



## Notice of Intended Regulatory Action (NOIRA) Agency Background Document

<b>Agency name</b>	Board of Dentistry, Department of Health Professions
<b>Virginia Administrative Code (VAC) citation</b>	18VAC60-20-10 et seq.
<b>Regulation title</b>	Regulations Governing the Practice of Dentistry and Dental Hygiene
<b>Action title</b>	Periodic review
<b>Date this document prepared</b>	March 12, 2010

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Purpose

*Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.*

The goal of this action is to update, clarify and reorganize regulations consistent with current practices of the professions and policies of the board. The intent is to repeal the current Chapter 20 and reorganize into four new chapters – Chapter 15 for general disciplinary provisions; Chapter 21 for the practice of dentistry; Chapter 30 for the practice of dental hygiene; and Chapter 40 for the practice of dental assisting. For the most part, the regulations will be consistent with current requirements, but the board intends to add provisions stated in several guidance documents relating to professional conduct, patient health records, reporting of adverse reactions, and administration of controlled substances. Additionally, to update the rules for sedation and anesthesia, the board will utilize the 2007 Guidelines of the American Dental and the 2006 Academy of Pediatric Dentistry Guidelines.

### Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.*

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 regulatory authority for the Board of Dentistry is found in Chapter 27 of Title 54.1.

**Need**

*Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.*

The purpose of the board’s action is to provide the practitioner with clearer rules for practice and treatment of patients and to make the practice of dentistry safer and more transparent for patients. Issues that may need to be addressed as the regulation is developed primarily relate to the provision of anesthesia and sedation in dental practices. While guidelines from the American Dental Association will be utilized, the board will examine each regulation in relation to its effect on public health and safety.

**Substance**

*Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.*

The Regulatory/Legislative Committee of the Board served as the workgroup to conduct the periodic review and recommended that Chapter 20 be repealed and regulations for the professions of dentistry, dental hygiene and dental assisting be reorganized into three new chapters for each profession – Chapter 21, Chapter 30 and Chapter 40. Additionally, the board may adopt a new chapter (Chapter 15) for general disciplinary provisions relating to delegation to an agency subordinate and recovery of disciplinary costs. The structure and content of each chapter is intended to be as follows:

## CHAPTER 21

### REGULATIONS GOVERNING THE PRACTICE OF DENTISTRY

#### Part I General Provisions

Definitions – currently section 10 of Chapter 20

*Several of the terms defined are used in the context of regulation for sedation/anesthesia. Terms and definitions may be amended for consistency with the current American Dental Association (ADA) guidelines.*

Practice of dentistry - new section with reference to practice defined in § 54.1-2711

Exceptions to practice of dentistry – currently 18VAC60-20-240 plus reference to §§ 54.1-2701 and 54.1-2712

Licensee addresses - Section 16 of Chapter 20

Posting requirements - new section with reference to requirements in §§ 54.1-2720 and 54.1-2721 and language from section 110

Required fees – currently in sections 20, 30, 40, 250 and 310 of Chapter 20

#### Part II Standards of Professional Conduct -18VAC60-20-170

Patient information and records -18VAC60-20-15 for required content

*To include language from 2005 Guidance Document 60-3 on the meaning of an updated health history. The section will also reference law on confidentiality and release of records. The board will consider amending the time period for maintenance of records from three to five years and expansion of information on services provided, drugs administered and images taken in order to have sufficient information by which to evaluate treatment. A new subsection will also be included to specify the content of a record relating to provision of sedation or anesthesia.*

Scope of practice

- *A new section on professional conduct may be added to include provisions currently set out in a 2009 Guidance Document 60-15 on treating and prescribing for self and family; duty to patients, professional boundaries; billing and financial transactions; and reporting abuse and neglect.*
- Reporting adverse reactions – currently in 18VAC60-20-140 with clarifying amendments
- Advertising – currently in 18VAC60-20-180 and Guidance Document 60-15
- *A new section may be added on compliance with applicable laws and regulations, such as Code of Virginia sections applicable to all health professions as well as*

*those specific to dentistry, and federal requirements for health, safety and sanitation*

