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Final 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	1/10/14

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

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

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 final regulations replace the emergency regulations.

In response to comment, the Board amended several provisions to further clarify the regulations. Additionally, the Board extended the ability for dentists who were self-certified in conscious/moderate sedation to administer under a temporary permit from one year after the effective date of the emergency regulations (September 14, 2014) to one year from the effective date of final regulations.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency or board taking the action, and (3) the title of the regulation.

On January 10, 2014, the Board of Dentistry adopted final amendments to 18VAC60-20-10 et seq., Regulations Governing Dental Practice.

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. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

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 identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the “All changes made in this regulatory action” 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 there are 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.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar’s office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
107	Section 107 sets out the general requirements for administration of sedation or anesthesia in a dental office.	1) <i>Subsection E is amended to clarify that the content of the patient record of administration of sedation or anesthesia is the responsibility of the dentist.</i> 2) <i>Subsection F –The term “child” is deleted and replaced with “patient” because the rule is applicable if the person under age 12 years is a patient.</i> 3) <i>Subsection I (and all other sections of regulation in which conscious sedation is used) is amended for consistency with the definition for the term “conscious/moderate” sedation.</i> 4) <i>Subsection J is added to clarify that, regardless of who is</i>	<i>All changes were intended to clarify the language or to response to questions from dentists. Questions have been raised about the dentist’s responsibilities if they utilize another provider for the sedation or anesthesia. Required equipment may be brought to the office by the other provider, but the patient’s dentist must be aware of what is required and ensure that it is available.</i>

		<i>administering the sedation or anesthesia, it is the responsibility of the patient’s dentist to ensure that all required equipment is in good working order and immediately available and that qualified persons are administering and monitoring the patient.</i>	
110	Sets out the requirements for administration of deep sedation or anesthesia	<i>Based on public comment, the Board deleted “heart rate” in Subsection G on monitoring requirements as redundant of “pulse” which is already required.</i>	<i>The change is clarifying.</i>
		<i>Subsection D was amended in response to concerns from self-certified dentists about meeting the requirements for a conscious/moderate sedation permit. The ability to administer under a temporary permit was from one year after the effective date of the emergency regulations (September 14, 2014) to one year from the effective date of final regulations. Based on public comment, the Board deleted “heart rate” in Subsection J on monitoring requirements as redundant of “pulse” which is already required.</i>	
120	Sets out the requirements for administration of conscious/moderation sedation	<i>*Subsection D was amended to extend the temporary permit for a dentist who was self-certified in 1989 from one year after the effective date of the emergency regulations (September 14, 2014) to one year from the effective date of final regulations (which will likely be sometime in 2015). Based on public comment, the Board deleted “heart rate” in Subsection J on monitoring requirements as redundant of “pulse” which is already required.</i>	<i>The change was adopted in response to concerns from self-certified dentists about meeting the requirements for a conscious/moderate sedation permit. The Board believes specified training and education is necessary but wanted to grant dentists more time to comply.</i>

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Proposed regulations were published and posted for comment from November 7, 2013 to December 6, 2013; a public hearing was conducted on November 8, 2013.

Commenter at Public Hearing	Comment	Board Response to Comment
Dr. Preston Burns Va. Association of Dentists by Intravenous Sedation	Organization has been providing CE courses for dentists administering conscious sedation for nearly 10 years. Organization supports proposed regulations, except proposal to end self-certification and opposition to some of the required equipment. Was self-certified for conscious sedation in 1989 & should be allowed to continue with a permanent conscious/moderate sedation permit without additional qualifications. Contrary to the stated goal of allowing persons currently qualified to administer sedation, the proposed regulations would preclude one category of qualified dentists from practicing conscious sedation. The estimated expense for a course is \$75,000 to \$100,000.	The Board does not agree that dentists who were self-certified in conscious sedation should be exempt from the requirements for specified education and training. Under the proposed regulations, compliance with permit requirements was required by September 14, 2014, which was one year from the effective date of the emergency regulations for the self-certified dentists to meet the requirements and be issued a permanent permit. However, the Board amended the proposed regulations to allow an additional period of time for compliance of one year from the effective date of the final regulations. Self-certified dentists have been issued a temporary permit to allow continuation of practice until the compliance deadline.
Dr. James Pollard	Received training in IV sedation at MCV in '72 and have used it successfully. Opposed to limitation on ability to treat patients with that modality. The death of 3 children is reason for emergency regulations. Only a few places in the U. S. that offer the training. Self-certified dentists have an impeccable record, so the risks are very slight. Patients will have to seek other dentists, which restricts their access to good care. Oral medication may be the bigger problem but getting the titration accurate can be guesswork & then if there is a problem, you have to start an IV.	Same response as above.
Dr. Scott Leaf	Is a pediatric dentist; has a temporary permit. Had courses in conscious sedation in residency at Georgetown but cannot produce documentation of training content from the 1980's. Met all the requirements at the time but proof of training content is problematic. Requests modification of documentation requirement.	Same response as above. No changes to the documentation requirements were adopted.
Dr. Rod Mayberry	Been practicing moderate/conscious since	Same response as above. There were

