxillofacial surgeons are not required to obtain permits if they maintain membership in the American Association of Oral and Maxillofacial Surgeons (AAOMS). The Board has no estimate of the number of permits that will be issued before the end of March, 2013.</p>

<p>All projected costs of the <i>new regulations or changes to existing regulations</i> for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. 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.</p>	<p>All dentists who administer conscious/moderate sedation or deep sedation/general anesthesia will incur a cost of \$100 for a permit. Those who do not already have the required equipment in their offices will incur costs for purchases. For example, an EKG machine costs approximately \$2,000 and a stethoscope costs approximately \$700. There are no new equipment requirements in the proposed regulations, so if a dentist is administering sedation or anesthesia during the period of emergency regulations, he will already have the required equipment.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>With sedation and anesthesia permit regulations, patients should have greater assurance that there is adequate education and training of practitioners who administer and monitor, that there is adequate equipment available in the dental office and that all staff are trained to monitor and respond to an emergency situation.</p>

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.

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.”*

Regulatory flexibility analysis

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.

The Board has a mandate to promulgate regulations which *“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.”*

There are no alternative methods that achieve the mandate for permits and establishments of standards for safe administration and monitoring of sedation and anesthesia.

Public comment

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

The Notice of Intended Regulatory Action was published on 10/8/12 with comment requested until 11/7/12. Comment received was primarily on the emergency regulations in effect.

Commenter	Comment	Agency response
Tontra Lowe	EKG should not be required for	Board eliminated requirement for EKG for

	moderate oral sedation (enteral)	moderate sedation administered in a single dose by an enteral method
Benjamin Watson	<ul style="list-style-type: none"> EKG should not be required for moderate oral sedation (enteral) Trained office personnel should be able to monitor oral sedation patients if dentists is in the office 	<ul style="list-style-type: none"> Board eliminated requirement for EKG for moderate sedation administered in a single dose by an enteral method Proposed regulations allow for monitoring by a 2nd person provided dentist remains on the premises
Gregory Johnson	<ul style="list-style-type: none"> EKG should not be required for moderate oral sedation (enteral) Trained office personnel should be able to monitor oral sedation patients if dentists is in the office 	<ul style="list-style-type: none"> Board eliminated requirement for EKG for moderate sedation administered in a single dose by an enteral method Proposed regulations allow for monitoring by a 2nd person provided dentist remains on the premises
Christopher Hamlin	Opposed to prohibition on pre-medicating pediatric patients prior to arrival in dental office	American Academy of Pediatric Dentistry position is: "...administration of sedating medication at home poses an unacceptable risk" Board elected to retain the prohibition
Michael Rogers	EKG should not be required for moderate oral sedation (enteral)	Board eliminated requirement for EKG for moderate sedation administered in a single dose by an enteral method
William Griffin	<ul style="list-style-type: none"> EKG should not be required for moderate oral sedation (enteral) Trained office personnel should be able to monitor oral sedation patients if dentists is in the office 	<ul style="list-style-type: none"> Board eliminated requirement for EKG for moderate sedation administered in a single dose by an enteral method Proposed regulations allow for monitoring by a 2nd person provided dentist remains on the premises
Brad Spano	<ul style="list-style-type: none"> EKG should not be required for moderate oral sedation (enteral) Trained office personnel should be able to monitor oral sedation patients if dentists is in the office 	<ul style="list-style-type: none"> Board eliminated requirement for EKG for moderate sedation administered in a single dose by an enteral method Proposed regulations allow for monitoring by a 2nd person provided dentist remains on the premises
Corey Sheppard	<ul style="list-style-type: none"> EKG should not be required for moderate oral sedation (enteral) Trained office personnel should be able to monitor oral sedation patients if dentists is in the office 	<ul style="list-style-type: none"> Board eliminated requirement for EKG for moderate sedation administered in a single dose by an enteral method Proposed regulations allow for monitoring by a 2nd person provided dentist remains on the premises
Caroline Wallace	EKG should not be required for moderate oral sedation (enteral)	Board eliminated requirement for EKG for moderate sedation administered in a single dose by an enteral method
Shepherd Sittason	<ul style="list-style-type: none"> EKG should not be required for moderate oral sedation (enteral) Trained office personnel should be able to monitor oral sedation patients if dentists is in the office 	<ul style="list-style-type: none"> Board eliminated requirement for EKG for moderate sedation administered in a single dose by an enteral method Proposed regulations allow for monitoring by a 2nd person provided dentist remains on the premises
Jerry Caravas	<ul style="list-style-type: none"> EKG should not be required for moderate oral sedation (enteral) Trained office personnel should be able to monitor oral sedation patients if dentists is in the office 	<ul style="list-style-type: none"> Board eliminated requirement for EKG for moderate sedation administered in a single dose by an enteral method Proposed regulations allow for monitoring by a 2nd person provided dentist remains on the premises