Part III. Direction, delegation and supervision

Dentists' responsibilities - 18VAC60-20-200, 210

Treatment or practices restricted to dentists - 18VAC60-20-190

Dental hygienists - 18VAC60-20-200,210,220

Dental assistants - 18VAC60-20-230

Part IV. License and registration requirements

Article 1. Application requirements – currently in 18VAC60-20-100

Article 2. Unrestricted dental license

Education -18VAC60-20-60

Licensure by examination -18VAC60-20-70

Licensure by credentials -18VAC60-20-71

Article 3. Restricted dental license

Temporary license for residents and interns - 18VAC60-20-91

Temporary permit -18VAC60-20-90

Full time faculty license - 18VAC60-20-90

Teacher's license - 18VAC60-20-90

Volunteer temporary registration - 18VAC60-20-106

Volunteer restricted license - 18VAC60-20-106

Article 4. Additional requirements to practice oral maxillofacial surgery

Registration - 18VAC60-20-250

Profile of information - 18VAC60-20-260

Required reporting - 18VAC60-20-270

Noncompliance or falsification - 18VAC60-20-280

Certification to perform cosmetic procedures - 18VAC60-20-290

Required credentials - 18VAC60-20-310

Restricted procedures - 18VAC60-20-290

Exempt procedures - 18VAC60-20-300

Quality assurance reviews - 18VAC60-20-330

Complaints management - 18VAC60-20-331

Article 5. Registration of mobile facilities and portable operations -18VAC60-20-332

Part V. License and registration renewal

Unrestricted license -18VAC60-20-20

Inactive license - 18VAC60-20-20, 105

Restricted license - 18VAC60-20-20

Registration of oral & maxillofacial surgeons - 18VAC60-20-260

Certification for cosmetic procedures - 18VAC60-20-320

Registration of mobile facilities and portable operations – 18VAC60-20-332

Continuing education - 18VAC60-20-50

Part VI. Reinstatement - 18VAC60-20-20

From lapsed license

From inactive license  
From suspension or revocation

#### Part VII Controlled Drugs, Sedation and Anesthesia

- *Amendments will be considered for consistency with revised ADA guidelines on sedation and anesthesia.*
- *A new section on compliance with Drug Enforcement Administration and Drug Control Act will be added.*
- *General provisions - 18VAC60-20-107 with clarifying amendments and the addition of language for administration to children under the age of 12.*
- *Requirements for education and training to administer, assist or monitor*  
Licensed health professionals 18VAC60-20-110  
Dental assistants §54.1-3408, 18VAC60-20-135
- *General requirements for minimal sedation, moderate sedation and general anesthesia (18VAC60-20-108, 18VAC60-20-110 and 18VAC60-20-120)*
- *A new section on patient monitoring may be added to specify what constitutes monitoring.*

### CHAPTER 30

#### REGULATIONS GOVERNING THE PRACTICE OF DENTAL HYGIENE

##### Part I. General Provisions

- *Applicable definitions from 18VAC60-20-10;*
- *A new section on practice of dental hygiene with reference to §54.1-2722 and the exceptions in exceptions 18VAC60-20-240 and §§54.1-2701 and 54.1-2712*
- *Required fees from 18VAC60-20-20, 30, 40, 250, 310*
- *Requirements for licensee addresses - 18VAC60-20-16*
- *Posting requirements new section with reference to §54.1-2727*

##### Part II. Standards of Professional Conduct 18VAC60-20-170

Patient information and records - 18VAC60-20-15 for required content

*To include language from 2005 Guidance Document 60-3 on the meaning of an updated health history. The section will also reference law on confidentiality and release of records. The board will consider an expansion of information on services provided, drugs administered and images taken in order to have sufficient information by which to evaluate treatment. A new subsection will also be included to specify the content of a record relating to provision of sedation or anesthesia.*

Scope of practice

- *A new section on professional conduct may be added to include provisions currently set out in a 2009 Guidance Document 60-15*
- *A new section may be added on compliance with applicable laws and regulations, such as Code of Virginia sections applicable to all health professions as well as those specific to dentistry*

##### Part III. Direction and supervision

Direction required (levels of supervision) - 18VAC60-20-200, 210  
Supervision of dental assistants - 18VAC60-20-230

