

Since 18VAC60-20-10 et seq. is being repealed and re-promulgated in 4 separate chapters, the Board is submitting 4 separate agency background documents compiled into one submission on Townhall.

Final Regulation Agency Background Document

Agency name	Board of Dentistry, Department of Health Professions	
Virginia Administrative Code (VAC) citation	18VAC60-15	
Regulation title	Regulations Governing the Disciplinary Process in Dentistry	
Action title	Promulgation of new chapter resulting from periodic review and reorganization	
Date this document prepared	3/11/14	

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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

The new regulations result from a periodic review of Chapter 20 and the action of the Board to divide the Chapter into three separate sets of regulations for dentists, dental hygienists and dental assistants. Therefore, the two sections of current Chapter 20 that would apply to all professions in the disciplinary process have been moved to a new Chapter 15 rather than repeating regulations in the three new chapters.

Statement of final agency action

Form: TH-03

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

On March 7, 2014, the Board of Dentistry adopted 18VAC65-15-10 et seq., Regulations Governing the Disciplinary Process.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

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

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

- 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.

Purpose

Form: TH-03

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

The two sections of this chapter set out provisions for recovery of disciplinary costs in a case in which there is a finding of a violation and for establishment of criteria for delegation of informal fact-finding to an agency subordinate. Final regulations for the recovery of costs were adopted in April 2011 and are not yet effective, but are included in proposed Chapter 15 since Chapter 20 will be repealed in this action. The regulations are intended to facilitate the disciplinary process so cases can be adjudicated in a more timely and cost-effective manner. Assessment of costs for violations of the dental practice act may have the effect of deterring unprofessional conduct that is detrimental to the health and safety of dental patients.

Substance

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

The two sections of this chapter set out provisions for recovery of disciplinary costs in a case in which there is a finding of a violation and for establishment of criteria for delegation of informal fact-finding to an agency subordinate.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and
- 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.
 - 1) The primary advantage to the public is the potential to reduce expenditures of the Board and its licensees for the investigation and monitoring by assessing a dentist who has violated law and/or regulation a portion of the costs the Board incurred. Offsetting expenditures relating to discipline will have a positive effect on the Board's budget and may result in stability in fees charged to licensees, which in turn benefits patients of those licensees. There are no disadvantages.
 - 2) The ability to delegate non-patient care cases to an agency subordinate allows a board to expedite some disciplinary proceedings and meet agency goals for case resolution. There are no disadvantages.

3) These are <u>current</u> regulations restructured in a new chapter.

Changes made since the proposed stage

Form: TH-03

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

There were no changes made since publication of the proposed stage.

Public comment

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

Proposed regulations were published on November 4, 2013 with public comment accepted through January 11, 2014. A public hearing was held on January 10, 2014. No public comment was received.

All changes made in this regulatory action

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

Proposed new section number, if applicable	Proposed change and rationale
10	Recovery of disciplinary costs.
	A. Assessment of cost for investigation of a disciplinary case.
	1. In any disciplinary case in which there is a finding of a violation against a licensee or registrant, the board may assess the hourly costs relating to investigation of the case by the Enforcement Division of the Department of Health Professions and, if applicable, the costs for hiring an expert witness and reports generated by such witness.
	2. The imposition of recovery costs relating to an investigation shall be included in the order from an informal or formal proceeding or part of a consent order agreed to by the parties. The schedule for payment of investigative costs imposed shall be set forth in the order.
	3. At the end of each fiscal year, the board shall calculate the average hourly cost for enforcement that is chargeable to investigation of complaints filed against its regulants and shall state those costs in a guidance document to be used in imposition of recovery costs. The average hourly cost multiplied times the number of hours spent in investigating the specific case of a respondent shall be

used in the imposition of recovery costs.

- B. Assessment of cost for monitoring a licensee or registrant.
 - 1. In any disciplinary case in which there is a finding of a violation against a licensee or registrant and in which terms and conditions have been imposed, the costs for monitoring of a licensee or registrant may be charged and shall be calculated based on the specific terms and conditions and the length of time the licensee or registrant is to be monitored.

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- 2. The imposition of recovery costs relating to monitoring for compliance shall be included in the board order from an informal or formal proceeding or part of a consent order agreed to by the parties. The schedule for payment of monitoring costs imposed shall be set forth in the order.
- 3. At the end of each fiscal year, the board shall calculate the average costs for monitoring of certain terms and conditions, such as acquisition of continuing education, and shall set forth those costs in a guidance document to be used in the imposition of recovery costs.

C. Total of assessment.

In accordance with § 54.1-2708.20f the Code of Virginia, the total of recovery costs for investigating and monitoring a licensee or registrant shall not exceed \$5,000, but shall not include the fee for inspection of dental offices and returned checks as set forth in 18VAC60-20-30or collection costs incurred for delinquent fines and fees.

The rationale is to continue the current regulation without any change. Current regulations became effective November 21, 2012.

20

Criteria for delegation of informal fact-finding proceedings to an agency subordinate.

A. Decision to delegate.

In accordance with §54.1-2400 (10) of the Code of Virginia, the board may delegate an informal fact-finding proceeding to an agency subordinate at the time a determination is made that probable cause exists that a practitioner may be subject to a disciplinary action. If delegation to a subordinate is not recommended at the time of the probable cause determination, delegation may be approved by the president of the board or his designee.

- B. Criteria for an agency subordinate.
 - 1. An agency subordinate authorized by the board to conduct an informal fact-finding proceeding may include current or past board members and professional staff or other persons deemed knowledgeable by virtue of their training and experience in administrative proceedings involving the regulation and discipline of health professionals.
 - 2. The executive director shall maintain a list of appropriately qualified persons to whom an informal fact-finding proceeding may be delegated.
 - 3. The board may delegate to the executive director the selection of the agency subordinate who is deemed appropriately qualified to conduct a proceeding based on the qualifications of the subordinate and the type of case being heard.

The rationale is to continue the current regulation without any change. Current regulations were initially effective June 29, 2005 and amended effective November 29, 2007.



Final Regulation Agency Background Document

Form: TH-03

Agency name	Board of Dentistry, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC60-21
Regulation title	Regulations Governing the Practice of Dentistry
Action title	Promulgation of new chapter resulting from periodic review and reorganization
Date this document prepared	3/11/14

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

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

The new regulations result from a periodic review of Chapter 20 and the action of the Board to divide the Chapter into three separate sets of regulations for dentists, dental hygienists and dental assistants. Chapter 21 is promulgated as a new chapter with all the sections and provisions from current regulation that pertain to the licensure requirements for and practice of dentists.

Statement of final agency action

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

On March 7, 2014, the Board of Dentistry adopted 18VAC65-21-10 et seq., Regulations Governing the Practice of Dentistry.

Legal basis

Form: TH-03

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

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

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

- 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. ...

The specific statutory authority for the licensure and practice of dental hygienists is found in Chapter 27 of Title 54.1.

Purpose

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

The new regulations are a reorganization and restatement of current requirements for licensure and practice found in Chapter 20, Regulations Governing Dental Practice. Such requirements are necessary to ensure the health and safety of dental patients, while assuring appropriate access to care by dentists.

Form: TH-03

Substance

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

There are no substantive changes to regulations governing dentists, as amended by emergency action pursuant to Chapter 526 (Senate Bill 1146) of the 2011 Acts of the Assembly requiring the Board of Dentistry to revise its regulations for issuance of permits for dentists who provide or administer conscious/moderate sedation or deep sedation/general anesthesia in a dental office. Provisions in Chapter 20 on Dental Practice that are applicable to the licensure and practice and of dentists and oral and maxillofacial surgeons were identified and included in a new Chapter 21.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and
- 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.
- 1) Regulations for the practice of dentistry are necessary to assure minimal competency in the provision of dental services that protect public health and safety. There are no substantive new regulations, but reorganization and clarification should make current requirements more understandable and encourage compliance. There should be no disadvantages.
- 2) There are no disadvantages of these provisions to the agency or the Commonwealth; registration is required by law. Specificity about practice and qualifications should allow Board staff to direct persons with questions about those issues to the regulations.
- 3) These are generally current regulations restructured in a new chapter.