<p>Va. Society of Anesthesiologists</p>	<p>Requests amendment to section 110 to require nurse anesthetists to practice under medical direction and supervision, even in an outpatient surgery facility</p>	<p>Regulations for the practice of nurse anesthetists (CRNA) required them to practice under medical direction and supervision in accordance with a practice agreement with a physician. It is not required that the supervising physician be physically present at all times and in all places in which the CRNA is administering anesthesia. Further CRNA's are allowed to practice under the supervision of dentists, so the Board did not revise the regulation.</p>
<p>Scott Golrich</p>	<ul style="list-style-type: none"> • EKG should not be required for moderate oral sedation (enteral) • Trained office personnel should be able to monitor oral sedation patients if dentists is in the office 	<ul style="list-style-type: none"> • Board eliminated requirement for EKG for moderate sedation administered in a single dose by an enteral method • Proposed regulations allow for monitoring by a 2nd person provided dentist remains on the premises
<p>Frederick Smith</p>	<ul style="list-style-type: none"> • EKG should not be required for moderate oral sedation (enteral) • Trained office personnel should be able to monitor oral sedation patients if dentists is in the office 	<ul style="list-style-type: none"> • Board eliminated requirement for EKG for moderate sedation administered in a single dose by an enteral method • Proposed regulations allow for monitoring by a 2nd person provided dentist remains on the premises
<p>Va. Association of Nurse Anesthetists</p>	<p>Supports draft regulations but recommends certain clarifications:</p> <ul style="list-style-type: none"> • Change term "qualified dentist" to "dentist who holds a permit" to administer • Revise description of anesthesiologist and certified registered nurse anesthetist • Require all dentists who administer sedation or anesthesia or cause it to be administered to hold a permit • Eliminate requirement that a CRNA may be employed for deep sedation/general anesthesia only if there is a qualified anesthesiologist or permitted dentist present • Revise so dentist providing the treatment is not the anesthesia provider • Revise to require monitoring by person qualified in administration of anesthesia • Amend to ensure an RN is practicing with his scope of practice 	<ul style="list-style-type: none"> • Board adopted the recommended change • Board did not revise; terms are consistent with current understanding • Board did not include such a requirement; dentists who do not hold a permit are allowed to delegate administration to a qualified anesthesia provider • Proposed regulations allow for employment of CRNA in an outpatient facility but not in a dental office; the regulation was retained out of concern for patient safety • Regulation was not revised as unnecessarily burdensome • Regulation was not revised as unnecessarily burdensome • Regulation was not revised as deemed unnecessary
<p>William Martin</p>	<p>New regulations are costly and burdensome for oral conscious sedation</p>	<p>Since there were no specific requirements cited, the Board did not revise accordingly, except the EKG requirement was eliminated for administration of moderate sedation administered in a single dose by an enteral method.</p>

Family impact

Please assess the 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.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. 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
10	Establishes definitions for words and terms used in regulations	<p>1) Definitions are added or revised for words and terms used in regulations for sedation and anesthesia. Definitions for "Conscious/moderate sedation," "Deep sedation," "General anesthesia" and "Minimal sedation" are taken from the <i>Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students (2007)</i> of the American Dental Association.</p> <p>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.</p> <p>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.</p> <p>2) <i>Changes from the emergency regulation:</i> <i>To facilitate utilization of definitions in Section 10, they have been reorganized into three subsections: General terminology; terms relating to supervision; and terms relating to sedation and anesthesia.</i> <i>In the definitions of "conscious/moderate sedation" and</i></p>

		<p><i>“deep sedation/general anesthesia,” the sentence “Reflex withdrawal from a painful stimulus is not considered a purposeful response” was added for consistency with definitions recommended by the American Society of Anesthesiologists.</i></p> <p><i>Definitions for “anxiolysis” and “inhalation analgesia” are added to the definition of “minimal sedation” to clarify that minimal sedation is inclusive of those types of sedation.</i></p> <p><i>A new definition for the term “titration” is added because the word is used in proposed regulations.</i></p>
30	Sets out fees for issuance and renewal of a sedation or anesthesia permit.	<p>1) 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 L and M 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.</p> <p>2) <i>There are no changes from the emergency regulations.</i></p>
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.	<p>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.</p> <p>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.</p> <p>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 <i>Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students (2007)</i> to determine elements of a patient record.</p> <p>Some guidelines for monitoring and management specify that vital signs and physiological measures must be recorded at regular intervals. Others, such as, <i>Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures (2006)</i>,” specify that monitoring records should be recorded every five minutes. The Board adopted the specific standard as consistent with patient safety.</p>

		<p>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.</p> <p>Subsection G specifies that:</p> <p>1. <i>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.</i> The standard is quoted from the 2007 ADA Guidelines.</p> <p>2. <i>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.</i> 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.</p> <p>2) <i>Changes from the emergency regulations are:</i> <i>Subsection C – added “any level of” prior to “sedation or general anesthesia” because there was confusion about which level of sedation required discussion of risks, etc. and required consent.</i> <i>Subsection E – in response to comment and confusion about the difference between the dental “treatment” and the continuum of administration and monitoring of anesthesia or sedation, the word “procedure” has been replaced with “treatment” throughout the regulation to refer to the dental care being provided to the patient.</i> <i>Subsection G – For the purpose of emergency management, the dentist must stop the treatment if a patient enters a deeper level of sedation than was intended and for which the dentist was prepared to provide. The level “intended” is more accurate than the level for which the dentist “is qualified.”</i> <i>Subsection H – A requirement for reporting adverse reactions is applicable to all levels of sedation and anesthesia, so it was moved from section 140 into the section on General Provision; section 140 is being repealed.</i> <i>Subsection I – Additionally, the requirement for continuing education relating to sedation and anesthesia has been set out in subsection A of section 50. Since it relates to the General Provisions for administration of anesthesia or sedation, it has been repeated in section 107.</i></p>
108	Sets out requirements for administration of minimal sedation	<p><i>Change from emergency regulations</i> 2) <i>Based on questions received by phone and email, there appeared to be some confusion about whether inhalation</i></p>

		<p><i>analgesia was considered minimal or moderate sedation and thus whether or not the dentist was required to have a permit. For clarity, the title of section 108 was changed to "Administration of minimal sedation (anxiolysis or inhalation analgesia)" and, definitions in section 10 were also consolidated for clarity.</i></p> <p><i>Further, a provision was added to specify that if any other pharmacological agent is used in addition to nitrous and a local anesthetic (use of valium, etc.), the dentist must meet the requirements for the induced level of sedation.</i></p>
<p>110</p>	<p>Sets out the requirements for a permit to administer deep sedation/general anesthesia</p>	<p>1) Since there are no new qualifications for a dentist who is currently qualified to administer, the Board established a deadline of March 31, 2013 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.</p> <p>Subsection B sets out the required submission to determine eligibility for a permit; there are <u>no new requirements</u>.</p> <p>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.</p> <p>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.</p> <p>Subsection E sets out the requirements for delegation of administration consistent with recommendations of the 2007 Guidelines and with current practice.</p> <p>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.</p>

