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Proposed Regulation
Agency Background Document

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

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 (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

Brief Summary

Please 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, such as the use of a three-person team in the operatory during administration of moderate sedation.

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.

N/A

Mandate and Impetus

Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, board decision, etc.). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

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.

Legal Basis

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

Please 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 and a requirement for there to be a three-person team in the administration of moderate sedation 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

Please 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.
- Clarification of use of the terms continuously and continually, as used in the context of the regulation.
- Permitting consideration of extenuating patient circumstances in the monitoring and discharge requirements
- Adding oxygen saturation levels to the monitoring requirements.
- Requirement for a three-person team for moderate sedation – the operating dentist, one person to monitor the patient, and one person to assist the dentist.
- 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

Please 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

Please identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, 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

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, please identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic

impact, specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that this is change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	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 will incur no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Since most mailings to the PPG list are handled electronically, there is very little cost involved. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There are no on-going costs.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	No other agencies are affected
For all agencies: Benefits the regulatory change is designed to produce.	There are no benefits.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	None
Benefits the regulatory change is designed to produce.	None

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Licensed dentists who administer sedation or anesthesia in a dental office or those who utilize a qualified anesthesia providers to administer
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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are 7,463 dentists licensed in Virginia. It is likely the vast majority are small businesses. Of that number, 243 hold a moderate sedation permit, and 56 hold a permit for deep sedation/general anesthesia. Oral and maxillofacial surgeons who hold membership in the American Association of Oral and Maxillofacial Surgeons (AAOMS) are not required to hold a permit but are subject to regulations for sedation and anesthesia; there are 265 oral and maxillofacial surgeons.

	The Board has no estimate of the number of dentists who offer minimal sedation or nitrous oxide only because they are not required to hold a permit; they are subject to regulation for those types of sedation. The Board also has no estimate of the number who may employ an anesthesiologist or another qualified and permitted dentists.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	A dentist who provide inhalation analgesia may have to purchase a pulse oximeter to meet the requirement for monitoring oxygen saturation. One can be purchased for less than $15.
Benefits the regulatory change is designed to produce.	By reflecting national standards for administration of sedation or anesthesia, the regulations are beneficial to the public who may seek or require sedation administration as part of a dental procedure.

Alternatives

Please describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.

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. The Board responded that comments were not specific to the subject of that regulatory action, but that they would be considered in the context of an overall review of regulations for sedation and anesthesia.

To conduct such a review, the Board convened a Regulatory Advisory Panel (RAP), consisting of two board members, the Dean of the VCU School of Dentistry and Chair of the ADA committee that reviewed Guidelines for the Use of Sedation and General Anesthesia by Dentists, a pediatric dentist, and an oral and maxillofacial surgeon. The RAP held an open forum for public comment and then met on December 1, 2017 to review all comments and the ADA guidelines for regulation.

A second meeting of the RAP was held on February 2, 2018 to review draft amendments and approve recommendations to the Regulatory-Legislative Committee of the Board. At the March 8th meeting of the Committee, the proposed changes were reviewed and a motion to issue a NOIRA was forwarded to the Board for its adoption on March 9, 2018. The proposed changes address issues identified by public comment and reflect consistency with the 2016 ADA Guidelines. The Board believes they are the least restrictive requirements consistent with the safe administration of sedation and anesthesia in a dental office.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing 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 regulatory change.

There are no alternative regulatory methods consistent with public health and safety.

Public Comment

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

Commenter	Comment	Agency response
Jefferson Blackburn	Opposed to requiring a 3rd person in the room during moderate sedation	The Board discussed the comments in opposition to requiring a 3rd person but has proposed the amendment out of concern for patient safety. Typically, the 2nd person is assisting the dentist with the procedure, so there needs to be a 3rd person whose job it is to monitor the patient to ensure he or she does not slip into a deeper level of sedation or has complications.
Dr. Thomas Padgett	Noted an editorial change	Change was made
John Unkel, DDS	Opposed to requiring a 3rd person in the room during moderate sedation	See response above
Chris Richardson, DMD	Notes that national guidelines do not require a 3-person team in dental office in the delivery of moderate sedation.	While the ADA guidelines do not specify a 3-person team, they do specify that the person designated to monitor the patient "should not be a member of the procedural team." The Board believes there should be an assistant for the dental in performing the dental

		procedure and another person to monitor the patient receiving moderation sedation.
Jonathan Wong, DMD	Notes there is a separate regulatory action on conforming to ADA guidelines on moderate sedation. A second and third comment noted extensive questions and recommendations on language in the draft.	The referenced action related to qualification for a moderate sedation permit; it became effective 11/28/18. The Board considered the comments from Dr. Wong.
Lillie Pitman, DMD	Notes that the 3-person team for moderate sedation should read for "deep" sedation.	Currently, regulations already require a 3-person team for deep sedation; the Board made a policy decision relating to moderate sedation.
Benjamin Watson, DDS	Board seems to be heading towards requiring all sedations to have an IV permit. 2nd comment about minimal sedation restriction to maximum recommended dosage	The Board has made distinction among the various levels of sedation; delivery of nitrous oxide only or delivery of minimal sedation do not require a permit. The Board has not proposed such a requirement.
James Tom, DDS	Requiring a 3rd person on the team for moderate sedation is unnecessary because the patient himself is providing verbal and purposeful response to the dentist.	The Board chose to follow the recommendation of the RAP, which included Virginia dentists with expertise in anesthesia.
Aaron Stump, DDS	Asked for clarification on the monitoring of vital signs in minimal sedation	Monitoring requirements are specified in subsection F of 18VAC60-21-280.
Josh Hanson	Questioned deletion of the requirement for monitoring blood pressure every 5 minutes; can't be done every second. Disagreed with 3-person team	The commenter should read the definition of "continually" which replaced every five minutes. The RAP noted that every five minutes is too prescriptive, but the monitoring should be repeated "regularly" and frequently in a steady succession (definition of continually)
Dr. Kim Kitchen	Proposal places limits on oral sedation	The Board has not limited oral sedation or minimal sedation but has noted that if deeper level of sedation are produced, the provider needs to be prepared for that.
Dr. Austin Westover	Proposal places limits on oral sedation	The regulations for minimal sedation allow for one drug such as valium in combination with nitrous oxide. The administration in excess of the maximum recommended dosage or the use of two or more drugs is not minimal sedation and requires compliance with a higher level of sedation.
Tontra Lowe, DDS	Proposal places limits on oral sedation	The regulations for minimal sedation allow for one drug such as valium in combination with nitrous oxide. The administration in excess of the maximum recommended dosage or the use of two or more drugs is **not minimal sedation** and requires compliance with a higher level of sedation. Board regulations are consistent with ADA guidelines and are the established standard of care.