Part IV. License and registration requirements

- Article 1. Application requirements - 18VAC60-20-100
- Article 2. Unrestricted dental hygiene license
  - Education - 18VAC60-20-60
  - Licensure by examination - 18VAC60-20-70
  - Licensure by credentials - 18VAC60-20-71
- Article 3. Restricted dental hygiene license
  - Temporary permit - 18VAC60-20-90
  - Teacher's license - 18VAC60-20-90
  - Volunteer temporary registration - 18VAC60-20-106
  - Volunteer restricted license - 18VAC60-20-106

Part V. License renewal

- Unrestricted license - 18VAC60-20-20
- Inactive license - 18VAC60-20-20, 105
- Restricted license - 18VAC60-20-20
- Continuing education -18VAC60-20-50
  - Required hours
  - Required content
  - Required sponsors
  - Required documentation

Part VI. Reinstatement - 18VAC60-20-20

- From lapsed license
- From inactive license
- From suspension or revocation

Part VII. Controlled Drugs, Sedation and Anesthesia

- Administration
  - Authorization for topical drugs – reference to §§54.1-2722 and 54.1-3408
  - Requirements for administration of nitrous oxide/oxygen-18VAC60-20-81
  - Requirements for administration of local anesthesia - 18VAC60-20-81
- Assisting with sedation and general anesthesia - new section
- Monitoring patients during sedation and general anesthesia - new section

CHAPTER 40

REGULATIONS GOVERNING THE PRACTICE OF DENTAL ASSISTING

Part I. General Provisions

- Definitions – as applicable from 18VAC60-20-10

Practice of dental assisting - new section referencing §§ 54.1-2712 and 54.1-2729.01  
Fees required

Part II. Practice of Dental Assistants I

Direction required - 18VAC60-20-200, 230  
Requirements for taking x-rays, digital images - 18VAC60-20-195  
Requirements for administering topical drugs – reference to §§54.1-2722 and 54.1-3408  
A new section on assisting with sedation and anesthesia  
A new section on monitoring during sedation and anesthesia

Part III. Dental Assistants II

General Provisions

Practice of dental assistants II with reference to §54.1-2729.01  
Direction required - 18VAC60-20-200, 230  
Registrant addresses - 18VAC60-20-16  
    Address of record  
    Address for the public  
Posting requirements from 18VAC60-20-16 40, 250, 310

Registration requirements

National certification - 18VAC60-20-50  
Education and training - 18VAC60-20-61  
Registration by endorsement 18VAC60-20-72

Registration renewal 18VAC60-20-20

Reinstatement 18VAC60-20-20

From lapsed license  
From inactive license  
From suspension or revocation

**Alternatives**

*Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.*

The Board of Dentistry began a regulatory review process in October of 2007 with the intent of working through the regulations part by part to improve the flow of information, address inconsistencies with statutory provisions, clarify and develop language in areas where the meaning and application were questioned, and add provisions on practice topics of concern to licensees. The Regulatory/Legislative Committee (the Committee) began by focusing on Part II Licensure Renewal and Fees and Part III Entry and Licensure Requirements. The review was

tabled in March of 2008 to allow staff and Board members to focus on meeting Governor Kaine's key performance measures with intense activity to improve the Board's performance in processing patient care cases within 250 days.

Work on regulatory review resumed in December 2008, and the Committee has met on six occasions (12/3/08, 2/25/09, 4/22/09, 8/21/09, 11/20/09, and 1/22/10) to complete its review. The executive director of the Board prepared a review chart of statutes, regulations and issues for each part of the regulations to assist in the review. Part IV, on Anesthesia, Sedation and Analgesia, has been the subject of several petitions for rulemaking as well as public comment where divergent interests are advocated. Some have requested that the Board register and periodically inspect dental practices where sedation and anesthesia are administered, while others want the Board to relax the rules for administration of conscious sedation. A central theme in many of the comments is that the Board should consider and in large part conform to the **Guidelines for the Use of Sedation and General Anesthesia by Dentists** which were published by the American Dental Association in 2007. The one exception to this is the Virginia Association of Nurse Anesthetists, which says that the medical standards for administration should apply in dental practices.

