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Final Regulation Agency Background Document

Agency name	Board of Dentistry, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC60-21
VAC Chapter title(s)	Regulations Governing the Practice of Dentistry
Action title	Rules for sedation and anesthesia
Date this document prepared	12/14/20

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

The Board has amended regulations relating to administration of sedation or anesthesia in dental offices for greater consistency and clarity among the requirements, depending on the level of sedation and the risk to the patient, and closer alignment with the American Dental Association Guidelines for the Use of Sedation and General Anesthesia. The Board amended provisions that are problematic to dentists, such as compliance with current regulations with special needs patients. When appropriate for patient safety, the Board has incorporated guidelines and best practices for sedation and anesthesia.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

N/A

Statement of Final Agency Action

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 taking the action; and 3) the title of the regulation.

On December 11, 2020, the Board of Dentistry amended 18VAC60-21-10 et seq., Regulations for the Practice of Dentistry.

Mandate and Impetus

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously reported information, include a specific statement to that effect.

In the promulgation of regulations relating to revision of American Dental Association (ADA) guidelines for the education and training of dentists who administer moderate sedation, there were comments on the NOIRA and on proposed regulations that more broadly addressed the need to revise requirements for sedation and anesthesia. Commenters noted the need for changes relating to delegation to a certified registered nurse anesthetist and the need for consistency and clarification in the levels of sedation and anesthesia. That was the impetus for this regulatory action and the formation of a Regulatory Advisory Panel to review all regulations for administration of sedation and anesthesia.

There are no changes to the previously reported information.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Dentistry the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards
The general powers and duties of health regulatory boards shall be:

1. To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.

2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.

3. To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.

...

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. ...

Specific statutory reference to issuance of sedation and anesthesia permits and requirements for equipment standards 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

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

The Regulatory Advisory Panel of experts and the members of the Board heard comment on the current regulations for administration of sedation and anesthesia and reviewed current guidelines published by the American Dental Association. Accordingly, amendments are recommended to allow for exception to rules if there are extenuating circumstances in providing care to certain patients. Amendments are also recommended to address concerns about patient safety, such as a requirement for a dentist to follow the regulations for the level of sedation that has been induced during a dental procedure.

Administration of sedation and anesthesia in a dental office requires appropriate expertise, equipment and monitoring in order to adequately and immediately address any adverse reaction or emergency situation. Rules proposed by the Board specify what is required to protect public health and safety in such administration.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

The substantive provisions being proposed include:

- Clarification of supervision of certified registered nurse anesthetists
- Clarification that the regulations address administration to patients of any age, but that the specific guidelines for pediatric patients should be consulted when practicing pediatric dentistry.
- Requirement for a focused physician examination to be included in the patient evaluation for administration of controlled substances.
- Allowances for special needs patients in the evaluation for, administration, and monitoring of sedation and anesthesia with documentation in the patient record of the extenuating circumstances when necessitate exceptions to regulatory requirements.
- Clarification of the requirements for minimal sedation and inclusion of oxygen saturation with pulse oximeter as required equipment.
- Specific requirement that the dentist must follow requirements for the level of sedation that has been induced and that administration of one drug in excess of recommended dosage or of two or more drugs, exceeds minimal sedation.
- Clarification that no sedating medication can be administered to a child 12 years or younger prior to arrival at the dental office.
- Permitting consideration of extenuating patient circumstances in the monitoring and discharge requirements,
- Adding oxygen saturation levels to the monitoring requirements.
- Clarification that requirements for moderate sedation or deep/general anesthesia must be followed by the dentist if he administers controlled substances or if he provides it in his office with someone else doing the administration.
- Requirement for a longer period of monitoring if a pharmacological reversal agent has been administered.

Issues

Identify the issues associated with the regulatory change, 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, include a specific statement to that effect.

- 1) The primary advantage to the public is more clarity and greater protection for patients in the administration of various levels of sedation or anesthesia in a dental office. There are no disadvantages.
- 2) There are no advantages or disadvantages to the agency or the Commonwealth.
- 3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under § 54.1-2400 “*To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system...*” The rules for sedation and anesthesia in a dental office are mandated by the Code and are intended to protect the public receiving such services. Therefore, the proposed amendments are a foreseeable result of the statute requiring the Board to protect the safety and health of patients in the Commonwealth.