	<p>1978 & trained at MCV; have sedated many patients without serious complications. Regulations are an intrusion into practice and not in patient's best interest. Mandating ACLS and unnecessary training is unnecessary for doctors that have a proven history of success with IV sedation. Some equipment requirements are unnecessary as well, such as laryngoscopes, electrocardiograms, endotracheal tubes will never be used. CPR and cardiac defibrillators should be required for emergency but not much more is needed to preserve a life. Supports required CE updates. Problem is sedation in children; no need for blanket regulations and mandates.</p>	<p>no changes to the requirement for ACLS training or the emergency equipment; the Board believes both are required for patient safety.</p>
<p>Dr. Brian McAndrew</p>	<p>Representing the Va. Society of Oral and Maxillofacial Surgeons. Concern about definition of morbidity and which events have to be reported under the new guidelines. What events require a written report?</p>	<p>The Board has a current requirement for reporting adverse reactions or events (section 140). That requirement was moved to section 107, under General provisions. Guidance document 60-4 (adopted in 2006) provides the Board's guidance on the meaning of "morbidity" for reporting of adverse reactions.</p>
<p>Kenneth Stallard</p>	<p>Represents Va. Association of Dentists for Intravenous Sedation; providing information about how other states permit dentists to do conscious/moderate sedation. Maryland allowed all dentists who held a parenteral sedation permit and facility permit to convert under its new regulations. NC also grandfathered current permit holders. In WV, the Board accepted documented evidence of equivalent training or experience for issuance of a permit. SC allows educational requirements to be waived for dentists who have been utilizing conscious sedation for at least 10 years. IL and TN allowed grandfathering of dentists holding a permit for administration of conscious sedation. CT allows an application for conscious sedation permit to be qualified by documenting completion of 12 parentally-administered procedures per year for 3 years prior to the date of application with completion of CE. Several of these jurisdictions do not require EKG. Language regarding other appropriate airway management adjunct such as a laryngeal mask airway should be deleted from its present location and reinserted after the word "adult." The association does not believe precordial and pretracheal stethoscopes are warranted in</p>	<p>Same response regarding exemption for self-certified dentists and modification to equipment requirements.</p>

	conscious/moderate sedation of adult patients. Board should allow self-certified dentists to continue administration of conscious/moderate sedation without additional educational requirements.	
Dr. Michael Link	Concern about deletion of definition for anxiolysis. Should not use the term "minimum sedation" because it might increase malpractice rates if a dentist checks that he uses sedation.	The term and definition used by the Board is the American Dental Association (ADA) definition of "minimal sedation" so the Board has not amended it.

Other Commenters	Comment	Board response to comment
Dr. Stanley Dameron	Has been utilizing conscious sedation since 1979 with training at Univ. of Md hospital, general practice residency. Section 120 states that laryngeal mask airways are acceptable but a laryngoscope and blades are still necessary equipment; laryngoscopes are not used with LMA's. Self-certified dentists should be grandfathered so they can continue providing care to patients.	Same response regarding exemption for self-certified dentists and modification to equipment requirements.
Dr. Preston Burns Va. Association of Dentists for Intravenous Sedation	Provided an edited copy of the proposed regulations with amendments to: 1) add "moderate sedation" to the definition and usage of "conscious/moderate sedation;" 2) allow dentists who were self-certified in administration of moderate sedation to be issued a permit without additional education & training; 3) eliminate requirements training in interpretation of an EKG and an EKG in the dental office where parental sedation or sedation with titration is administered; 4) modify the requirement for airway management adjuncts; and 5) eliminate requirement for precordial and pretracheal stethoscope;	Same response regarding exemption for self-certified dentists and modification to equipment requirements.
Dr. Brian McAndrew Va. Society of Oral & Maxillofacial Surgeons	Recommends: 1) That the permit exemption remain but language be added to restrict an OMS to performing anesthesia only in their primary or affiliated surgery offices. The OMS should sign an affidavit that the satellite offices are held to the same standard as the inspected office for equipment and staff. 2) OMS who desire to provide "itinerant anesthesia" in offices of dentists who do not have permits are not covered under the exemption and must obtain a permit from the Board.	1) Section 54.1-2709.5 of the Code of Virginia specifies that: "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." Therefore, the law does not allow an OMS to sign an affidavit that a satellite office meets the same standard. An OMS exemption from the requirement for a sedation or anesthesia permit applies only to those who can provide a report of