		<p>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.</p> <p>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.</p> <p><i>2) Changes from the emergency regulations:</i> <i>The title of section 110 was changed from "Requirements for a permit to administer..." to "Requirements for the administration of..." to clarify that a dentist who does not qualify for a permit for deep sedation or general anesthesia but who allows such administration by a qualified provider is responsible for assuring the appropriate equipment is available and the monitoring of the patient.</i> <i>Subsection A was changed from no dentist may "employ or use" to may "administer" deep sedation/general anesthesia without a permit. A non-permitted dentist may employ or use a permitted dentist or another qualified anesthesia provider.</i> <i>Subsection D on posting of licenses and permits is reworded for greater clarity and to ensure that all such documents are current.</i> <i>Subsection E is amended for clarity to replace a dentist who is not "qualified" with a dentist "who does not hold a permit."</i> <i>Subsection F is amended to clarify that dentists who do not hold a permit are responsible for ensuring that equipment and monitoring requirements are met for the safety of the patient.</i> <i>Subsection F is edited to make the requirements for equipment more clearly stated.</i> <i>Subsection G is amended to clarify that: 1) the 2nd person on the treatment team may be the health professional delegated to administer sedation or anesthesia; 2) that the monitoring must take place during the continuum following induction and through recovery from anesthesia; 3) EKG readings are not considered "baseline vital signs" and must be separately named; and 4) that the IV line is established "during induction" and maintained through "recovery."</i></p>
120	Sets out the requirements for a permit to administer conscious sedation	<p>1) Since there are no new qualifications for a dentist who is currently qualified to administer, the Board established a deadline of March 31, 2013 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</p>

		<p>exception to the requirement for a deep sedation/general anesthesia permit for oral and maxillofacial surgeons is also included in subsection A.</p> <p>Subsection B states the automatic qualification of a dentist with an anesthesia permit to administer conscious/moderate sedation.</p> <p>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 until September 14, 2014 in which to obtain the necessary education and training for a conscious/moderate sedation permit. (see subsection D, #2)</p> <p>Subsections D, E and F clarify that the current education and training may qualify a dentist for a 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.</p> <p>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.</p> <p>Subsection H sets out the requirements for delegation of administration consistent with recommendations of the 2007 Guidelines and with current practice.</p> <p>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 (EKG), suction apparatus, a temperature measuring device, throat pack and a precordial or pretracheal stethoscope, which are all recommended for emergency management of patients.</p>
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		<p>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.</p> <p>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.</p> <p><i>2) Changes from the emergency regulations: The title of section 120 was changed from "Requirements for a permit to administer..." to "Requirements for the administration of..." to clarify that a dentist who does not qualify for a permit for conscious moderate sedation but who allows such administration by a qualified provider is responsible for assuring the appropriate equipment is available and the monitoring of the patient. Subsection A was changed from no dentist may "employ or use" to may "administer" deep sedation/general anesthesia without a permit. A non-permitted dentist may employ or use a permitted dentist or another qualified anesthesia provider. Subsection F on posting of licenses and permits is reworded for greater clarity and to ensure that all such documents are current. Subsection H is amended for clarity to replace a dentist who is not "qualified" with a dentist "who does not hold a permit." It is also amended in #5 to clarify that dentists who do not hold a permit are responsible for ensuring that equipment and monitoring requirements are met for the safety of the patient. Subsection I is amended so an electrocardiographic monitor (EKG) is required only if a patient is receiving parenteral administration of sedation or if the dentist is using titration. Dentists who do moderate sedation typically use the enteral method but some do titrate the patient during treatment. Subsection J is amended to clarify that: 1) the 2nd person on the treatment team may be the health professional delegated to administer sedation; 2) that the monitoring must take place during the continuum following induction and through recovery from anesthesia;</i></p>
135	<p>Establishes the requirements for ancillary personnel who assist in administration and monitoring of patients under conscious/moderate sedation, deep sedation or general anesthesia.</p>	<p>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 American Society of Anesthesiologists and the 2007 Guidelines)</p> <p><i>2) The title of section 135 was changed from "Ancillary personnel" to "Personnel assisting in sedation or anesthesia" to clarify the intent and applicability.</i></p>

DRAFT Proposed regulations

**BOARD OF DENTISTRY
Sedation/anesthesia permits**

Part I

General Provisions

18VAC60-20-10. Definitions.

A. The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"ADA" means the American Dental Association.

"Advertising" means a representation or other notice given to the public or members thereof, directly or indirectly, by a dentist on behalf of himself, his facility, his partner or associate, or any dentist affiliated with the dentist or his facility by any means or method for the purpose of inducing purchase, sale or use of dental methods, services, treatments, operations, procedures or products, or to promote continued or increased use of such dental methods, treatments, operations, procedures or products.

~~"Analgesia" means the diminution or elimination of pain in the conscious patient.~~

~~"Anxiolysis" means the diminution or elimination of anxiety through the use of pharmacological agents in a dosage that does not cause depression of consciousness.~~

"CODA" means the Commission on Dental Accreditation of American Dental Association.

~~"Conscious sedation" means a minimally depressed level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal commands, produced by pharmacological or nonpharmacological methods, including inhalation, parenteral, transdermal or enteral, or a combination thereof.~~

"Conscious/moderate sedation" means a drug induced depression of consciousness, during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

~~"Deep sedation/general anesthesia" means an induced state of depressed consciousness or unconsciousness accompanied by a complete or partial loss of protective reflexes, including the inability to continually maintain an airway independently and/or respond purposefully to physical stimulation or verbal command and is produced by a pharmacological or nonpharmacological~~

~~method or a combination thereof a drug induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.~~

"Dental assistant I " means any unlicensed person under the direction of a dentist who renders assistance for services provided to the patient as authorized under this chapter but shall not include an individual serving in purely a secretarial or clerical capacity.

"Dental assistant II" means a person under the direction and direct supervision of a dentist who is registered to perform reversible, intraoral procedures as specified in this chapter.

"Mobile dental facility" means a self-contained unit in which dentistry is practiced that is not confined to a single building and can be transported from one location to another.

