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Proposed Regulation Agency Background Document

Agency name	Board of Dentistry, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC60-21 18VAC60-30
VAC Chapter title(s)	Regulations Governing the Practice of Dentistry Regulations Governing the Practice of Dental Assistants
Action title	Training in infection control
Date this document prepared	06/17/21

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

Brief Summary

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

In response to a petition for rulemaking from the Virginia Dental Hygiene Program Directors' Consortium, the Board decided to initiate rulemaking to consider adoption of a requirement for training in infection control for dental assistants.

The amended regulation requires a dental assistant to complete annual training in infection control standards as recommended by the Centers for Disease Control through the Occupational Safety and Health Administration. Newly employed assistants must receive training within 60 days of hire. Dentists are required to assure that such training take place and to maintain documentation of training for three years.

Acronyms and Definitions

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

CDC = Centers for Disease Control
OSHA = Occupational Safety and Health Administration

Mandate and Impetus

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

The impetus for the regulatory change was a petition (#313) from the Virginia Dental Hygiene Program Directors' Consortium requesting an amendment to require dental assistants to be certified in infection control procedures recognized by the Dental Assisting National Board or the National Entry Level Dental Assistant. The Board concurred that the comment and concerns expressed warranted rulemaking.

Legal Basis

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

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

§ 54.1-2400 - General powers and duties of health regulatory boards

The general powers and duties of health regulatory boards shall be:

- 1. To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.*
- 2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*
- 3. To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*

...

6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...

Specific authority for regulation of the profession of dental assisting is found in Chapter 27 of Title 54.1:

§ 54.1-2729.01. 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.

Purpose

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

The purpose of the action is to address concerns about breaches in infection control techniques that endanger the health and safety of the public. In several other states, there have been egregious cases of infection with long term consequences for patients who were exposed to pathogens during the course of dental treatment. While the Board is not aware of such reports in Virginia, it did review several disciplinary cases within the past few years in which dentists were disciplined for a lack of infection control in sterilization of instruments and other risky practices. Since dental assistants I are not regulated by the Board, the dentist is accountable for infection control practice, but it is often the dental assistant who is responsible for infection control processes and procedures. The purpose of a regulatory action is to ensure some consistency in training and a level of competency that protects dental patients.

The goal of the proposed action is to ensure dental assistants are properly trained in practices that mitigate the chances of infections in dental practices.

Substance

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

New section 85 in Chapter 30 requires that a dental assistant complete annual training in infection control standards as recommended by the Centers for Disease Control through the Occupational Safety and Health Administration. A newly employed assistant must receive training within 60 days of hire.

New section 175 in Chapter 21 requires a dentist to be responsible for assuring that dental assistants complete annual training in infection control and that newly employed assistants receive training within 60 days of hire. Dentists are required to maintain documentation of training for three years.

Issues

Identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

- 1) The primary advantage to the public is a standardized expectation of training in infection control for patient safety throughout the Commonwealth, at all dental offices. There are no disadvantages. Dentists are already expected to adhere to OSHA and CDC guidelines for infection control.
- 2) There are no advantages or disadvantages to the agency or the Commonwealth.
- 3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under § 54.1-2400 “*To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system...*” The requirement that all dental assistants obtain infection control training prior to being allowed to engage in clinical work is intended to protect the public from cross contamination and spread of disease due from untrained or inadequately trained dental assistants. Therefore, the proposed regulation is a foreseeable result of the statute requiring the Board to protect the safety and health of patients in the Commonwealth. The proposal is intended to ensure all dental assistants are trained on current best practices of sterilization and disinfection, thereby ensuring that patients receive the same standard of care from every dental office in the Commonwealth.

Requirements More Restrictive than Federal

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

There are no applicable federal requirements. Dental assistants are regulated through each state’s Dental Practice Act.

Agencies, Localities, and Other Entities Particularly Affected

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

Other State Agencies Particularly Affected - None

Localities Particularly Affected – None

Other Entities Particularly Affected – None

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is change versus the status quo.

Impact on State Agencies

<i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	There are no projected costs, savings, fees or revenues to the agency resulting from the regulatory change.
<i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no costs to other state agencies.
<i>For all agencies:</i> Benefits the regulatory change is designed to produce.	The regulation will have no impact that will benefit or harm the agencies.

Impact on Localities

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

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be	Dental assistants and dentists. Dental assistants will be required to obtain infection control training as required by OSHA. Dentists will be required to
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affected, include a specific statement to that effect.	maintain documentation of such training on all dental assistants employed by the dentist.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	The Board currently licenses 7,675 dentists. Dental assistants I are not licensed by the Board, and so it is unclear how many dental assistants I will be affected by the regulation.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	CDC guidelines and OSHA training are available on-line for health care practitioners, so training should be of no costs to dental assistants who can complete the on-the-job training.
Benefits the regulatory change is designed to produce.	The primary benefit this regulatory change is designed to produce is increased knowledge of infection control standards to prevent or mitigate against cases of patient harm.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

The Board considered several alternatives in the development of a regulatory change, including certification in infection control procedures recognized by the Dental Assisting National Board or the National Entry Level Dental Assistant, as proposed by the petitioner. It chose the least burdensome alternative of in-office OSHA training that is available on-line.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the

proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

There is no alternative to regulation to ensure that dental patients in the Commonwealth receive the same standard of care in regards to infection control, other than the promulgation of regulations requiring registered dentists to ensure all dental assistants have achieved such training.

