Virginia Regulatory Town Hall

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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.

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.	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.
Projected cost of the *new regulations or changes to existing regulations* on localities.	There is no cost on localities.
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	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.
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.	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.

All projected costs of the *new regulations or changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and include all costs. 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.	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.
Beneficial impact the regulation is designed to produce.	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.

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	• 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	• 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	• 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	• 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 mediation 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	• 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	• 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	• 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	• 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	• 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	• 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	• 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	• 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	• 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	• 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

Va. Society of Anesthesiologists	Requests amendment to section 110 to require nurse anesthetists to practice under medical direction and supervision, even in an outpatient surgery facility	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.
Scott Golrich	• 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	• 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
Frederick Smith	• 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	• 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
Va. Association of Nurse Anesthetists	Supports draft regulations but recommends certain clarifications: • 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 the 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	 • 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
William Martin	New regulations are costly and burdensome for oral conscious sedation	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.

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	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 *Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students (2007)* of the American Dental Association. The definition of "immediate supervision" is intended to ensure that the dentist is present in the operatory to supervise the administration of sedation or provision of treatment. The definition of "monitoring" is intended to fully describe the functions appropriate to the task in order to clarify that more than observation is required when monitoring a patient. 2) *Changes from the emergency regulation:* *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.* *In the definitions of "conscious/moderate sedation" and*

		"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. *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.* *A new definition for the term "titration" is added because the word is used in proposed regulations.*
30	Sets out fees for issuance and renewal of a sedation or anesthesia permit.	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. *2) There are no changes from the emergency regulations.*
107	Establishes general rules for application to administration of all types of sedation and anesthesia, with the exception of local anesthesia and administration in a hospital or federal facility.	Changes in section 107 are primarily intended to clarify and further specify the information relating to administration of sedation or anesthesia that should be included in a patient record. Subsection B is amended to clarify that the dentist must <u>document</u> that he has had a consultation with a medical doctor prior to administration of general anesthesia or any type of sedation to a patient in risk category Class III. Without documentation in the record, there is no assurance that consultation took place. The complete required content of the patient record is set forth in subsection E and includes all information necessary to assure that the patient has been appropriately assessed, administered and monitored. The Board used curriculum included in *Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students (2007)* to determine elements of a patient record. Some guidelines for monitoring and management specify that vital signs and physiological measures must be recorded at regular intervals. Others, such as, *Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures (2006),"* specify that monitoring records should be recorded every five minutes. The Board adopted the specific standard as consistent with patient safety.

		Subsection F specifies that no sedating medication can be prescribed or administered to a child aged 12 and under prior to arrival at the dental office due to the risk of unobserved respiratory obstruction during transport by untrained individuals. The standard is found in the 2007 ADA Guidelines and in the 2006 pediatric guideline. Subsection G specifies that: 1. *If a patient enters a deeper level of sedation than the dentist is qualified and prepared to provide, the dentist shall stop the dental procedure until the patient returns to and is stable at the intended level of sedation*. The standard is quoted from the 2007 ADA Guidelines. 2. *A dentist in whose office sedation or anesthesia is administered shall have written basic emergency procedures established and staff trained to carry out such procedures*. ADA Guidelines and recommendations of other bodies such as the American Society of Anesthesiologists specify that the dentist must have written procedures in place to handle emergencies and staff regularly trained on such procedures. 2) *Changes from the emergency regulations are:* *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.* *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.* *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 that the level for which the dentist "is qualified."* *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.* *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.*
108	Sets out requirements for administration of minimal sedation	*Change from emergency regulations* *2) Based on questions received by phone and email, there appeared to be some confusion about whether inhalation*

		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. *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.*
110	Sets out the requirements for a permit to administer deep sedation/general anesthesia	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. Subsection B sets out the required submission to determine eligibility for a permit; there are no new requirements. Subsection C clarifies that the current education and training may qualify a dentist for an anesthesia permit. The requirement for current certification in ACLS or PALS is further specified to include hands-on simulated airway and megacode training, including basic electrocardiographic interpretation. Professional standards, as cited above, also specify the type of advanced resuscitative techniques that a dentist with an anesthesia permit should have. In order to provide patients with some evidence that a dentist is qualified to administer sedation or anesthesia, the Board currently requires posting of the certificate of education (along with the dental license and current DEA registration). Subsection D is amended to require posting of the Board-issued permit or certificate from AAOMS if an oral and maxillofacial surgeon is exempt from the permit requirement. Subsection E sets out the requirements for delegation of administration consistent with recommendations of the 2007 Guidelines and with current practice. Subsection F sets out the emergency equipment that must be available in the areas where patients will be sedated and will recover from sedation or anesthesia. All are currently required with the exception of suction apparatus, a throat pack and a precordial or pretracheal stethoscope, which are recommended for emergency management of patients.

		Subsection G sets out the monitoring requirements. Further specification about the essential functions of monitoring are included in #3 in accordance with the 2007 Guidelines and other standards for oral and maxillofacial surgeons and anesthesia providers. Subsection H sets out the specific requirements for discharge of a patient who has been under general anesthesia or deep sedation; the provisions are consistent with national standards followed by the Board in the adoption of regulations. *2) Changes from the emergency regulations:* *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.* *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 D on posting of licenses and permits is reworded for greater clarity and to ensure that all such documents are current.* *Subsection E is amended for clarity to replace a dentist who is not "qualified" with a dentist "who does not hold a permit."* *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.* *Subsection F is edited to make the requirements for equipment more clearly stated.* *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."*
120	Sets out the requirements for a permit to administer conscious sedation	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. Subsection B states the automatic qualification of a dentist with an anesthesia permit to administer conscious/moderate sedation. Subsection C sets out the required submission to determine eligibility for a permit; there are no new requirements for a dentist who is qualified to administer conscious sedation by any method or by the enteral method only. The permit will indicate the extent of the dentist's qualification. For dentists who self-certified their qualification prior to January 1989 (the date on which specific qualifications were added to the regulations), a temporary permit may be issued, which will allow them until September 14, 2014 in which to obtain the necessary education and training for a conscious/moderate sedation permit. (see subsection D, #2) Subsections D, E and F clarify that the current education and training may qualify a dentist for 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. In order to provide patients with some evidence that a dentist is qualified to administer sedation or anesthesia, the Board currently requires posting of the certification of resuscitative technique training (along with the dental license and current DEA registration). Subsection G is amended to require posting of the Board-issued permit or certificate from AAOMS if an oral and maxillofacial surgeon is exempt from the permit requirement. Subsection H sets out the requirements for delegation of administration consistent with recommendations of the 2007 Guidelines and with current practice. Subsection I sets out the emergency equipment that must be available in the areas where patients will be sedated and will recover from sedation. All are currently required with the exception of a defibrillator, electrocardiographic monitor (EKG), suction apparatus, a temperature measuring device, throat pack and a precordial or pretracheal stethoscope, which are all recommended for emergency management of patients.

		Subsection J sets out the monitoring requirements. Further specification about the essential functions of monitoring are included in #3 in accordance with the 2007 Guidelines and other standards for oral and maxillofacial surgeons and anesthesia providers. Subsection K sets out the specific requirements for discharge of a patient who has been under sedation; the provisions are consistent with national standards followed by the Board in the adoption of regulations. *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;*
135	Establishes the requirements for ancillary personnel who assist in administration and monitoring of patients under conscious/moderate sedation, deep sedation or general anesthesia.	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) *2) The title of section 135 was changed from "Ancillary personnel" to "Personnel assisting in sedation or anesthesia" to clarify the intent and applicability.*