"Portable dental operation" means a nonfacility in which dental equipment used in the practice of dentistry is transported to and utilized on a temporary basis at an out-of-office location, including patients' homes, schools, nursing homes, or other institutions.

"Radiographs" means intraoral and extraoral x-rays of hard and soft tissues to be used for purposes of diagnosis.

B. The following words and terms relating to supervision as used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Direct supervision" means that the dentist examines the patient and records diagnostic findings prior to delegating restorative or prosthetic treatment and related services to a dental assistant II for completion the same day or at a later date. The dentist prepares the tooth or teeth to be restored and remains immediately available to the dental assistant II for guidance or assistance during the delivery of treatment and related services. The dentist examines the patient to evaluate the treatment and services before the patient is dismissed.

"Direction" means the level of supervision that a dentist is required to exercise with a dental hygienist, a dental assistant I or a dental assistant II or that a dental hygienist is required to exercise with a dental assistant to direct and oversee the delivery of treatment and related services.

~~"Enteral" is any technique of administration in which the agent is absorbed through the gastrointestinal tract or oral mucosa (i.e., oral, rectal, sublingual).~~

"General anesthesia" means a drug induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and

positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

"General supervision" means that a dentist completes a periodic comprehensive examination of the patient and issues a written order for hygiene treatment that states the specific services to be provided by a dental hygienist during one or more subsequent appointments when the dentist may or may not be present. The order may authorize the dental hygienist to supervise a dental assistant performing duties delegable to dental assistants I.

"Immediate supervision" means the dentist is in the operatory to supervise the administration of sedation or provision of treatment.

"Indirect supervision" means the dentist examines the patient at some point during the appointment, and is continuously present in the office to advise and assist a dental hygienist or a dental assistant who is (i) delivering hygiene treatment, (ii) preparing the patient for examination or treatment by the dentist or dental hygienist, or (iii) preparing the patient for dismissal following treatment.

C. The following words and terms relating to sedation or anesthesia as used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Conscious/moderate sedation" means a drug-induced depression of consciousness, during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from a painful stimulus is not considered a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

"Deep sedation " means a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. Reflex withdrawal from a painful stimulus is not considered a purposeful response. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

Enteral" is any technique of administration in which the agent is absorbed through the gastrointestinal tract or oral mucosa (i.e., oral, rectal, sublingual).

"Inhalation" means a technique of administration in which a gaseous or volatile agent, including nitrous oxide, is introduced into the pulmonary tree and whose primary effect is due to absorption through the pulmonary bed.

"General anesthesia" means a drug induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilator

function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

~~"Inhalation analgesia" means the inhalation of nitrous oxide and oxygen to produce a state of reduced sensibility to pain without the loss of consciousness.~~

"Local anesthesia" means the loss of sensation or pain in the oral cavity or the maxillofacial or adjacent and associated structures generally produced by a topically applied or injected agent without depressing the level of consciousness.

"Minimal sedation" means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilator and cardiovascular functions are unaffected. Minimal sedation includes "anxiolysis" (the diminution or elimination of anxiety through the use of pharmacological agents in a dosage that does not cause depression of consciousness) and includes "inhalation analgesia" (the inhalation of nitrous oxide and oxygen to produce a state of reduced sensibility to pain without the loss of consciousness).

~~"Mobile dental facility" means a self-contained unit in which dentistry is practiced that is not confined to a single building and can be transported from one location to another.~~

"Moderate sedation" (see meaning of conscious/moderate sedation)

"Monitoring" means to observe, interpret, assess and record appropriate physiologic functions of the body during sedative procedures and general anesthesia appropriate to the level of sedation as provided in Part IV.

"Parenteral" means a technique of administration in which the drug bypasses the gastrointestinal tract (i.e., intramuscular, intravenous, intranasal, submucosal, subcutaneous, or intraocular).

~~"Portable dental operation" means a nonfacility in which dental equipment used in the practice of dentistry is transported to and utilized on a temporary basis at an out-of-office location, including patients' homes, schools, nursing homes, or other institutions.~~

~~"Radiographs" means intraoral and extraoral x-rays of hard and soft tissues to be used for purposes of diagnosis.~~

"Titration" means the incremental increase in drug dosage to a level that provides the optimal therapeutic effect of sedation.

18VAC60-20-30. Other fees.

A. Dental licensure application fees. The application fee for a dental license by examination, a license to teach dentistry, a full-time faculty license, or a temporary permit as a dentist shall be \$400. The application fee for dental license by credentials shall be \$500.

B. Dental hygiene licensure application fees. The application fee for a dental hygiene license by examination, a license to teach dental hygiene, or a temporary permit as a dental hygienist shall be \$175. The application fee for dental hygienist license by endorsement shall be \$275.

C. Dental assistant II registration application fee. The application fee for registration as a dental assistant II shall be \$100.

D. Wall certificate. Licensees desiring a duplicate wall certificate or a dental assistant II desiring a wall certificate shall submit a request in writing stating the necessity for a wall certificate, accompanied by a fee of \$60.

E. Duplicate license or registration. Licensees or registrants desiring a duplicate license or registration shall submit a request in writing stating the necessity for such duplicate, accompanied by a fee of \$20. If a licensee or registrant maintains more than one office, a notarized photocopy of a license or registration may be used.

F. Licensure or registration certification. Licensees or registrants requesting endorsement or certification by this board shall pay a fee of \$35 for each endorsement or certification.

G. Restricted license. Restricted license issued in accordance with § 54.1-2714 of the Code of Virginia shall be at a fee of \$285.

H. Restricted volunteer license. The application fee for licensure as a restricted volunteer dentist or dental hygienist issued in accordance with § 54.1-2712.1 or § 54.1-2726.1 of the Code of Virginia shall be \$25.

I. Returned check. The fee for a returned check shall be \$35.

J. Inspection fee. The fee for an inspection of a dental office shall be \$350 with the exception of a routine inspection of an office in which the dentist has a conscious/moderate sedation permit or a deep sedation/general anesthesia permit.