In addition to the concerns coming from the public, the Board has had two high profile cases on administration of sedation and anesthesia. The Board found that its regulations are less than adequate in ensuring that:

- only appropriately trained and supervised staff is participating on the treatment team,
- adequate emergency equipment and procedures are in place, and
- patients are adequately assessed and monitored.

To address these and other issues relating to sedation and anesthesia, the executive director and the Committee are analyzing the ADA Guidelines and those published by the American Academy of Pediatric Dentistry, the American Association of Oral and Maxillofacial Surgeons and the American Society of Anesthesiologists to identify the standards the Board might want to consider during the promulgation of amended regulations.

## Public participation

*Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.*

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.



Anyone wishing to submit written comments may do so by mail, email or fax to Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, (804) 527-4434 (fax) or [Elaine.yeatts@dhp.virginia.gov](mailto:Elaine.yeatts@dhp.virginia.gov) or comment may be posted on the Regulatory Townhall at [www.townhall.virginia.gov](http://www.townhall.virginia.gov) Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

In addition, the agency is seeking information on (1) the continued need for the regulation; (2) the complexity of the regulation; (3) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

A public hearing will be held after the Board has adopted proposed regulations. Notice of the hearing may be found on the Virginia Regulatory Town Hall website [www.townhall.virginia.gov](http://www.townhall.virginia.gov) and can be found in the Calendar of Events section of the Virginia Register of Regulations. Both oral and written comments may be submitted at that time.

**Family impact**

*Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

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There is no impact on the family.

**Periodic review - Public comment**

*If this NOIRA is the result of a periodic review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 36, e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.*

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A Notice of Periodic Review of Regulations and request for public comment was sent in October 2007. There were comments received from:

The American Society of Plastic Surgeons – comment that the certification requirements allow the performance of cosmetic procedures by oral and maxillofacial surgeons without any formal training; patients should be assured that plastic surgery is being provided by someone with the requisite education and training; current regulations expose Virginia patients to unnecessary risks and potentially dangerous outcomes.

The Virginia Association of Nurse Anesthetists – comment in support of clearer guidance to practitioners for the administration of anesthesia; urges uniformity in the office-based anesthesia safety rules, regardless of the delivery setting and practitioner performing; rules for dental offices are significantly less stringent than for a physician office.

The Virginia Society of Oral and Maxillofacial Surgeons – comment in request of clarification of several issues relating to administration of controlled substances by persons other than the dentist; request to provide information on extensive training in anesthesia.

The Board of Dentistry has determined that the regulation is necessary for the protection of public health, safety and welfare. It is being reorganized and amended to make it more clearly written and more easily understandable.

### Periodic review - Discussion

*If this NOIRA is the result of a periodic review or if the periodic review is to be performed in combination with the NOIRA, please include a discussion of the agency's consideration of: (1) the continued need for the rule; (2) the complexity of the regulation; (3) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, include a discussion of the agency's determination whether the regulation should be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact of regulations on small businesses.*

- 1) There is a continued need for the regulation because it is mandated by statute (Chapter 27 of Title 54.1), which requires the promulgation of regulations for the licensure and practice of dentists, dental hygienists and dental assistants.
  - 2) The regulation has been amended repeatedly as necessary for consistency with changes in law and practice for the professions. Through the periodic review of regulations, amendments have been identified that are needed for clarity or to delete out-dated language or requirements. Since it has become increasingly difficult for practitioners and the public to determine the requirements for each of the dental professions, the board is recommended repeal of the current Chapter 20 and reorganization into three separate chapters for dentistry, dental hygiene and dental assisting;
  - 3) The regulation does not overlap with federal law or regulation; licensure of dental practice is a power exercised by individual states. In its review, the board did not identify any regulation that overlaps with the Code; in several sections of law, the board is expressly required to adopt a regulation, such as requirements for continuing competency.
  - 4) A periodic review was last completed for Chapter 20 in 2005, and 15 regulatory actions have been completed on the chapter since that time. Amendments have been adopted as needed or mandated by changes in the Code of Virginia.
- The regulation should be amended to eliminate unnecessary provisions and to render the Chapter more user-friendly to regulated entities.