Changes made since the proposed stage

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

Emergency regulations for sedation/anesthesia permits have been in effective since 9/14/12 and are set to expire 3/15/14. The Board has adopted final regulations (Action 3564 / Stage 6862) to

replace the emergency regulations. Changes to those regulations have been incorporated into the action on this chapter for consistency.

Section number	Requirement at proposed stage	What has changed	Rationale for change
10	Sets out definitions for words and terms used in regulation	For consistency with the sedation permits regulations, section 10 has been reorganized into subsections that group words and terms in categories according to their use in the regulation. The term "AAOMS" is defined so the acronym can be used in the chapter.	Definitions are consistent with current regulations and/or the sedation/anesthesia regulations awaiting final approval.
20	Sets out requirement for posting of a license in the dental office	Adds a modifier to the word "license" for clarification.	The amendment specifies that it is the "dental" license that must be posted.
40	Establishes fees for licensees and applicants	The dental teacher's license and the phrase "full-time" before the faculty license are deleted.	The change resulted from legislation passed in 2012 in which all licenses to teach are "faculty" licenses; there is no longer a distinction between full-time and part-time.
70	Sets out the acts that may be considered unprofessional practice by a dentist	Subsection A is amended to delete dental hygienist because this chapter regulates the practice of dentistry; Chapter 25 regulates dental hygienists. Registered dental assistants II are added to the list of persons that would have professional competence and to whom services may be delegated by the dentist.	The changes are clarifying only.
80	Establishes the rules regarding advertising by dentists	Subsection C is amended by adding "if any" after "nondiscounted or full fee" to allow for the possibility that a dentist may never charge a fee for a free service. Therefore, it would be impossible for him to advertise the nondiscounted or full fee for that service. *Subsection D is amended by	The amendment was adopted in response to a scenario that has recently been presented in the context of an investigation. Since the internet offers a
		deleting "broadcast" and "radio or television" and adding "or archived" to the requirement for a prerecorded copy to be maintained. The maintenance period was changed from 12 months to 2 years.	variety of platforms for advertising a dental practice, the current language of subsection D was outdated. To ensure that internet advertising is available for review in response to a consumer complaint and during the investigation and possible board proceeding, the section was amended to require

		Subsection G is amended to update the date of the latest ADA document on dental specialties.	"archiving" of such material and retention for 2 years.
90	Subsection A specifies the information that must be included in a patient record	Adds identification of the teeth to the information needed for visual images and the treatment rendered to the notation about provision of services Subsection G is amended to clarify that records may be transferred to a licensed dentist, not to any "licensee."	In reviewing proposed regulations for all professions, board members identified the elements of a complete record that were missing and are essential to determining whether adequate, competent care was provided.
100	Sets out rules for events that must be reported to the Board	Adds a provision that the injury or complication that must be reported "was related to the dental treatment or service provided." The Board also added that emergency treatment by a hospital related to sedation anesthesia must be reported.	The changes are consistent with the sedation and anesthesia permit regulations.
140	Sets out requirements for delegation to dental hygienists	Subsection A #1 is amended to substitute "non-surgical" for "athermal" lasers and to delete the phrase "by the dentist" at the end of the sentence. Subsection B is also amended to use the term "non-surgical" instead of "athermal."	The term "athermal" was not clearly understood or defined in the literature, so "non-surgical" has been substituted and defined. The intent is the same. The term "by the dentist" is deleted because dental hygienist with certain qualifications can also administer types of anesthesia.
160	Sets out the appropriate delegation of duties to a dental assistant	Clarifies that the customary level of supervision for dental assistant is indirect supervision.	The references to "general supervision" and section 18VAC60-21-120 are deleted as they were confusing and inaccurate.
190	Sets out the general application requirements for dental licensure	A reference to the section on educational qualification is added to the requirement for submission of a transcript. The requirement for a HIPDB is deleted on the application requirements.	There is now only one national practitioner databank – known as NPDB.
230	Sets out the qualifications for a restricted dental license	All of subsection B is deleted as there is no longer a "teacher's license." Subsection E is amended to clarify that a license held in another U. S.	With legislation passed in 2012, the teacher's license was eliminated; all licenses to teach are faculty licenses.

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0.10		jurisdiction is acceptable.	-
240	Sets out requirements for renewal and reinstatement of	Subsection B is amended to eliminate references to "full-time" faculty licenses and the "teacher's	The faculty license <u>is</u> a license so there is no need to make a distinction. The teacher's
250	Sets out the requirements for continuing education for renewal of dental licensure	license". Subsection A is amended to: 1) eliminate the provision allowing credit for passage of the online Dental Law Exam; and 2) add "for health care providers" after certification in basic cardiopulmonary resuscitation.	license no longer exists. 1) There is no longer an online Dental Law Exam; applicants attest to having read and understood the laws and regulations; 2) Dentists are required to take the CPR course designed for health care providers rather than for the general public. The additional phrase is consistent with the dental hygiene regulations.
		Subsection C is amended to insert "continuing education" before "providers (##1and 6); to add the Dental Auxiliary Learning and Education Foundation (#14) and the Council of Interstate Testing Agencies (CITA) (#15) to the list of approved sponsors of CE	The amendment is in response to a request from the Dental Assisting National Board; the Board concurred with the comment. CITA has been added to the list of testing agencies acceptable for licensure and continuing education since regulations were proposed.

Public comment

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

Proposed regulations were published on November 4, 2013 with public comment accepted through January 11, 2014. A public hearing was held on January 10, 2014.

Commenter	Comment	Board Response to Comment
Katherine	Recommends adding the Dental Auxiliary	The Board accepted the
Landsberg	Learning and Education Foundation (DALE),	recommendation and amended
DANB and the	an affiliate of the Dental Assisting National	Chapters 21, 25 and 30 accordingly.
DALE Foundation	Board (DANB), to the list of approved	
	sponsors for continuing education courses	

All changes made in this regulatory action

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

In addition to changes made in the adoption of final regulations, as noted above:

- 41			
Section number	Proposed requirements	Other regulations and law that	Intent and likely impact of proposed requirements
10	Several words and terms	apply This section repeats applicable	The intent and impact is to
10	used in regulation are	definitions from section 10 in Chapter	continue the current
	being defined in all	20 that is being repealed.	regulation with the additional
	chapters broken out from	20 that is being repeared.	definitions for words and
	Chapter 20. They are:	Several terms relating to the	terms which are used but
	CODA	administration of anesthesia or	have previously been
		sedation were revised or newly	undefined.
	Code	defined in emergency regulations for	
	Monitoring	sedation/anesthesia permits:	
		The state of the s	
		"Deep sedation" was previously	
		joined with "general anesthesia." The	
		terms are now separately defined	
		consistent with Guidelines for	
		Teaching Pain Control and Sedation	
		to Dentists and Dental Students	
		(2007) of the American Dental	
		Association.	
		"Immediate supervision" is defined as	
		a level of direction used in the	
		regulation.	
		"Minimal sedation" replaces the term	
		"anxiolysis" and the definition is	
		updated for consistency with current	
		standards.	
		"Topical oral anesthetic" is defined as	
		used in this chapter and Chapter 25	
20	Cata out requirements for	for dental hygienists.	The intent and impact is to
20	Sets out requirements for address of record to be	This section repeats requirements from section 16 A in Chapter 20.	The intent and impact is to continue the current
	maintained with the	Hom section to A in Chapter 20.	regulation without change.
	board.		regulation without change.
	oouru.		
30	Sets out requirements for	Subsection A on display of names of	The intent and impact is to
	posting of the dental	dentists practicing under a firm or	continue the current
	license and other	another dentist's name is required by	regulation and Code
	additional credentials.	§ 54.1-2720 of the Code.	requirements without change.
		Subsection B, requiring display of a	
		dental license is currently in section	An additional requirement for
		16 B in Chapter 20 and also required	all dentists who prescribe,
		by § 54.1-2721 of the Code.	administer or dispense
		Subsection C, requiring display of a	controlled substances to
		current DEA registration for dentists	display a current DEA
		who administer, prescribe or dispense	registration is intended to
		controlled substances is current	inform the public of the
		required for dentists in the anesthesia/	practitioner's authorization to
		sedation requirements (sections 110 C	possess such drugs.