Periodic Review and Small Business Impact Review Report of Findings

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable.

In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency’s consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency’s decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

This proposed action is not being used to announce a periodic review or a small business impact review.

Public Comment

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

There were 75 comments on the NOIRA received on the Regulatory Town Hall.

Commenter	Comment	Agency response
45 comments posted on Town Hall in opposition	Opposed to the an action as proposed by the petitioner for the following reasons: 1) Does not add protection for the public; already required to complete OSHA or CDC training. 2) Will undermine qualified dentists who train all new assistants 3) No COVID outbreaks have been traced back to dental offices,	The Board has considered the comments and adopted the least burdensome alternative, which is OSHA training on the CDC guidelines. According to comments, there is an expectation that annual training is already required. Therefore, it should not create any additional costs for dental offices.

	<p>indicating that sterilization is being performed adequately</p> <ol style="list-style-type: none"> 4) Will hurt dental assistants in rural areas who do not have access to an accredited assisting school 5) Will create an undue burden on dental assistants expected to pay for the training themselves 6) Regulation is unfairly aimed only at dental assistants, not hygienists and the entire profession 7) Will harm rural dental practices who have high staff turnover and need to have dental assistants ready to work prior to fulfilling 16 hours of infection control training 	<p>Newly hired dental assistants will have 60 days to complete the training.</p>
<p>30 comments posted on Town Hall in support</p>	<p>In favor of the proposed action for the following reasons:</p> <ol style="list-style-type: none"> 1) Will ensure that all dental assistants are aware of airborne and bloodborne pathogens and the differences between sterilization and disinfection, and standard precautions in preventing cross-contamination 2) Will provide dental assistants confidence in their ability to prevent disease transmission, leading to fewer dental assistants leaving their roles in times of crisis 3) Will comply with the position of the American Dental Assistants Association that dental assistants educated in infection control will add to the protection of the public 4) Believes infection control training is needed to ensure updated information and current-ness 5) OSHA is insufficient training for protecting patients because its training focuses on protecting employees 6) Concern that COVID-19 and future viruses will place patients at additional risk unless infection control training is specifically required 7) Creates consistency of dental assistant training among all dental practices in Virginia 	<p>The Board concurred that annual training in infection control is necessary for patient protection, but did not agree with a recommendation to require an additional certification for dental assistants.</p>
<p>Dr. Frank Luorno, Pres. Va. Dental Association</p>	<p>Since the Board currently requires OSHA and CDC training, such a requirement is redundant.</p>	<p>Commenters have referred to the Board's "requirement" for training. In fact, there is no such regulation. The standard is noted in a guidance document (60-15) on professional conduct, but a guidance document is</p>

		not enforceable. Since dentists already believe they are required to do OSHA and CDC training, it should not be problematic to ensure that their assistants also have such training.
Trey Lawrence Amer. Assoc. of Orthodontists	Notes the "requirement" for training in CDC infection control guidelines in 60-15. Therefore, regulations should defer to CDC or replicate CDC guidelines. Given the limited scope of a dental assistant I, no other task-specific infection control not covered in the training modules offered by OSHA or the CDC should be required.	See response above. The Board concurred with the comment that no additional training should be required.
Tracy Martin Va. Dental Hygienist Assoc.	Supports training in infection control; should be either continuing education offered by an approved CE sponsor, or certification from a national certifying body.	Since dental assistants I are not regulated by the Board, they do not renew and are not required to have CE. The Board concluded that an additional certification was not warranted.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

The Board of Dentistry is seeking comments on this regulation, including but not limited to: ideas to be considered in the development of this regulation, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation. Also, the agency/board is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the *Code of Virginia*. Information may include: 1) projected reporting, recordkeeping, and other administrative costs; 2) the probable effect of the regulation on affected small businesses; and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at <https://www.townhall.virginia.gov>. Written comments must include the name and address of the commenter. Comments may also be submitted by mail, email or fax to Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (<http://www.townhall.virginia.gov>) and on the Commonwealth Calendar website (<https://www.virginia.gov/connect/commonwealth-calendar>). Both oral and written comments may be submitted at that time.

A Regulatory Advisory Panel will not be used. Proposed regulations were developed by the Regulation Committee of the Board following receipt of public comment on the NOIRA.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
21-175	N/A	<p>Subsection A requires a dentist to be responsible for assuring that dental assistants complete annual training in infection control standards required by OSHA as recommended by the CDC. Newly employed dental assistants must receive training as soon as possible, but no later than 60 days from employment.</p> <p><i>All dental offices are currently expected to do OSHA/CDC training on an annual basis. Since dental assistants are often the office personnel responsible for sterility and preparation of equipment and the offertory, it is essential for them to understand the methods recommended by OSHA and the potential consequences to their patients and the staff. Newly hired assistants will not be delayed in their employment but will need to complete the training as soon as possible.</i></p> <p>Subsection B requires that documentation records show the dates of completion of initial and annual training, including the date of employment for new dental assistants. All documentation of training in infection control shall be maintained by the dentist for three years.</p> <p><i>The record-keeping requirement is necessary to have documentation in the event there is a problem relating to infection control. Training records can be maintained along with other employment records for assistants.</i></p>
30-85	N/A	<p>Section 85 requires a dental assistant to complete annual training in infection control standards required by OSHA as recommended by the CDC. Newly employed dental assistants must receive training as soon as possible, but no later than 60 days from employment.</p>