K. Mobile dental clinic or portable dental operation. The application fee for registration of a mobile dental clinic or portable dental operation shall be \$250. The annual renewal fee shall be \$150 and shall be due by December 31. A late fee of \$50 shall be charged for renewal received after that date.

L. Conscious/moderate sedation permit. The application fee for a permit to administer conscious/moderate sedation shall be \$100. The annual renewal fee shall be \$100 and shall be due by March 31. A late fee of \$35 shall be charged for renewal received after that date.

M. Deep sedation/general anesthesia permit. The application fee for a permit to administer deep sedation/general anesthesia shall be \$100. The annual renewal fee shall be \$100 and shall be due by March 31. A late fee of \$35 shall be charged for renewal received after that date.

Part IV

Anesthesia, Sedation and Analgesia

18VAC60-20-107. General provisions.

- A. This part (18VAC60-20-107 et seq.) shall not apply to:
1. The administration of local anesthesia in dental offices; or
 2. The administration of anesthesia in (i) a licensed hospital as defined in § 32.1-123 of the Code of Virginia or state-operated hospitals or (ii) a facility directly maintained or operated by the federal government.
- B. Appropriateness of administration of general anesthesia or sedation in a dental office.
1. Anesthesia and sedation may be provided in a dental office for patients who are Class I and II as classified by the American Society of Anesthesiologists (ASA).
 2. Conscious sedation, deep sedation or general anesthesia shall not be provided in a dental office for patients in ASA risk categories of Class IV and V.
 3. Patients in ASA risk category Class III shall only be provided general anesthesia or any level of sedation by:
 - a. A dentist after he has documented a consultation with their primary care physician or other medical specialist regarding potential risk and special monitoring requirements that may be necessary; or
 - b. An oral and maxillofacial surgeon after performing an evaluation and documenting the ASA risk assessment category of the patient and any special monitoring requirements that may be necessary.
- C. Prior to administration of any level of sedation or general anesthesia, the dentist shall discuss the nature and objectives of the anesthesia or sedation planned along with the risks, benefits and alternatives and shall obtain informed, written consent from the patient or other responsible party. The written consent shall be maintained in the patient record.
- D. The determinant for the application of these rules shall be the degree of sedation or consciousness level of a patient that should reasonably be expected to result from the type and dosage of medication, the method of administration and the individual characteristics of the patient as documented in the patient's record. The drugs and techniques used must carry a

margin of safety wide enough to render unlikely an unintended reduction of or loss of consciousness when factoring in titration, and the patient's age, weight and ability to metabolize drugs.

E. A dentist who is administering anesthesia or sedation to patients prior to June 29, 2005 shall have one year from that date to comply with the educational requirements set forth in this chapter for the administration of anesthesia or sedation. When conscious/moderate sedation, deep sedation or general anesthesia is administered, the patient record shall also include:

1. Notation of the patient's American Society of Anesthesiologists classification;
2. Review of medical history and current conditions;
3. Written informed consent for administration of sedation and anesthesia and for the dental procedure treatment to be performed;
4. Pre-operative vital signs;
5. A record of the name, dose, strength of drugs and route of administration including the administration of local anesthetics with notations of the time sedation and anesthesia were administered;
6. Monitoring records of all required vital signs and physiological measures recorded every five minutes; and
7. A list of staff participating in the administration, treatment and monitoring including name, position and assigned duties.

F. Pediatric patients.

No sedating medication shall be prescribed for or administered to a child aged 12 and under prior to his arrival at the dentist office or treatment facility.

G. Emergency management.

1. If a patient enters a deeper level of sedation than the dentist is qualified intended and was prepared to provide, the dentist shall stop the dental procedure treatment until the patient returns to and is stable at the intended level of sedation.
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.

H. Reporting of adverse reactions.

A written report shall be submitted to the board by the treating dentist within 30 days following any mortality or morbidity which directly results from the administration of any level of

sedation or anesthesia and which occurs in the facility or during the first 24 hours immediately following the patient's departure from the facility.

I. Continuing education.

A dentist who administers or a dental hygienist who monitors patients under general anesthesia, deep sedation or conscious sedation shall complete four hours every two years of approved continuing education directly related to administration or monitoring of such anesthesia or sedation as part of the hours required for licensure renewal as specified in 18VAC60-20-50.

18 VAC60-20-108. Administration of minimal sedation (anxiolysis or inhalation analgesia).

A. Education and training requirements. A dentist who utilizes anxiolysis or inhalation analgesia shall have training in and knowledge of:

1. Medications used, the appropriate dosages and the potential complications of administration.
2. Physiological effects of nitrous oxide and potential complications of administration.

B. Equipment requirements. A dentist who utilizes anxiolysis or inhalation analgesia or who directs the administration of inhalation analgesia by a dental hygienist shall maintain the following equipment in his office and be trained in its use:

1. Blood pressure monitoring equipment.
2. Positive pressure oxygen.
3. Mechanical (hand) respiratory bag.

C. Monitoring requirements.

1. The treatment team for anxiolysis shall consist of the dentist and a second person in the operatory with the patient to assist, monitor and observe the patient. Once the administration of anxiolysis has begun, the dentist shall ensure that a person qualified in accordance with 18VAC60-20-135 is present with the patient at all times to determine the level of consciousness by continuous visual monitoring of the patient.
2. A dentist or a dental hygienist who utilizes inhalation analgesia shall ensure that there is continuous visual monitoring of the patient to determine the level of consciousness.

3. If inhalation analgesia is used, monitoring shall include making the proper adjustments of nitrous oxide machines at the request of or by the dentist or a dental hygienist qualified in accordance with requirements of 18VAC60-20-81 to administer nitrous oxide during administration of the sedation and observing the patient's vital signs.

4. If any other pharmacological agent is used in addition to nitrous oxide/oxygen and a local anesthetic, requirements for the induced level of sedation must be met.

D. Discharge requirement. The dentist shall ensure that the patient is not discharged to his own care until he exhibits normal responses.

18VAC60-20-110. Requirements for a permit to administer the administration of deep sedation/general anesthesia.