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		and 120 D) but is added for all dentists. A requirement to display a copy of the permit issued to a dentist administering anesthesia/sedation is currently in sections 110 C and 120 D.	
40	Establishes the fees applicable to all dentists regulated under this chapter.	This section repeats requirements for fees from sections 20, 30, and 40 in Chapter 20. It also includes fees currently listed in sections 106, 250, 310 and 320. Other requirements for renewal, etc. in section 20 are set out in other sections in the new chapter for dentists. Fees for anesthesia or sedation permits are identical to those	The intent and impact is to continue the current regulation without change.
		established in emergency regulations for such permits.	
50	Sets out the scope of practice for dentists.	Language in section 50 relating to treatment and prescribing based on a bona fide patient/practitioner relationship is the current standard for the profession.	The intent is to specify and clarify scope of practice consistent with current professional standards and law.
60	Sets out the general responsibilities of dentists for patients.	Section 60 enumerates responsibilities and standards of care that are consistent with safeguards for patient protection and professional practice including: • Maintaining a safe and sanitary practice, including containing or isolating pets away from the treatment areas of the dental practice. An exception shall be made for a service dog trained to accompany its owner or handler; • Consulting with or referring patients to other practitioners with specialized knowledge, skills and experience when needed to safeguard and advance the health of the patient; • Treating according to the patient's desires only to the extent that such treatment is within the bounds of accepted treatment and only after the patient has been given treatment recommendation and an explanation of the	The intent and impact is incorporate standards of professional practice that are currently set out in a guidance document (60-15) into regulations, so a violation of standards could be grounds for disciplinary action. In its review of some investigations, the Board has become aware of behaviors or actions that may not currently constitute a violation of law or regulation but which are clearly unprofessional and fail to adequately protect the public. The specification of professional practice detailed in section 60 is intended to provide a regulatory framework for dental practices and grounds for disciplinary action for deviation from the professional standard.

		 acceptable alternatives; Only delegating patient care and exposure of dental x-rays to qualified, properly trained and supervised; Giving patients at least 30 days written notice of a decision to terminate the dentist-patient relationship; Knowing the signs of abuse and neglect and reporting suspected cases to the proper authorities consistent with state law; Accurately representing to a patient and the public the materials or methods and techniques to be used in treatment. Subsection B enumerates the dentist's responsibility for conducting his financial responsibilities to patients and third party payers in an ethical and honest manner by: Maintaining a listing of customary fees and representing all fees being charged clearly and accurately; Making a full and fair disclosure to his patient of all terms and considerations before entering into a payment agreement for services; Not obtaining, attempting to obtain or cooperating with others in obtaining payment for services by misrepresenting procedures performed, dates of service or status of treatment; Making a full and fair disclosure to his patient of any financial incentives he received for promoting or selling products; Not exploiting the dentist and patient relationship for personal gain related in non-dental transactions. 	
70	Specifies the acts which may constitute unprofessional practice	The provisions of section 70 are taken from the current section on acts constituting unprofessional conduct found in section 170 of Chapter 20.	The intent is to continue the current regulation; with the addition of provisions on violating drug laws and

		Language about adherence to requirements on maintenance and dispensing of scheduled drugs and on sexual misconduct have been added to include standards that are understood but not currently specified in regulation.	engaging in sexual misconduct, the impact will be more clarity and specificity about conduct that is considered unprofessional and grounds for disciplinary action. The Board reviewed regulations of other professions on sexual misconduct and concluded that the emphasis should be on non-consensual contact and on exploitation of the professional relationship.
80	Specifies the standards for advertisement of dental services	The provisions of section 80 are taken from the current section on advertising in 180 of Chapter 20.	The intent and impact is to continue the current regulation without any substantive change.
90	Specifies the required content of a patient record and the information that must be provided to a patient	The provisions of section 90 are taken from the current requirements for recordkeeping found in section 15 of Chapter 20. Subsection A on the retention period for patient records is taken from regulations for medical doctors in 18VAC85-20-26. Subsection B is taken from the current regulation in section 15 for dentists, but expanded to address questions from practitioners and to include recordkeeping requirements currently found in other sections of regulation. For example, the current regulation requires an "updated health history" but it is unclear about how often that must occur. Board members determined that it was unnecessary to update the history at each visit but it should be done when analgesia, sedation or anesthesia are to be administered, when medically indicated or at least annually. Radiographs are currently required in the record, but digital images or photographs are not referenced. There are other examples of how the regulations have been updated or further specified to produce a patient	The intent of the provisions in section 90 is to continue the current requirements for recordkeeping but include additional specificity and clarity. The record should include options discussed and consent for treatment. The intent and impact is also to ensure that patient information is held in confidence or disclosed as permitted or required by law. Additionally, the Board has added several provisions that address specific situations in which patient records have been incomplete, destroyed or abandoned inappropriately or withheld for financial reasons. Practitioners are often uncertain about their responsibilities for patient records or about the amount that can be charged to copy such records.

		record that accurately indicates the	
		record that accurately indicates the services rendered.	
		Subsection C references the law on confidentiality and provisions of patient records upon request.	
		Subsections D – H provide a regulatory standard for handling, copying and disposal of records. All are consistent with current law on patient records.	
100	Sets out the requirements for reporting within 15 days patient events resulting in physical injury, respiratory, cardiovascular or neurological complication that necessitated admission to the hospital or a patient	Currently, section 140 of Chapter 20 requires a written report of any adverse reaction from the administration of any form of analgesia, sedation or anesthesia whether in the facility or during the first 24 hours after the patient's departure. The revised regulation expands the	The intent and impact is to continue the current requirement for reporting but to give dentists more direction about what type of patient harm triggers a report.
	death.	reporting requirement to include any event but offers more specificity about what constitutes a reportable event.	
110	Sets out the rule for utilization of dental hygienists and dental assistants II	Provisions in section 110 are identical to current section 100 of Chapter 20.	The intent and impact is to continue the current regulation.
120	Sets out the requirements for direction and general supervision.	Provisions in section 120 are identical to current section 210 of Chapter 20. Practice of dental hygienists is currently established in section 220, which specifies the duties that may be performed under indirect supervision (defined in section 10).	The intent and impact is to continue the current regulation without change.
130	Sets out those duties that are non-delegable and may only be performed by a dentist	Provisions in section 130 are identical to current section 190 of Chapter 20 with the clarification that performance of gingival curettage by a dental hygienist is an exception to the prohibition on delegating surgical or cutting procedures.	The intent and impact is to continue the current regulation with one clarification.
140	Sets out those duties that may only be delegated to a dental hygienist	Provisions of section 140 are taken from section 220 in the current chapter 20.	The intent and impact is to continue the current regulation without change.
		Subsection A sets out those duties	Subsection B has been