Requirements More Restrictive than Federal

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously reported information, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Please identify any other state agencies, localities, or other entities particularly affected by the regulatory change. “Particularly affected” are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. “Locality” can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected - None

Localities Particularly Affected - None

Other Entities Particularly Affected - None

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

There was a 60-day comment period from 9/14/20 to 11/13/20.

The following comments were made on 11/13/20 at 9:30 a.m. during the public hearing on proposed regulations for the administration of sedation and anesthesia.

Commenter	Comment	Board response
Dr. Christopher Richardson	Opposed to requiring a 3 rd person in the room during moderate sedation. Stated that national guidelines from the American Dental Association only require one person in addition to the dentist. Raised concern over the danger of an additional person during the Covid-19 pandemic. Proposal will raise costs to patients.	In response, the Board amended subsection C of section 291 to maintain the current requirement for a 2-person team.
Dr. Thomas Glazier	Believes 3-person team is not rooted in evidence. He stated that moderate sedation has a 99% safety record with the current two-person team.	
Dr. Stephanie Voth	Dr. Voth agrees with Dr. Richardson’s comments. Expressed concern that regulation will make it more difficult for patients to receive moderate sedation.	
Dr. Yousuf Al-Aboosi	Agrees with the other iterations. Believes additional person may make a patient more nervous.	
Ms. Michele Satterlund, Representing Virginia Association of Nurse Anesthetists	Concerned that certified registered nurse anesthetists (CRNAs) are limited to administering moderate sedation only under the supervision and direction of dentists who hold moderate sedation permits. Believes these permits are unnecessary as CRNAs are licensed to administer moderate sedation just as anesthesiologists.	In response, the Board amended subsection A of section 291 to allow CRNAs to administer moderate sedation in a dental office with a dentist who does not hold a sedation permit.

The following comments were received by email or in the regular mail:

Commenter	Comment	
Erik Roper	Recommends the Board to follow the 2-person standard set by national guidelines. Notes record of safety with 2-person	See response above

<p>Dr. Stephanie Voth, Representing Virginia Family Dentistry Yousuf Al-Aboosi Dr. Neil Turnage</p>	<p>teams. Concerned that additional person adds unnecessary danger during the coronavirus pandemic.</p> <p>Same as comments made during public hearing on 11/13</p> <p>Same as comments made during public hearing on 11/13</p> <p>Concern for patient safety during coronavirus pandemic. Believes regulations will not make patients safer but will make it more difficult for patients with severe anxiety to receive care.</p>	
<p>Dr. Tyler Perkinson</p>	<p>Believes 3-person team will not add to patient safety but will make it harder for patients to access care. Concern for increased exposure to coronavirus. Worried that fewer dentists will be able to perform sedation for patients with extreme anxiety and extensive dental restorative needs who need a general dentist rather than a specialist.</p>	
<p>Dr. Shravan Renapurkar, President and Dr. N. Ray Lee, Anesthesia Comm. Chair Virginia Society of Oral & Maxillofacial Surgeons</p>	<p>Recommends more specification for the supervision required for administration of sedation or anesthesia by a CRNA. Interprets current supervision as allowing sedation to occur without the supervising physician physically in the facility. Concern for patient safety during anesthetic emergencies. Dentists without sedation/anesthesia permits may not be trained in anesthesia emergencies and may not have appropriate equipment and drugs.</p> <p>Suggests Board adopt a clear time interval requirement for recording the vital signs to uphold patient safety. Notes the standard of care is 5 minutes. Offers that pediatric patients could be considered for exclusion from the standard of care with proper documentation, but would not apply this deference to all patient cases.</p>	<p>Regulations governing the practice of CRNAs do not require the physical presence of a supervising physician, so the Board did not impose such a requirement.</p> <p>In response, the Board amended subsection E of section 301 to maintain the current requirement of recording every five minutes.</p>

<p>Jean Snyder, President, Virginia Association of Nurse Anesthetists</p>	<p>Believes regulations arbitrarily give preference to anesthesiologists over CRNAs. Notes that Virginia law does not limit CRNA delegation to outpatient surgery centers. Suggests the Board allow CRNAs to administer sedation in dental offices with non-permitted dentists as the Board allows anesthesiologists to do.</p>	<p>See response to CRNAs above</p>
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Detail of Changes Made Since the Previous Stage