A. Educational requirements After March 31, 2013, no dentist may ~~employ or use~~ administer deep sedation/general anesthesia in a dental office unless he has been issued a permit by the board. The requirement for a permit shall not apply to 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. Such an oral and maxillofacial surgeon shall be required to post a certificate issued by AAOMS.

B. To determine eligibility for a deep sedation/general anesthesia permit, a dentist shall submit the following:

1. A completed application form;

2. The application fee as specified in 18VAC60-20-30;

3. A copy of the certificate of completion of a CODA accredited program or other documentation of training content which meets the educational and training qualifications specified in subsection C; and

4. A copy of current certification in ACLS or PALS as required in subsection C.

C. Educational and training qualifications for a deep sedation/general anesthesia permit.

1. A dentist may ~~employ or~~ be issued a permit to use deep sedation/general anesthesia on an outpatient basis in a dental office by meeting one of the following educational criteria, and by posting the educational certificate, in plain view of the patient, which verifies completion of the advanced training as required in subdivision 1 or 2 of this subsection. These requirements shall not apply nor interfere with requirements for obtaining hospital staff privileges.

1-a. Has completed Completion of a minimum of one calendar year of advanced training in anesthesiology and related academic subjects beyond the undergraduate

dental school level in a training program in conformity with published guidelines by the American Dental Association (Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry) in effect at the time the training occurred; or ~~2.b.~~ Completion of an American Dental Association approved a CODA accredited residency in any dental specialty which incorporates into its curriculum a minimum of one calendar year of full-time training in clinical anesthesia and related clinical medical subjects (i.e. medical evaluation and management of patients), comparable to those set forth in published guidelines by the American Dental Association for Graduate and Postgraduate Training in Anesthesia in effect at the time the training occurred.

~~After June 29, 2006, dentists~~ 2. Dentists who administer deep sedation/general anesthesia shall hold current certification in advanced resuscitative techniques with hands-on simulated airway and megacode training for healthcare providers, including basic electrocardiographic interpretation, such as courses in Advanced Cardiac Life Support (ACLS) for Health Professionals or Pediatric Advanced Life Support (PALS) for Health Professionals and current Drug Enforcement Administration registration.

B. Exceptions.

~~1. A dentist who has not met the requirements specified in subsection A of this section may treat patients under deep sedation/general anesthesia in his practice if a qualified anesthesiologist or a dentist who fulfills the requirements specified in subsection A of this section, is present and is responsible for the administration of the anesthetic.~~

~~2. If a dentist fulfills the requirements specified in subsection A of this section, he may employ the services of a certified nurse anesthetist.~~

~~C.D. Posting. The deep sedation/general anesthesia permit or AAOMS certificate required under subsection A of this section Any dentist who utilizes deep sedation/general anesthesia shall post shall be posted along with the dental license and current registration with the Drug Enforcement Administration, the certificate of education deep sedation/general anesthesia permit or AAOMS certificate required under subsection A of this section. All licenses and permits must be current.~~

E. Delegation of administration.

1. A dentist not qualified who does not hold a permit to administer deep sedation and general anesthesia shall only use the services of a dentist with a current deep sedation/general anesthesia permit or an anesthesiologist to administer deep sedation or general anesthesia in a dental office. In a licensed outpatient surgery center, a dentist

not qualified who does not hold a permit to administer deep sedation or general anesthesia shall use either a permitted dentist, an anesthesiologist or a certified registered nurse anesthetist to administer deep sedation or general anesthesia.

2. A dentist qualified pursuant to subsection B who does hold a permit may administer or use the services of the following personnel to administer deep sedation or general anesthesia:

a. A dentist with a current deep sedation/anesthesia permit;

b. An anesthesiologist; or

c. A certified registered nurse anesthetist under the medical direction and indirect supervision of a dentist who meets the educational requirements of subsection C of this section.

3. Preceding the administration of deep sedation or general anesthesia, a permitted dentist may use the services of the following personnel under indirect supervision to administer local anesthesia to anesthetize the injection or treatment site:

a. A dental hygienist with the training required in 18VAC60-20-81 to parenterally administer Schedule VI local anesthesia to persons age 18 or older; or

b. A dental hygienist, dental assistant, registered nurse or licensed practical nurse to administer Schedule VI topical oral anesthetics.

4. A dentist who delegates administration of deep sedation/general anesthesia shall ensure that:

a. All equipment required in subsection F is present, in good working order and immediately available to the areas where patients will be sedated and treated and will recover; and

b. Qualified staff is on site to monitor patients in accordance with requirements of subsection G.

D-F. Emergency Required equipment and techniques. A dentist who administers deep sedation/general anesthesia shall be proficient in handling emergencies and complications related to pain control procedures, including the maintenance of respiration and circulation, and immediate establishment of an airway and cardiopulmonary resuscitation, and. He shall have available maintain the following emergency equipment in sizes for adults or children as appropriate for the patient being treated and shall maintain it in the dental facility working order and immediately available to the areas where patients will be sedated and treated and will recover:

1. Full face mask masks ~~for children or adults, as appropriate for the patient being treated;~~
2. Oral and nasopharyngeal airways airway management adjuncts;
3. Endotracheal tubes for children or adults, or both, with appropriate connectors or other appropriate airway management adjunct such as a laryngeal mask airway;
4. A laryngoscope with reserve batteries and bulbs and appropriately sized laryngoscope blades for children or adults, or both;
5. Source of delivery of oxygen under controlled positive pressure;
6. Mechanical (hand) respiratory bag;
7. Pulse oximetry and blood pressure monitoring equipment available and used in the treatment room;
8. Appropriate emergency drugs for patient resuscitation;
9. EKG monitoring equipment and temperature measuring devices;
10. Pharmacologic antagonist agents;
11. External defibrillator (manual or automatic); ~~and~~
12. For intubated patients, an End-Tidal CO² monitor;
13. Suction apparatus;
14. Throat pack; ~~and~~
15. Precordial or pretracheal stethoscope.

E.G. Monitoring requirements.