150	Sets out those duties that	that may only be performed under indirect supervision. Subsection B sets out those duties that be performed under indirect supervision or may be delegated to be performed under general supervision. Provisions of section 150 are identical	updated to include instruments and procedures not currently included in delegated tasks. The intent and impact is to
	may only be delegated to a dental assistant II who has been qualified under requirements set forth in the new chapter 30.	to subsection C of section 230 in current regulations.	continue the current regulation without change.
160	Sets out those duties that may be delegated to a dental assistant I or II	Provisions of section 160 are identical to subsections A and B of section 230 in current regulations.	The intent and impact is to continue the current regulation without change.
170	Sets out the qualifications necessary for a person who exposes dental x-ray film in a dental office	Provisions of section 170 are identical to the provisions of section 195 in chapter 20, as amended by a fast-track action in June 2011.	The intent and impact is to continue the current regulation without change.
180	Delineates the dental activities that do not constitute the practice of a licensed profession	Provisions of section 180 are taken from section 230 in current regulations.	The intent and impact is to continue the current regulation without change.
190	Establishes the general application provisions for dentistry	Provisions of subsections A and C of section 190 are taken from section 100 in chapter 20. Subsection B, requiring an attestation on laws and regulations for all applicants for licensure, is taken from subsection E of section 70 in chapter 20. Subsections D and E are current requirements but are included in section 190 for clarification.	Applicants for a restricted volunteer license or a volunteer exemption are exempted from these requirements to make such applications less burdensome.
200	Establishes the educational requirements for licensure as a dentist	Provisions of section 200 are taken from subsection A of section 60 in current regulations.	The additional clarification of a post-doctoral dental education in a specialty other than general dentistry (at least 24 months which includes a clinical component) is consistent with the Board's current interpretation of a qualifying post-doctoral dental education.

210	Establishes the qualifications for an unrestricted dental license	Subsection A of section 210 (licensure by examination) is taken from subsection A of section 70 in current regulations.	The intent and impact is to continue the current regulation without change.
		Subsection B of section 210 (licensure by credentials) is taken from section 71 in current regulations.	
220	Establishes the process for obtaining or reactivating an inactive dental license	Subsection A of section 220 is taken from subsection A of section 105 in Chapter 20. Subsection B on reactivation is taken from subsection B of section 105. In addition to consideration of continuing education as evidence of competency to return to active practice, the Board lists other evidence that may be evaluated, such as active practice in another state or federal service, specialty board certification, recent passage of a clinical examination or a refresher course.	The intent of the regulation is to mirror the current requirements for reactivation of an inactive license, with some additional evidence of competency required if continuing education is not sufficient to indicate minimal competency to return to active practice on patients in Virginia.
230	Establishes the qualifications for a restricted license to practice dentistry.	Subsection A (temporary permit for practice in public health settings or charitable organizations) is taken from provisions in section 90 of Chapter 20. Section 54.1-2715 provides that such a permit cannot be issued to an applicant who has failed an examination for licensure; the regulation reiterates that restriction. Subsection B (teacher's license) is authorized in § 54.1-2713, and the regulation further clarifies those provisions of law. Subsection C (full-time faculty license) is taken from section 90 of Chapter 20 and authorized by § 54.1-2714. Subsection D (temporary license for persons enrolled in advanced dental	There are several types of restricted licenses in the practice of Virginia. The intent is to describe the qualifications for all types in one section for ease of compliance. There are no substantive changes to the qualifications or requirements for practice.
		education programs) is taken from section 91 of Chapter 20. Subsection E (restricted volunteer license) is taken from subsection A of	

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		section 106 in Chapter 20.	
		Subsection F (registration for voluntary practice by out-of-state licensees) is taken from subsection B of section 106 in Chapter 20.	
240	Sets out the requirements for renewal of licensure in dentistry	Provisions of section 240 are taken from section 20 in Chapter 20, with the exception of the fees which are set out separately in the new chapter in section 40.	The intent and impact is to continue the current regulation without change.
250	Establishes the requirements for continuing education for renewal of licensure	Provisions of section 250 are taken from section 50 in Chapter 20. All substantive requirements, provisions for exemptions, maintenance of documents, and sponsoring organizations or entities remain the same.	The intent and impact is to continue the current regulation with only one change. An additional requirement is an attestation that the licensee has read, understands and will remain current with laws and regulations governing practice. CE credit is available for passage of the online law exam.
260	Sets out the general provisions for administration of anesthesia or sedation	Provisions in section 260 are taken from section 107 in current Chapter 20 as amended in the emergency action for sedation and anesthesia permits. Subsection A sets out the practice settings in which the regulations are applicable (dental offices, mobile dental clinics, and portable dental operations). Subsection B states the requirement for a DEA registration is the dentist administers or dispenses controlled substances. Subsection C describes the evaluation required to determine whether the patient is an appropriate candidate for anesthesia or sedation in a dental office. The dentist must document that he has had a consultation with a medical doctor prior to administration of general anesthesia or any type of sedation to a patient in risk category Class III. Without documentation in	The intent and impact is to continue the current regulation (as amended for issuance of anesthesia and sedation permits) without change.

the record, there is no assurance that consultation took place.

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The complete required content of the patient record is set forth in subsection D and includes all information necessary to assure that the patient has been appropriately assessed, administered and monitored. The Board used curriculum included in Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students (2007) to determine elements of a patient record. Some guidelines for monitoring and management specify that vital signs and physiological measures must be recorded at regular intervals. Others, such as, Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures (2006)," specify that monitoring records should be recorded every five minutes. The Board adopted the specific standard as consistent with patient safety.

Subsection E specifies that no sedating medication can be prescribed or administered to a child aged 12 and under prior to arrival at the dental office due to the risk of unobserved respiratory obstruction during transport by untrained individuals. The standard is found in the 2007 ADA Guidelines and in the 2006 pediatric guideline.

Subsection F is taken from subsection C in section 107. It specifies the consent that must be obtained and *recorded* prior to administration of sedation or anesthesia to include the risks, benefits and alternatives.

Subsection G is taken from subsection D in Chapter 20. While the requirement is identical, an additional standard is added: *The drugs and techniques used must carry*

		a margin of safety wide enough to render an unintended reduction of or loss of consciousness unlikely factoring in titration, and the patient's age, weight and ability to metabolize drugs. Subsection H specifies that: If a patient enters a deeper level of sedation than the dentist is qualified and prepared to provide, the dentist shall stop the dental procedure until the patient returns to and is stable at the intended level of sedation. The standard is quoted from the 2007	
		ADA Guidelines. Subsection I, on use of ancillary personnel, is taken from section 135 in current Chapter 20 (as amended for the sedation and anesthesia permits). The amendment to the qualification clarifies that the BCLS training must be a course for health providers and must include hands-on airway training, which is a recommendation of the American Society of Anesthesiologists and the 2007 Guidelines.	
		Subsection J generally states who can assists in administration of anesthesia or sedation, depending on the level of anesthesia or sedation planned and appropriate to the qualifications of the practitioner used for such assistance. Subsection K specifies the requirements for monitoring a patient for whom anesthesia or sedation has	
		been administered. Monitoring requirements are taken from sections 110 and 120 in Chapter 20. ADA Guidelines and	
		recommendations of other bodies such as the American Society of Anesthesiologists specify that the dentist must have written procedures in place to handle emergencies and staff regularly trained on such procedures.	
270	Sets out the requirements for administration of	This section lists the personnel and their qualifications who may	The intent of this regulation is to set apart requirements for

	local anesthesia	administer local anesthesia in a dental office. Currently, this information is	local anesthesia from other more stringent requirements
		found in Guidance Document 60-13.	for anesthesia.
280	Sets out the requirements for administration of minimal sedation	Subsection A is taken from subsection A in section 108 in Chapter 20 (Administration of anxiolysis or inhalation analgesia).	The intent and impact is to continue the current regulation as stated in section 108 and interpreted in Guidance Document 60-13.
		Subsection B repeats the prohibition stated in section 260 about administration of sedating medication to children under age 12 prior to arrival at the dentist's office.	
		Subsection C sets out those practitioners who may administer minimal sedation or may administer local anesthesia to numb an injection or treatment site. There are no new restrictions or expansions in scope of practice; the qualifications are listed for clarity.	
		Subsection D lists the equipment requirements for minimal sedation and is taken from subsection B in current regulations with the addition of suction apparatus.	
		Requirements for staffing and monitoring are currently found in subsection C of section 108, with the exception that the new regulations make it clear that a second person is not needed to monitor the patient if only nitrous oxide is administered by either a dentist or qualified dental hygienist.	
		Subsection E specifies that baseline vital signs should be taken and that monitoring should include checking those indicators.	
		Subsection F specifies the requirements for discharge of patients for whom minimal sedation has been administered. Currently, the regulation states that the patient cannot be discharged until he exhibits	