*List all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Current chapter-section number	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
21-291	Clarification that a dentist without a sedation permit for utilize services of a qualified anesthesia provider to administer sedation in a dental office	Inclusion of a certified registered nurse anesthetist to provide sedation services	The change will allow a CRNA to be the provider of moderate sedation in a dental office when the dentist does not hold a moderate sedation permit. A CRNA must practice under supervision, but it is not required that the supervising dentist or doctor be physically present when sedation or anesthesia is administered by a CRNA. Since a dental office that provides sedation must have all of the required equipment available (whether or not the dentist holds a permit), a CRNA is trained (as is an anesthesiologist) to handle emergency situations that might arise. Therefore, subsection A was amended to take away the restriction that a CRNA could only provide sedation services in an outpatient surgery center with an unpermitted dentist.
21-291	Requirement for a three-person treatment team when moderate sedation is administered during a dental procedure	Deletion of “three-person” and return to the requirement for a “two-person team	The Board responded to comment that the three-person team exceeded new guidelines from the ADA, that is would add to cost, and would reduce access to sedation dentistry. The Board is satisfied that the safety record for sedation of adults with a two-person team is adequate to protect the public.
21-301	Requirement in subsection E that vital signs be monitored continually and recorded	Return to current requirement for specific time frame for recording of vital signs of every five minutes	The Board responded to comment that it was not in the interest of patient safety to eliminate the specific time frame for recording of vital signs. Recording every five minutes is the standards in sedation, so that language was reinstated.

Detail of All Changes Proposed in this Regulatory Action

List all changes proposed in this action and the rationale for the changes. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
10	Defines words and terms used in the chapter	<p>In subsection C, amendments are proposed to:</p> <p>“Direction” to include a certified registered nurse anesthetist” to whom sedation or anesthesia may be delegated.</p> <p>“Indirect supervision” to include a certified registered nurse anesthetist” and to add the administration of sedation or anesthesia as authorized by law or regulation.</p> <p>In subsection D, definitions are added for the words “continual or continually” and “continuous or continuously” to provide context for the use of those terms in regulation of monitoring sedation or anesthesia.</p> <p>“Minimal sedation” is amended to delete the words “anxiolysis” and “anxiolytic” as those terms are no longer used in dentistry.</p> <p>The word “provide” is defined in the context of regulations for moderate sedation and deep sedation/general anesthesia to clarify the a dentist who does not hold a permit cannot be the “provider” of the sedation or anesthesia.</p>
260	Sets out the general provisions for sedation and anesthesia in dental practices	<p>Subsection A is amended to reference specific guidelines for pediatric patients that should be consulted by any dentist practicing pediatric dentistry.</p> <p><i>The RAP did not recommend that the guidelines be incorporated by reference but believed it was important to note the need to consult if a dentist has pediatric patients.</i></p> <p>Subsection B is amended to require an appropriate medical history and patient evaluation and a focused exam before the decision is made to administer controlled substances.</p> <p><i>Current regulations require that the decision to administer must be based on a documented evaluation of the health history and current medical condition of the patient. The</i></p>

		<p><i>amended requirement stipulates what is involved in doing the documented evaluation.</i></p> <p>Subsection D is amended to change the requirement for monitoring vital signs and physiological measures every five minutes to monitoring continually.</p> <p><i>Five minutes is an arbitrary timeframe; what is necessary is monitoring continually, which means repeated regularly and frequently.</i></p> <p>Subsection E is amended to clarify that a sedating medication cannot be prescribed for administration to a pediatric patient prior to arrival at the dentist office.</p> <p><i>There was question about whether the current rule only meant the dentist could not administer. (The same change is made in other sections relating to administration to a patient 12 years of younger.)</i></p> <p>Subsection M is added to establish exceptions for special needs patients.</p> <p><i>The RAP and the Board have heard comment from dentists describing patients and situations in which there are physical or mental conditions that make it impossible to follow the process for administration of sedation or anesthesia. Such conditions and circumstances preclude the patient from receiving the needed dental care. The determination of when a patient is “mentally or physically challenged” is made by the dentist who is responsible for documenting in the patient record to reasons preventing the recommended preoperative management.</i></p>
270	Establishes the requirements for administration of <u>local</u> anesthesia	In #5, the word “medical” is deleted because a certified registered nurse anesthetist is under the direction of a dentist in the context of these regulations.
279	Establishes the requirements for the administration of only nitrous oxide or inhalation analgesia	<p>Subsection D is amended to add equipment that must be available and used to monitor a patient under minimal sedation to include pulse oximeter (unless extenuating circumstances exist).</p> <p><i>Currently, there are requirements for monitoring vital signs and observing the patient’s color, respiratory rate, etc. The way to measure oxygen saturation is with a pulse oximeter, so that was added to required equipment.</i></p> <p>Subsection F was amended to provide that baseline vital signs should be monitoring during the dental procedure as necessary.</p> <p>Subsection G on discharge requirements was amended to mirror the language about monitoring vital signs during the procedure, unless extenuating circumstances exist and are documented.</p>