1. The treatment team for deep sedation/general anesthesia shall at least consist of the operating dentist, a second person to monitor and observe the patient and a third person to assist the operating dentist, all of whom shall be in the operatory with the patient during the dental ~~procedure~~ treatment. The second person may be the health professional delegated to administer sedation or anesthesia.
2. Monitoring of the patient ~~under~~ undergoing deep sedation/general anesthesia, including direct, visual observation of the patient by a one member of the treatment team, is to begin prior to induction ~~of anesthesia~~ and shall take place continuously following induction, during the dental treatment and during recovery from anesthesia. The person who administered the anesthesia or another licensed practitioner qualified to administer the same level of anesthesia must remain on the premises of the dental facility until the patient has regained consciousness and is discharged.

3. Monitoring deep sedation/general anesthesia shall include the following: ~~recording and reporting of blood pressure, pulse, respiration and other vital signs to the attending dentist.~~

a. EKG readings and baseline vital signs shall be taken and recorded prior to administration of any controlled drug at the facility to include: temperature, blood pressure, pulse, oxygen saturation, respiration and heart rate. b. The EKG readings and patient's vital signs shall be monitored, recorded every five minutes and reported to the treating dentist throughout the administration of controlled drugs and recovery. When depolarizing medications are administered temperature shall be monitored constantly.

e.b. A secured intravenous line must be established during induction and maintained through recovery the procedure.

H. Discharge requirements.

1. The patient shall not be discharged until the responsible licensed practitioner determines that the patient's level of consciousness, oxygenation, ventilation and circulation are satisfactory for discharge and vital signs have been taken and recorded.

2. Postoperative instructions shall be given verbally and in writing. The written instructions shall include a 24-hour emergency telephone number for the dental practice.

3. Patients shall be discharged with a responsible individual who has been instructed with regard to the patient's care.

18VAC60-20-120. Requirements for a permit to administer administration of conscious/moderate sedation.

A. After March 31, 2013, no dentist may employ or use administer conscious/moderate sedation in a dental office unless he has been issued a permit by the board. The requirement for a permit shall not apply to 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. Such an oral and maxillofacial surgeon shall be required to post a certificate issued by AAOMS.

B. Automatic qualification. Dentists qualified who hold a current permit to administer deep sedation/general anesthesia may administer conscious/moderate sedation.

C. To determine eligibility for a conscious/moderate sedation permit, a dentist shall submit the following:

1. A completed application form indicating one of the following permits for which the applicant is qualified:

- a. Conscious/moderate sedation by any method;
 - b. Conscious/moderate sedation by enteral administration only; or
 - c. Temporary conscious/moderate sedation permit (may be renewed one time);
2. The application fee as specified in 18VAC60-20-30;
 3. A copy of a transcript, certification or other documentation of training content which meets the educational and training qualifications as specified in D or E, as applicable;
and
 4. A copy of current certification in ACLS or PALS as required in subsection F.

B-D. Educational requirements for administration—of a permit to administer conscious/moderate sedation by any method.

1. A dentist may be issued a conscious/moderate sedation permit to employ or use any method of conscious sedation by meeting one of the following criteria:

- a. Completion of training for this treatment modality according to guidelines published by the American Dental Association (Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry) in effect at the time the training occurred, while enrolled at an accredited dental program or while enrolled in a post-doctoral university or teaching hospital program; or
- b. Completion of an approved a continuing education course, offered by a provider approved in 18VAC60-20-50, and consisting of 60 hours of didactic instruction plus the management of at least 20 patients per participant, demonstrating competency and clinical experience in parenteral conscious sedation and management of a compromised airway. The course content shall be consistent with guidelines published by the American Dental Association (Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry) in effect at the time the training occurred.

2. A dentist who was self-certified in anesthesia and conscious sedation prior to January 1989 may be issued a temporary conscious/moderate sedation permit to continue to administer only conscious sedation until September 14, 2014. After September 14, 2014, a dentist shall meet the requirements for and obtain a conscious/moderate sedation permit by any method or by enteral administration only.

C-E. Educational requirement for enteral administration of conscious sedation only. A dentist may be issued a conscious/moderate sedation permit to only administer conscious sedation by an enteral method if he has completed an approved a continuing education program, offered by a provider approved in 18VAC60-20-50, of not less than 18 hours of didactic instruction plus 20

clinically-oriented experiences in enteral and/or combination inhalation-enteral conscious sedation techniques. The course content shall be consistent with the guidelines published by the American Dental Association (Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry) in effect at the time the training occurred. The certificate of completion and a detailed description of the course content must be maintained.

D-F. Additional training required.

~~After June 29, 2006, dentists~~ Dentists who administer conscious sedation shall hold current certification in advanced resuscitation techniques with hands-on simulated airway and megacode training for health care providers, including basic electrocardiographic interpretation, such as Advanced Cardiac Life Support (ACLS) for Health Professionals or Pediatric Advanced Life Support (PALS) for Health Professionals as evidenced by a certificate of completion posted with the dental license, and current registration with the Drug Enforcement Administration.

G. Posting. The conscious/moderate sedation permit required under subsection A and issued in accordance with subsection C of this section or the AAOMS certificate issued to an oral and maxillofacial surgeon ~~Any dentist who utilizes deep sedation/general anesthesia shall post shall be posted along with the dental license and current registration with the Drug Enforcement Administration~~ the conscious/moderate sedation permit required under subsection A and issued in accordance with subsection C of this section or the AAOMS certificate issued to an oral and maxillofacial surgeon. All licenses and permits must be current.

H. Delegation of administration.

1. A dentist not qualified who does not hold a permit to administer conscious/moderate sedation shall only use the services of a permitted dentist or an anesthesiologist to administer such sedation in a dental office. In a licensed outpatient surgery center, a dentist not qualified who does not hold a permit to administer conscious/moderate sedation shall use either a permitted dentist, an anesthesiologist or a certified registered nurse anesthetist to administer such sedation.