		"normal responses." For some	
		patients, the baseline vital signs may	
		not be "normal" for most patients, so	
		the amended regulation is more	
		specific about the expectations for	
		discharge.	
290	Establishes the	Requirements in section 290 are taken	The intent and impact is to
	requirements for a	from subsections A through F of	continue the emergency
	conscious/moderate	section 120, as amended in the	regulation without change.
	sedation permit	emergency action for issuance of	
		sedation or anesthesia permits.	
291	Establishes the	Requirements in section 291 are taken	The intent and impact is to
	requirements for	from subsections H through K of	continue the emergency
	administration of	section 120, as amended in the	regulation without change.
	conscious/moderate	emergency action for issuance of	
	sedation	sedation or anesthesia permits.	
300	Establishes the	Requirements in section 300 are taken	The intent and impact is to
	requirements for a deep	from subsections A through C of	continue the emergency
	sedation/general	section 110, as amended in the	regulation without change.
	anesthesia permit	emergency action for issuance of	
		sedation or anesthesia permits.	
301	Establishes the	Requirements in section 301 are taken	The intent and impact is to
	requirements for	from subsections E through H of	continue the emergency
	administration of deep	section 110, as amended in the	regulation without change.
	sedation/general	emergency action for issuance of	
	anesthesia	sedation or anesthesia permits.	
310	Sets out the requirements	With the exception of fees listed in	The intent and impact is to
	for registration of oral	section 250 in Chapter 20, section 310	continue the current
	and maxillofacial (O/M)	is identical. All fees are now found in	regulation without change.
	surgeons	section 40.	
320	Sets out required content	This section is identical to section 260	The intent and impact is to
	of a profile of O/M's	in Chapter 20.	continue the current
			regulation without change.
330	Establishes the criteria	This section is identical to section 270	The intent and impact is to
	for reporting of	in Chapter 20.	continue the current
	malpractice paid claims		regulation without change.
	and disciplinary actions.		
340	Sets out the consequence	This section is identical to section 280	The intent and impact is to
	for noncompliance or	in Chapter 20.	continue the current
	falsification of one's		regulation without change.
	profile		
350	Establishes the	This section is identical to section 290	The intent and impact is to
	requirements for	in Chapter 20.	continue the current
	certification to perform		regulation without change.
	cosmetic procedures		
360	Lists the types of	This section is identical to section 300	The intent and impact is to
	procedures for which	in Chapter 20.	continue the current
	certification is not	^	regulation without change.

	required		
370	Sets out the credentials required for certification to perform cosmetic procedures	This section is identical to section 310 in Chapter 20.	The intent and impact is to continue the current regulation without change.
380	Establishes the requirements for renewal of certification	This section is identical to section 320 in Chapter 20.	The intent and impact is to continue the current regulation without change.
390	Establishes the requirements for a quality assurance review of procedures performed by certificate holders	This section is identical to section 330 in Chapter 20.	The intent and impact is to continue the current regulation without change.
400	Sets out the process for handling complaints against certificate holders	This section is identical to section 331 in Chapter 20.	The intent and impact is to continue the current regulation without change.
410	Establishes the requirements for registration of mobile dental clinics or portable dental operations	This section is identical to section 332 in Chapter 20.	The intent and impact is to continue the current regulation without change.
420	Establishes the requirements for operation of a clinic or operation	This section is identical to section 342 in Chapter 20.	The intent and impact is to continue the current regulation without change.
430	Sets out the entities that are exempt from the requirements for registration	This section is identical to section 352 in Chapter 20.	The intent and impact is to continue the current regulation without change.



Final Regulation Agency Background Document

Form: TH-03

Agency name	Board of Dentistry, Department of Health Professions	
Virginia Administrative Code (VAC) citation	18VAC60-25	
Regulation title	Regulations Governing the Practice of Dental Hygiene	
Action title	Promulgation of new chapter resulting from periodic review and reorganization	
Date this document prepared	3/11/14	

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

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

The new regulations result from a periodic review of Chapter 20 and the action of the Board to divide the Chapter into three separate sets of regulations for dentists, dental hygienists and dental assistants. Chapter 25 is promulgated as a new chapter with all the sections and provisions from current regulation that pertain to the practice of dental hygiene.

Statement of final agency action

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

On March 7, 2014, the Board of Dentistry adopted 18VAC65-25-10 et seq., Regulations Governing the Practice of Dental Hygiene.

Legal basis

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Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

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

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

- 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. ...

The specific statutory authority for the licensure and practice of dental hygienists is found in Chapter 27 of Title 54.1.

Purpose

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

The new regulations are a reorganization and restatement of current requirements for licensure and practice found in Chapter 20, Regulations Governing Dental Practice. Such requirements are necessary to ensure the health and safety of dental patients, while assuring appropriate access to care by dental hygienists.

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Substance

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

There are no substantive changes to current regulations governing dental hygienists. Provisions in Chapter 20 on Dental Practice that are applicable to the registration, practice and renewal for dental hygienists were identified and included in a new Chapter 25.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and
- 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.
- 1) Regulations for the practice of dental hygiene establish the qualifications for licensure and standards of practice. There are advantages to the public if those standards and requirements are reasonable and clearly stated, so practitioners and consumers understand the scope of practice of a hygienist. There should be no disadvantages.
- 2) There are no disadvantages of these provisions to the agency or the Commonwealth; licensure is required by law. Specificity about direction and the levels of supervision should allow Board staff to direct persons with questions about those issues to the regulations.
- 3) These are <u>current</u> regulations restructured in a new chapter.

Changes made since the proposed stage

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

Section number	•	What has changed	Rationale for change
10	Sets out definitions for words and terms used in regulation	The term "non-surgical" is defined.	The term is defined because it is used in section 40. The Board adopted a definition from the Texas State Board of

			Dental Examiners.
20	Sets out requirement for posting of a license in the dental office	Adds a modifier to the word "license" for clarification.	The amendment specifies that it is the "dental hygienist" license that must be posted.
40	Establishes the scope of practice for dental hygienists under direction and varying levels of supervision	Subsection C #1 is amended to substitute "non-surgical" for "athermal" lasers and to delete the phrase "by the dentist" at the end of the sentence. Subsection D is also amended to use the term "non-surgical" instead of "athermal." Subsection F is added; it is taken from a current regulation that became effective 11/21/12.	The term "athermal" was not clearly understood or defined in the literature, so "non-surgical" has been substituted and defined. The intent is the same. The term "by the dentist" is deleted because dental hygienist with certain qualifications can also administer types of anesthesia. The language in subsection F was adopted as an exempt action in 2012 to implement legislation for "remote" supervision of dental hygienists employed at VDH. That section did not exist when proposed regulations for this action were adopted.
70	Sets out the rules for delegation of services to a dental assistant	Amendments to subsection A delete the "dentist" and add "those that may only be delegated to a dental assistant II."	Amendments are consistent with delegation provisions in chapter for dentist. Since this chapter regulates dental hygienists, the "dentist" was deleted.
100	Establishes rules for administration of controlled substances by dental hygienists	Subsection A #3 is amended to change the placement of the adverb "parenterally." All of current subsection C is deleted and replaced with a new subsection C.	The change is grammatical and not substantive. As proposed, subsection C set out the requirements for administration of both nitrous and local anesthesia. There was a section for nitrous only, but there was no section for local anesthesia only. The new subsection C sets out requirements for local anesthesia only, so if a hygienist wants to administer both types of sedation and anesthesia, he would meet requirements of both sections B and C. The total number of hours remains the same (8 for nitrous; 28 for local anesthesia for a total of 36 hours)
110	Subsection A specifies the information that must be included in a patient record	Adds identification of the teeth to the information needed for visual images and the treatment rendered to the notation about provision of	In reviewing proposed regulations for all professions, board members identified the elements of a complete record