280	Establishes the requirements for minimal sedation	<p>Subsection C is amended to correct a regulatory cite and to clarify that a dental hygienist qualified in the administration of nitrous oxide may do so under indirect supervision. <i>That is not a change in policy; it is a clarification.</i></p> <p>#3 in subsection C is deleted because no sedation is to be administered to a pediatric patient prior to arrival at the dental office. <i>The current rule is inconsistent with other provisions of regulation.</i></p> <p>Subsection F is amended to include oxygen saturation as a vital sign to be taken and monitored. The requirement to monitor vital signs is changed from “continuously” to “continually” which is consistent with the new definition and the intent of the requirement. The possibility of extenuating circumstances was inserted. <i>That is a standard of care for all types of sedation.</i></p> <p>#4 in subsection F is amended to specify that nitrous may be used with one other pharmacological agent in the recommended dosage for minimal sedation. The regulation also requires that if deeper levels of sedation are produced, the regulations for that level must be followed. The administration of a drug in excess of recommended maximum dosage or administration two or more drugs exceeds minimal sedation. <i>Despite comment from some dentists to the contrary, the ADA standards for minimal sedation have been adopted in regulation and are necessary to ensure patient safety. If dentists are allowed to exceed the <u>maximum</u> recommended dosage or to administer more than one controlled substance, the patient is at risk of a deeper level of sedation than was intended.</i></p> <p>#5 is added to move the current language that was stricken in #4.</p> <p>Subsection G is amended to include oxygen saturation and the extenuating circumstances language.</p>
290	Establishes the requirements for a moderate sedation permit	<p>Subsection A is amended to mirror the language in the Code stating that no dentist may “provide or administer” moderate sedation in a dental office unless he has been issued a permit.</p>
291	Establishes the requirements for administration of moderate sedation	<p>In adoption of final regulations, Subsection A is was amended to allow a dentist without a permit to utilize the services of a permitted dentist, an anesthesiologist, or a certified registered nurse anesthetist to administer moderate sedation. Amendments in subdivision c clarify that the certified nurse anesthetist may work under the direction of a dentist with a sedation permit or under the supervision of a doctor.</p>

		<p>#3 is amended to delete conflicting language relating to administration of a sedating medication for a pediatric patient prior to his arrival at the dental office. It is clearly prohibited in the second sentence.</p> <p>Subsection B is amended to clarify that a dentist who provides or administers or who utilizes a qualified anesthesia provider to administer is responsible for have all required equipment in working order and immediately available.</p> <p>There are two amendments to the equipment requirements: 1) changing throat pack to airway protective device as an update in terminology; and 2) adding equipment necessary to establish intravenous or intraosseous access in case a rescue medication must be administered.</p> <p>In subsection C, in response to public comment, the requirement for a three-person treatment team for moderate sedation was changed back to a requirement for a two-person treatment team.</p> <p>Subsection D is amended to specify which vital signs should be monitored. <i>Some dentists had requested more specificity.</i> It is also amended to change the requirement for monitoring vital signs every five minutes to monitoring continually, unless precluded or invalidated by the nature of the patient, procedure, or equipment. <i>Five minutes is an arbitrary timeframe; what is necessary is monitoring continually, which means repeated regularly and frequently.</i></p> <p>Subsection E is amended to change “circulation” to blood pressure and heart rate, which are measurable vital signs. Additional language is included to specify that oxygen and suction equipment must be immediately available if a separate area is used for recovery. <i>Such a requirement is standard of care and a common sense provision.</i></p> <p>Finally, there is a requirement for a patient to be monitored for a longer period of time if a reversal agent has been administration because there is a risk of re-sedation.</p>
300	Establishes the requirements for a deep sedation/general anesthesia permit	Subsection A is amended to mirror the language in the Code stating that no dentist may “provide or administer’ deep sedation or general anesthesia in a dental office unless he has been issued a permit.
301	Establishes the requirements for administration of deep sedation or general anesthesia	In section 301, there are the same additions and amendments as those found in section 291 for consistency in delegation and patient care with requirements for moderate sedation.