2. A qualified dentist who holds a permit may administer or use the services of the following personnel to administer conscious/moderate sedation:

- a. A dentist with the training required by subsection E to administer by an enteral method;
- b. A dentist with the training required by subsection D to administer by any method;
- c. An anesthesiologist;

- d. A certified registered nurse anesthetist under the medical direction and indirect supervision of a dentist who meets the education and training requirements of subsection D or E; or
 - e. A registered nurse upon his direct instruction and under the immediate supervision of a dentist who meets the education and training requirements of subsection D.
- 3. If minimal sedation is self-administered by or to a patient age 13 or above before arrival at the dental office, the dentist may only use the personnel listed in subdivision 2 of this subsection to administer local anesthesia. No sedating medication shall be prescribed for or administered to a child aged 12 and under prior to his arrival at the dentist office or treatment facility.
- 4. Preceding the administration of conscious/moderate sedation, a qualified permitted dentist may use the services of the following personnel under indirect supervision to administer local anesthesia to anesthetize the injection or treatment site:
 - a. A dental hygienist with the training required by 18VAC60-20-81 to parenterally administer Schedule VI local anesthesia to persons age 18 or older; or
 - b. A dental hygienist, dental assistant, registered nurse or licensed practical nurse to administer Schedule VI topical oral anesthetics.
- 5. A dentist who delegates administration of conscious/moderate sedation shall ensure that:
 - a. All equipment required in subsection I is present, in good working order and immediately available to the areas where patients will be sedated and treated and will recover; and
 - b. Qualified staff is on site to monitor patients in accordance with requirements of subsection J.

E.I. Emergency Required equipment and techniques. A dentist who administers conscious sedation shall be proficient in handling emergencies and complications related to pain control procedures, including the maintenance of respiration and circulation, immediate establishment of an airway and cardiopulmonary resuscitation, and shall maintain the following emergency airway equipment in the dental facility working order and immediately available to the areas where patients will be sedated and treated and will recover:

1. Full face mask for children or adults, as appropriate for the patient being treated;
2. Oral and nasopharyngeal airways airway management adjuncts;
3. Endotracheal tubes for children or adults, or both, with appropriate connectors or other appropriate airway management adjunct such as a laryngeal mask airway and a

laryngoscope with reserve batteries and bulbs and appropriately sized laryngoscope blades for children or adults, or both. ~~In lieu of a laryngoscope and endotracheal tubes, a dentist may maintain airway adjuncts designed for the maintenance of a patent airway and the direct delivery of positive pressure oxygen;~~

4. Pulse oximetry;
5. Blood pressure monitoring equipment;
6. Pharmacologic antagonist agents;
7. Source of delivery of oxygen under controlled positive pressure;
8. Mechanical (hand) respiratory bag; ~~and~~
9. Appropriate emergency drugs for patient resuscitation;
10. Defibrillator;
11. Suction apparatus;
12. Temperature measuring device;
13. Throat pack;
14. Precordial and pretracheal stethoscope; and
15. Electrocardiographic monitor, if a patient is receiving parenteral administration of sedation or if the dentist is using titration.

F. J. Monitoring requirements.

1. ~~The administration~~ treatment team for conscious sedation shall at least consist of the operating dentist and a second person to assist, monitor and observe the patient. Both shall be in the operatory with the patient throughout the dental procedure treatment. The second person may be the health professional delegated to administer sedation.
2. Monitoring of the patient ~~under conscious~~ undergoing conscious/moderate sedation, including direct, visual observation of the patient by a one member of the treatment team, is to begin prior to administration of sedation, or if medication is self-administered by the patient, ~~when the patient arrives~~ immediately upon the patient's arrival at the dental office and shall take place continuously during the dental ~~procedure~~ treatment and during recovery from sedation. The person who administers the sedation or another licensed practitioner qualified to administer the same level of sedation must remain on the premises of the dental facility until the patient is responsive evaluated and is discharged.
3. Monitoring conscious/moderate sedation shall include the following:
 - a. Baseline vital signs shall be taken and recorded prior to administration of any controlled drug at the facility and prior to discharge; and

b. Blood pressure, oxygen saturation, pulse and heart rate shall be monitored continually during the administration and recorded every five minutes.

c. Monitoring of the patient under moderate sedation is to begin prior to administration of sedation, or, if pre-medication is self-administered by the patient, immediately upon the patient's arrival at the dental office and shall take place continuously during the dental procedure and recovery from sedation. The person who administers the sedation or another licensed practitioner qualified to administer the same level of sedation must remain on the premises of the dental facility until the patient is evaluated and is discharged.

K. Discharge requirements.

1. The patient shall not be discharged until the responsible licensed practitioner determines that the patient's level of consciousness, oxygenation, ventilation and circulation are satisfactory for discharge and vital signs have been taken and recorded.

2. Postoperative instructions shall be given verbally and in writing. The written instructions shall include a 24-hour emergency telephone number of the dental practice.

3. Patients shall be discharged with a responsible individual who has been instructed with regard to the patient's care.

18VAC60-20-135. Ancillary personnel Personnel assisting in sedation or anesthesia.

~~After June 29, 2006, dentists~~ Dentists who employ ancillary personnel to assist in the administration and monitoring of any form of conscious/moderate sedation or deep sedation/general anesthesia shall maintain documentation that such personnel have:

1. Minimal training resulting in current certification in basic resuscitation techniques, with hands-on airway training for healthcare providers, such as Basic Cardiac Life Support for Health Professionals or ~~an approved~~, a clinically oriented course devoted primarily to responding to clinical emergencies offered by an approved provider of continuing education as set forth in 18 VAC 60-20-50 C; or

2. Current certification as a certified anesthesia assistant (CAA) by the American Association of Oral and Maxillofacial Surgeons or the American Dental Society of Anesthesiology (ADSA).

18VAC60-20-140. Report of adverse reactions [Repealed].

~~A written report shall be submitted to the board by the treating dentist within 30 days following any mortality or morbidity which directly results from the administration of local anesthesia, general anesthesia, conscious sedation, or nitrous oxide oxygen inhalation~~

~~analgesia and which occurs in the facility or during the first 24 hours immediately following the patient's departure from the facility.~~