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		services	that were missing and are essential to determining whether adequate, competent care was provided.
130	Sets out the general application requirements for dental hygiene licensure	The word "teacher's" is deleted and "faculty" substituted. The requirement for a HIPDB is deleted on the application requirements.	The change resulted from legislation passed in 2012 in which all licenses to teach are "faculty" licenses. There is now only one national practitioner databank – known as NPDB.
160	Sets out rules for temporary permits and faculty licenses	The term "teacher's" is deleted and substituted with "faculty" license.	Consistent with 2012 legislation.
190	Sets out the requirements for continuing education for renewal of dental hygiene licensure	Subsection A is amended to eliminate the requirement of 4 hours of CE every 2 years for hygienists who administer nitrous oxide or non-topical local anesthesia.	The amendment is in response to a request from the Dental Hygiene Association; the Board concurred with the comment.
		Subsection C is amended to add the Dental Auxiliary Learning and Education Foundation to the list of approved sponsors of CE.	The amendment is in response to a request from the Dental Assisting National Board; the Board concurred with the comment.
		Subsection C is also amended to add: 1) the American Academy of Dental Hygiene (AADH); and 2) the Council of Interstate Testing Agencies (CITA).	1) The AADH was added to the list by a fast-track action, effective 9/26/13, in response to a petition for rulemaking. 2) CITA has been added to the list of testing agencies acceptable for licensure and continuing education since regulations were proposed.

Public comment

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

Proposed regulations were published on November 4, 2013 with public comment accepted through January 11, 2014. A public hearing was held on January 10, 2014.

Commenter	Comment	Board Response to Comment
Katherine	Recommends adding the Dental Auxiliary	The Board accepted the
Landsberg	Learning and Education Foundation (DALE),	recommendation and amended
DANB and the	an affiliate of the Dental Assisting National	Chapters 21, 25 and 30 accordingly.
DALE Foundation	Board (DANB), to the list of approved	
	sponsors for continuing education courses	
Maureen Thompson	Recommended: 1) Including a separate	1) The Board adopted amendments to
American Dental	section listing requirements for	section 100 to separate the
Hygienists'	administration of local anesthesia only to	requirements for nitrous and local

Association	reduce confusion and frustration; and 2) Deleting the age restriction (18 and older) for administration of local anesthesia; and 3) Amending the requirement for 4 hours of CE every 2 years on administration of nitrous oxide and non-topical anesthesia by dental hygienists.	anesthesia; 2) The age restriction for local anesthesia is statutory – subsection J of § 54.1-3408 of the Drug Control Act. No regulatory action can supersede the Code. 3) The Board adopted amendments to section 190 to delete the required CE for dental hygienists who administer
		nitrous or non-topical local anesthesia.

All changes made in this regulatory action

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

In addition to changes made in the adoption of final regulations, as noted above:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
10	Several words and terms used in regulation are being defined in all chapters broken out from Chapter 20. They are: CODA Code Monitoring	This section repeats applicable definitions from section 10 in Chapter 20 that is being repealed. Two terms used in this new chapter are defined: "Active practice" is defined as 600 hours per year in order to have clarity about the qualification for licensure by endorsement or for evidence of active practice to reinstate or reactive a license. "Topical oral anesthetic" is defined as used in section 40 on Scope of Practice	The intent and impact is to continue the current regulation with the additional definitions for words and terms that are used but have previously been undefined.
20	Sets out requirements for address of record to be maintained with the board and for posting of the dental hygienist license.	This section repeats requirements from section 16 in Chapter 20.	The intent and impact is to continue the current regulation without change.
30	Establishes the fees applicable to dental hygienists	This section repeats requirements for fees from sections 20, 30 and 40 in Chapter 20. Other	The intent and impact is to continue the current regulation without change.

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		requirements for renewal, etc. in section 20 are set out in other sections in the new chapter for dental hygienists.	
40	Sets out the scope of practice for dental hygienists.	-	The intent and impact is to continue the current regulation without substantive changes. Some provisions are clarified consistent with current practice and updated by inclusion of new techniques or technology (such as use of athermal lasers).
		in subsection B of section 220 in Chapter 20. Subsection E lists those duties that may be delegated to a dental assistant II; they are	

		currently found in subsection C of section	
50	Specifies the utilization of dental hygienists and dental assistant II by a dentist.	230 in Chapter 20. All provisions of section 50 are the same as those in section 200 in Chapter 20	The intent and impact is to continue the current regulation without change.
60	Sets out the requirements for delegation of services to a dental hygienist.	Subsection A is identical to subsection A of section 210 in Chapter 20. Subsection B is identical to subsection B of section 210 in Chapter 20, with the exception of the reference to teaching licenses or providing oral health education. The provisions of section 60 are not applicable so an exception is unnecessary. Subsection C is taken from subsection C of section 210. The requirements are substantively the same, but the current provision stating that no anesthesia can be provided is amended to state that "only topical oral anesthetics" can be administered to manage pain. Subsection D is	The intent and impact is to continue the current regulation without change. The current regulation on provision of anesthesia under general supervision is misleading because the hygienist is allowed to provide topical oral anesthetics to manage pain. In subsection D, language is amended for consistency with definitions. "Direction" is defined as the level of supervision required, so the current regulation is unclear. The proposed regulation specifies that the dentist may choose to direct another level of supervision if it is necessary to meet the needs of the patient.
70		substantively the same as subsection D of section 210.	
70	Specifies requirements for delegation to a dental assistant I or II.	Provisions of subsection A are similar to subsection A of section 230 in Chapter 20. Provisions of subsection B are identical to subsection B of section 230.	The intent and impact is to continue the current regulation without any substantive change.
80	Specifies the requirements for an unregulated person to place or	Provisions of section 80 are similar to section 195 in Chapter 20.	Since the Board does not regulate unlicensed persons, the responsibility

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	expose dental x-rays.		is placed on a dentist or dental hygienist to not permit someone to do dental x-rays unless she has the specified qualifications.
90	Specifies the acts that do not constitute dental or dental hygiene practice.	Similar to section 240 is Chapter 20 but amends "preliminary dental screenings in any setting" to specific screening in free clinics, public health programs or in voluntary practice.	The Board amended dental screening because dental hygienists are allowed to practice under general supervision with written orders in those settings.
100	Sets out the scope of practice for a hygienist in the administration of controlled substances and the qualifications necessary for such administration.	Subsection A, ## 1 and 2 are restatements of provisions in the Drug Control relating to current authority for hygienists to administer. # 3 in subsection A is similar to subsection A of section 81 in current regulations. Subsection B is identical to subsection B in section 81. Subsection C is amended (see changes to proposed regulations above) Subsection D is identical to subsection D in section 81.	The intent and impact is to continue the current regulation without change.
110	Sets out the requirements for maintenance of patient records and for confidentiality of patient information.	The content in subsection A is similar to section 15 on recordkeeping in Chapter 20. The hygienist is responsible for recording those services she is authorized to provide. The requirement is updated to include digital images and photographs. Requirements in subsection B for compliance with patient	The intent and impact of the requirements for patient records is assurance that records are complete and accurate. In proposed regulations for both hygienists and dentists, the health history requirement is clarified so it is not required to take a health history at each appointment but only annually, when medically indicated, or when administering anesthesia