		<p>the periodic office examinations required by AAOMS.</p> <p>2) To address the use of “itinerant anesthesia” provided in dental offices where the dentist does not hold a permit, the Board has added subsection J of section 107.</p>
<p>Dr. Brian Hoard UVA Dept. of Dentistry</p>	<p>Recommends:</p> <p>1) Leave the definitions of anesthesia and sedation but go strictly by the ASA definition</p> <p>2) Isn’t necessary to have written consent in patient record for any level of sedation, such as nitrous. (section 107)</p> <p>3) Should include an exception for patients under the age of 12 to have medication administered prior to arrival at dental office if “there is a previously documented trial period with the sedative medication and dose or the patient’s physician prescribes an anxiolytic in advance to facilitate entrance to the facility.” (section 107)</p> <p>4) Wants clarification about whether the 2nd person in the operatory can act as both the dental assistant and the monitor.(sections 108 and 120)</p> <p>5) Should restate “pulse and heart rate” as they are redundant; does the Board mean “heart rate and rhythm”</p>	<p>1) Definitions are consistent with ADA; the ASA does not define those terms in the context of office-based anesthesia.</p> <p>2) The requirement for written consent in the patient record is not new; its intent has been clarified to specify that it applies to all levels of sedation and anesthesia.</p> <p>3) The Board has followed the guidelines of the Academy of Pediatric Dentistry and the American Academy of Pediatrics in its proposed rule.</p> <p>4) The Board has concurred that the 2nd person can act as both assistant and monitor.</p> <p>5) The Board has amended the regulation accordingly.</p>
<p>Dr. M. Scott Gore Dr. Jared Hoover Dr. Amanda Hoover</p>	<p>Opposed to the requirement for an EKG when performing oral sedation with titration. Patients are monitored for heart rate, blood pressure and oxygen saturation; EKG monitoring is not necessary for patient safety. Costs will increase. Patients will have to partially disrobe and there isn’t an adequate space for privacy. Other states do not require EKG for oral sedation.</p>	<p>The Board does not require EKG for a single dose of oral sedation; but if a dentist is titrating, there is a risk of the patient entering a deeper level of sedation than what was intended. In the interest of patient safety, the Board believes an EKG should be available should an emergency arise.</p>

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.

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.</p> <p>Definitions for "Conscious/moderate sedation," "Deep sedation," General anesthesia” and “Minimal sedation” are taken from the <i>Guidelines for Teaching Pain Control and</i></p>

		<p><i>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>There are no changes from the proposed regulation</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 proposed 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</p>

		<p>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 patient 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> <ol style="list-style-type: none"> 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. <p>2) <i>Changes from the proposed regulations are:</i> <i>Subsection E is amended to clarify that the content of the patient record of administration of sedation or anesthesia is the responsibility of the dentist.</i> <i>Subsection F –The term “child” is deleted and replaced with “patient” because the rule is applicable if the person under age 12 years is a patient.</i> <i>Subsection I (and all other sections of regulation in which conscious sedation is used) is amended for consistency with the definition for the term “conscious/moderate” sedation.</i> <i>Subsection J is added to clarify that, regardless of who is administering the sedation or anesthesia, it is the responsibility of the patient’s dentist to ensure that all required equipment is in good working order and immediately available and that qualified persons are administering and monitoring the patient. Questions have been raised about the dentist’s responsibilities if they utilize another provider for the sedation or anesthesia. Required equipment may be brought to the office by the other provider, but the patient’s dentist must be aware of what is required and ensure that it is available.</i></p>
108	Sets out requirements for	1) Based on questions received by phone and email, there

	<p>administration of minimal sedation</p>	<p>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.</p> <p>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.</p> <p>2) <i>There are no changes from the proposed regulations.</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</p>

		<p>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. 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.”</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) Change from the proposed regulations: Based on public comment, the Board deleted “heart rate” in the subsection on monitoring requirements as redundant of “pulse” which is already required.</i></p>
120	Sets out the requirements for a permit to administer conscious sedation	<p>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.</p> <p>1) 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.</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</p>

		<p>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 to allow time to obtain the necessary education and training for a permanent 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> <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 proposed regulations:</i></p>
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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). The title of section 135 was changed from “Ancillary personnel” to “Personnel assisting in sedation or anesthesia” to clarify the intent and applicability.</p> <p><i>2) There were no changes to the proposed regulations.</i></p>
140	<p>Sets out requirements for reporting adverse reactions</p>	<p>The section is repealed as the requirements for reporting are contained in section 107 on General Requirements.</p>