Joseph McIntyre, DDS	Same comment as above	Same response
Bryant Ash, DDS	Same comment as above	Same response
Nadia Armentrout, DDS	Same comment as above	Same response
Daniel Whiting, DMD	Same comment as above Also opposed to requiring 3rd person in operatory	Same response A 3rd person is not a requirement for a dentist using minimal sedation.
Christopher Salas, DDS	Same comment as above	Same response
Mesfin Zelleke	Same comment as above	Same response
John Bitting, Counsel for DOCS	Opposed to restriction of recommended dosage of a drug; should be able to exceed recommended dosage on a case by case basis.	The Board respectively disagrees and has conformed its regulation to the ADA guidelines.
Julie Hawley, DDS	Same comment as above	Same response
Damon Thompson	Same comment as above	Same response
Myra Branch, President Va. Association of Nurse Anesthetists	Language inconsistent with statute that requires any dentist who provides or administers sedation or anesthesia in a dental office to have a permit. Draft regulation would allow delegation to an anesthesiologist.	The draft regulation was amended to define "provide" to mean, in the context of regulations for sedation, to supply, give or issue. The Board did not believe the General Assembly intended for a dentist to be unable to employ an MD with a specialty in anesthesia to administer anesthesia during a dental procedure. The sections on moderate sedation and deep sedation/general anesthesia were also amended to be consistent with the statute by saying that no dentist who does not hold a permit can "provide or administer." The regulations were further amended to specify that a dentist without a permit can "utilize" the services for a qualified dentist or an anesthesiologist to administer.

Public Participation

Please include a statement that in addition to any other comments on the regulatory change, the agency is seeking comments on the costs and benefits of the regulatory change and the impacts of the regulated community. Also, indicate whether a public hearing will be held to receive comments.

In addition to any other comments, the Board of Dentistry 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 comments may do so via the Regulatory Town Hall website (**http://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 midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action 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 (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

Detail of 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	In subsection C, amendments are proposed to: "Direction" to include a certified registered nurse anesthetist" to whom sedation or anesthesia may be delegated. "Indirect supervision" to include a certified registered nurse anesthetist" and to add the administration of sedation or anesthesia as authorized by law or regulation. 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. "Minimal sedation" is amended to delete the words "anxiolysis" and "anxiolytic" as those terms are no longer used in dentistry. 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.
260	Sets out the general provisions for sedation and anesthesia in dental practices	Subsection A is amended to reference specific guidelines for pediatric patients that should be consulted by any dentist practicing pediatric dentistry.

		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. 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. *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 amended requirement stipulates what is involved in doing the documented evaluation.* Subsection D is amended to change the requirement for monitoring vital signs and physiological measures every five minutes to monitoring continually. *Five minutes is an arbitrary timeframe; what is necessary is monitoring continually, which means repeated regularly and frequently.* 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. *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.)* Subsection M is added to establish exceptions for special needs patients. *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.*
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	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). *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.*

		Subsection F was amended to provide that baseline vital signs should be monitoring during the dental procedure as necessary. 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.
280	Establishes the requirements for minimal sedation	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. *That is not a change in policy; it is a clarification.* #3 is subsection C is deleted because no sedation is to be administered to a pediatric patient prior to arrival at the dental office. *The current rule is inconsistent with other provisions of regulation.* 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. *That is a standard of care for all types of sedation.* #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. *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.* #5 is added to move the current language that was stricken in #4. Subsection G is amended to include oxygen saturation and the extenuating circumstances language.
290	Establishes the requirements for a moderate sedation permit	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.

291	Establishes the requirements for administration of moderate sedation	Subsection A is amended to mirror language in the Code but to clarify that a dentist without a permit can utilize the services of a permitted dentist or anesthesiologist to administer moderate sedation. Amendments in subdivision c clarify that the certified nurse anesthetist may work under the direction of a dentist but practices under the supervision of a doctor. #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. 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. 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. Subsection C is amended to require a three-person treatment team for moderate sedation. *The Board does not believe that the dentist doing the dental procedure nor the person assisting the operating dentist can appropriately monitor the patient while doing other duties. Therefore, the amended rule is adopted for the sake of patient safety.* Subsection D is amended to specify which vital signs should be monitored. *Some dentists had requested more specificity.* 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. *Five minutes is an arbitrary timeframe; what is necessary is monitoring continually, which means repeated regularly and frequently.* 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. *Such a requirement is standard of care and a common sense provision.* 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.

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.