		record confidentiality and disclosure law is added in this chapter and those for dentists and dental hygienists.	or analgesia. Additionally, the record should include consent for treatment, with the exception of a prophylaxis, which is routine. For hygienists, treating a patient under general supervision, it is necessary to note or document an order given by the dentists. The intent and impact is also to ensure that patient information is held in confidence or disclosed as permitted or required by law.
120	Establishes the acts constituting unprofessional conduct.	Section 120 is taken from section 170 in Chapter 20, with the exception of ## 8 and 9 which are specific to the practice of dentists rather than hygienists.	The intent and impact is to continue the current regulation and to include general provisions of Chapters 1 and 24 in Title 54.1 and the Drug Control Act.
130	Establishes the general application requirements.	Section 130 is taken from section 100 in Chapter 20. The requirement for an attestation on laws and regulations is currently found in the separate sections on licensure by examination or endorsement.	The intent and impact is to continue the current regulation without change.
140	Sets out the qualifications for licensure by examination, including completion of a CODA-accredited program and passage of the national examination and a board-approved clinical competency exam.	Subsections A and B are taken from subsection B of section 60 and subsection A of section 70 of Chapter 20. Subsection C is taken from subsection D of section 70 of Chapter 20.	The intent and impact is to continue the current regulation without change.
150	Sets out the qualifications for licensure by endorsement.	Provisions of section 150 are currently found in section 80 of Chapter 20, with the exception of a current requirement for "good moral character."	The intent and impact is to continue the current regulation but to eliminate the requirement for which there is currently no proof or documentation.

160	Establishes the switzwis for in-	Dravigions in sasting 160	The intent and inti-
160	Establishes the criteria for issuance of a temporary permit or a teacher's license.	Provisions in section 160 are taken from section 90 in the current Chapter 20.	The intent and impact is to continue the current regulation without change.
170	Establishes the criteria for voluntary practice by a dental hygienist.	All requirements in section 70 are currently found in section 106 of the current regulations.	The intent and impact is to continue the current regulation without change
180	Sets out requirements for renewal of a hygienist license.	The schedule for renewal of a hygienist license (annually by March 31 st) is identical to subsection A of section 20 of Chapter 20. The deadline for annual renewal of other licenses under this new chapter is set as June 30. The provisions in subsection B are currently specified in subsection C of section 20 in Chapter 20. Subsection C in the new chapter is similar to subsection B of section 20.	The intent of the change to June 30 for certain licenses is to have staggered renewals for some professions to lessen the workload at one time of year.
190	Sets requirements for continuing education for renewal of a dental hygiene license.	All requirements and provisions for continuing education are currently found in section 190 of Chapter 20. Other than some reorganization of provisions, there are no changes but there are additions (see changes to proposed regulations above).	The intent and impact is to continue the current regulation without change.
200	Sets requirements for holding an inactive license.	Section 200 is identical to subsection A of section 105 in Chapter 20.	The intent and impact is to continue the current regulation without change.
210	Sets requirements for reactivating an inactive license or reinstating a lapsed license.	Subsections A and B on reinstatement and reactivation are similar to subsection C in section 20 and subsection H of section 50 in Chapter 20. Currently, the Board may require evidence of competency including active practice or board	The basic regulation for reinstatement or reactivation is similar to current regulations, but the additional evidence of continuing competency such as practice in another state or a refresher course will be "required" rather than at the discretion of the

certifi	cation. The	Board. Simple
propo	sed regulations	completion of CE hours is
would	l allow recent	not sufficient evidence
passag	ge of a clinical	that a dental hygienist has
compe	etency examination	maintained skills
accept	ted by the board or	adequate to protect the
compl	letion of a refresher	public during a period in
progra	am offered by a	which her license was
	A accredited program	lapsed or inactive. There
as evid	dence.	are several options for
		demonstration of
		competency, including
		active practice in another
		state, so fulfillment of the
		requirement will not be
		burdensome.



Final Regulation Agency Background Document

Form: TH-03

Agency name	Board of Dentistry, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC60-30
Regulation title	Regulations Governing the Practice of Dental Assistants
Action title	Promulgation of new chapter resulting from periodic review and reorganization
Date this document prepared	3/11/14

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

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

The new regulations result from a periodic review of Chapter 20 and the action of the Board to divide the Chapter into three separate sets of regulations for dentists, dental hygienists and dental assistants. Chapter 30 is promulgated as a new chapter with all the sections and provisions from current regulation that pertain to the practice of dental assistants and the registration of dental assistants II.

Statement of final agency action

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

On March 7, 2014, the Board of Dentistry adopted 18VAC65-30-10 et seq., Regulations Governing the Practice of Dental Assistants.

Legal basis

Form: TH-03

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

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

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

- 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. ...

The specific statutory authority for promulgation of regulations pertaining to dental assistants II is found in:

§ <u>54.1-2729.01</u>. Practice of dental assistants.

A. A person who is employed to assist a licensed dentist or dental hygienist by performing duties not otherwise restricted to the practice of a dentist, dental hygienist, or dental assistant II, as prescribed in regulations promulgated by the Board may practice as a dental assistant I.

B. A person who (i) has met the educational and training requirements prescribed by the Board; (ii) holds a certification from a credentialing organization recognized by the American Dental Association; and (iii) has met any other qualifications for registration as prescribed in regulations promulgated by the Board may practice as a dental assistant II. A dental assistant II may perform duties not otherwise restricted to the practice of a dentist or dental hygienist under the direction of a licensed dentist that are reversible, intraoral procedures specified in regulations promulgated by the Board.

Form: TH-03

The Dental Practice Act (Chapter 27 of Title 54.1) permits the practice of dental assistants:

§ 54.1-2712. Permissible practices.

The following activities shall be permissible:

1. Dental assistants or dental hygienists aiding or assisting licensed dentists in accordance with regulations promulgated pursuant to $\S 54.1-2729.01$; ...

Purpose

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

To ensure the services can be safely provided by a dental assistant II (DAII), the Board set in the regulation the evidence of minimal competency that a dental assistant must demonstrate in order to be registered and authorized to perform expanded duties. Qualifications include specified hours of didactic education, clinical training and experience and examination in modules for the performance of specific duties delegated under direct supervision. While the applicant will have to demonstrate clinical knowledge and skills to be registered as a DAII, the dentist will have to be present in the facility, will have to examine the patient both before and after treatment by a DAII and will remain responsible for the care of the patient. Such requirements are necessary to ensure the health and safety of dental patients, while increasing the number of qualified dental personnel and access to care.

Substance

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

There are no substantive changes to current regulations governing dental assistants. Provisions in Chapter 20 on Dental Practice that are applicable to the registration, practice and renewal for Dental Assistants II were identified and included in a new chapter for the registration of dental assistants.

Issues

Form: TH-03

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and
- 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.
- 1) Regulations for expanded duty dental assistants became effective March 2, 2011. In promulgating those regulations, the agency stated that the primary advantage to the public is more accessibility for dental care by persons who are qualified by education, training and examination to perform certain restorative and prosthetic dental functions. The ability of dental practices to provide services to populations of patients is enhanced with expanded duty dental assistants and with an increase in the ratio of dentists to dental hygienists and/or dental assistants II from two per dentist to four per dentist. To the extent dental assistants acquire the additional qualifications and credentials for expanded functions as a DAII, the regulation has the potential to improve accessibility and reduce costs. If the dental assistants II are appropriately trained and clinically competent, and if the dentist provides direct supervision as specified in regulation, there should be no disadvantages.
- 2) There are no disadvantages of these provisions to the agency or the Commonwealth; registration is required by law. Specificity about direction and the levels of supervision should allow Board staff to direct persons with questions about those issues to the regulations.
- 3) These are current regulations restructured in a new chapter.

Changes made since the proposed stage

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

Section number	Requirement at proposed stage	What has changed	Rationale for change
Title	Referenced only Dental Assistants II	Deletion of II after Dental Assistants	While only dental assistants II are registered by the Board, there are specified activities and required supervision for "chairside" dental assistants or a DAI, so the Title was amended to be more consistent and inclusive.
10	Definition of "direction" includes the levels of supervision that are required for various types of practitioners and	Added the term "immediate supervision" in the definition of direction among the levels of supervision required.	It was defined in section 10 but omitted from listing of different levels of supervision in definition

	services		
20	Sets out requirement for posting of registration of DAII in dental office	Adds a provision for a DAII who may be employed in more than one office.	The amendment is consistent with current practice. An assistant employed in more than one office is allowed to display a duplicate registration obtained from the Board.
70	Sets out the appropriate delegation of duties to a dental assistant	Clarifies that the customary level of supervision for dental assistant is indirect supervision. Two minor changes of "the" to "any" and "a" to "any" emphasis the general applicability of the rule.	The references to "general supervision" and section 18VAC60-21-120 are deleted as they were confusing and inaccurate.
80	Sets out the requirement for obtaining radiation certification	Restates the sentence in the context of regulations for dental assistants I and II.	Proposed regulation did not clearly convey what a dental assistant had to do in order to obtain a radiation certificate. The amended language is more clearly stated.
100	Subsection A specifies the information that must be included in a patient record	Adds identification of the teeth to the information needed for visual images and the treatment rendered to the notation about provision of services	In reviewing proposed regulations for all professions, board members identified the elements of a complete record that were missing and are essential to determining whether adequate, competent care was provided.
115	Not in the proposed chapter	Adds a section on the general application requirements to clearly inform the applicant in the Part on entry requirements for a dental assistant II	Most of the provisions of section 115 are stated in section 130 (which is misplaced in the Part and is being deleted).
120	Sets out the educational requirements for registration as a dental assistant II	Subsection is modified for consistency with accrediting language in other sections.	There is no substantive change.
130	States the requirements for a registration certificate	Subsections A and C are restated in new section 115. Subsection B is deleted.	There are no board- approved examinations, so subsection B was inaccurately stated and is deleted entirely.
150	Sets out the requirements for renewal of registration	Subsection F is deleted.	Since there are no continuing education hours required for registration renewal, the provision of subsection F is inaccurate.
160	Sets out the requirements for reactivation of an inactive registration	*The section has been amended by dividing it into 3 subsections and adding a general requirement for	The Dental Assisting National Board (DANB) is recognized as the

		evidence of continuing clinical competency.	certifying body for dental assistants, so the Board has added clarity by naming that organization. Additionally, the Board realized that there was no requirement for evidence of clinical competency. The DANB certification is basic for all assistants and is not an indication of competency for the expanded duties of a DAII. To protect the public, the Board has added a requirement for clinical competency to return to practice and given two examples of how that may be demonstrated.
170	Sets out the requirements for reinstatement of a lapsed registration	*Section 170 has the same additions as Section 160.	Same as above.

Public comment

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

Proposed regulations were published on November 4, 2013 with public comment accepted through January 11, 2014. A public hearing was held on January 10, 2014. No public comment was received.

All changes made in this regulatory action

In addition to changes made in the adoption of final regulations, as noted above:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
10	Several words and terms used in regulation are being defined in all chapters broken out from Chapter 20. They are: CODA Code	This section repeats applicable definitions from section 10 in Chapter 20 that is being repealed. "Immediate supervision" is defined in Chapter 30 because it is a term used to	The intent and impact is to continue the current regulation with the additional definitions for words and terms that are used but have previously been undefined.

	Monitoring	describe direction for the practice of dental assistants.	
20	Sets out requirements for address of record to be maintained with the board and for posting of the DA II registration.	This section repeats requirements from section 16 in Chapter 20.	The intent and impact is to continue the current regulation without change.
30	Establishes the fees applicable to dental assistants II	This section repeats requirements for fees from sections 20, 30 and 40 in Chapter 20. Other requirements for renewal, etc. in section 20 are set out in other sections in the new chapter for DAII's.	The intent and impact is to continue the current regulation without change.
40	Sets out the general responsibilities for supervision and delegation of a dentist to a dental assistant.	Subsection A of section 40 is virtually identical to section 200 in Chapter 20. Subsection B of section 40 is identical to subsection A of section 210 in Chapter 20.	The intent and impact is to continue the current regulation without change.
50	Sets out the duties that cannot be delegated by a dentist to other personnel.	All provisions of section 50 are the same as those in section 190 in Chapter 20	The intent and impact is to continue the current regulation without change.
60	Sets out the duties that can be delegated by a dentist to a DAII	The duties set out in section 60 are identical to those in subsection C of section 230 in Chapter 20	The intent and impact is to continue the current regulation without change.
70	Specifies requirements for delegation to a dental assistant I or II	Provisions of subsection A are similar to subsection A of section 230 in Chapter 20. Provisions of subsection B are identical to subsection B of section 230.	The only change in the new regulations is the type of supervision applicable for delegation. Currently, regulations specify delegation under "direction" or "general supervision. "Direction" is defined as the level of supervision required, so in the new regulations the level is specified as "indirect" or "general."
80	Specifies the requirements for an unregulated person to place or expose dental x-rays.	Provisions of section 80 are similar to section 195 in Chapter 20.	Since the Board does not regulate unlicensed persons, the responsibility is placed on a dentist or dental hygienist to not

90	Specifies the acts that do not constitute dental or dental hygiene practice.	The content of section 90 is identical to section 240 in Chapter 20.	permit someone to do dental x-rays unless she has the specified qualifications. The intent and impact is consistency in language for all chapters regulating dentists, dental hygienists
100	Sets out the requirements for	The content in subsection	and dental assistants. The intent and impact of
	accurate and complete patient records and the content of a patient record for which a DAII can be responsible	A is similar to section 15 on recordkeeping in Chapter 20. The assistant is only responsible for recording those services she is authorized to provide. The requirement is updated to include digital images and photographs.	the requirements for patient records is assurance that records are complete and accurate, that it is apparent who provided services to the patient and that patient information is held in confidence or disclosed as permitted or required by law.
		Requirements in subsection B for compliance with patient record confidentiality and disclosure law is added in this chapter and those for dentists and dental hygienists.	
110	Sets out the act that constitute unprofessional conduct, as stated in §54.1-2706.	The provisions of section 110 are taken from section 170 in Chapter 20; only those applicable to a DAII are noted in this chapter.	The intent and impact is to continue the current regulation and to include general provisions of Chapters 1 and 24 in Title 54.1 and the Drug Control Act.
120	Establishes the educational qualifications for an applicant to be registered as a DAII.	Section 120 is identical to section 61 in Chapter 20.	The intent and impact is to continue the current regulation without change.
130	Establishes the general requirements for registration as a DAII.	Section 130 is identical to subsections C, D and E of section 70 in Chapter 20.	The intent and impact is to continue the current regulation without change.
140	Sets out the qualifications for registration by endorsement.	Section 140 is identical to section 72 in Chapter 20, except the requirement for "good moral character" is omitted.	The intent and impact is to continue the current regulation but to eliminate the requirement for which there is

			currently no proof or documentation.
150	Sets out requirements for renewal of a DAII registration, including current certification from the Dental Assisting National Board or other credentialing body.	The schedule for renewal (annually by March 31 st) and the requirement for a late fee is identical to subsection A of section 20; the requirements in subsection C and D are specified in subsection A of section 50 in Chapter 20. Subsection F is identical to subsection I of section 50.	The intent and impact is to continue the current regulation without change.
160	Sets out requirements for taking an inactive status and for reactivating one's registration.	Section 150 is identical to subsection C of section 105 in Chapter 20.	The intent and impact is to continue the current regulation without change.
170	Sets out requirements for reinstating a registration that has expired.	Provisions in section 170 are taken from section 20 of Chapter 20.	The intent and impact is to continue the current regulation without change