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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)		
VAC Chapter title(s)	Regulations Governing the Practice of Dentistry	
Action title	Training and supervision of digital scan technicians by dentists in the practice of teledentistry	
Date this document prepared	6/16/21	

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.

HB 165 and SB122 of the 2020 General Assembly defined a digital scan technician, as used in teledentistry, and required the Board to promulgate regulations for the training of technicians to practice under the direction of a dentist licensed in Virginia.

# **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.

### **Mandate and Impetus**

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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the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."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 this action is found in HB 165 and SB122 of the 2020 General Assembly. The legislation mandated that digital scan technicians complete the "training requirements of the Board." To specify training requirements for digital scan technicians to practice under the direction of a dentist licensed in Virginia, it is necessary to promulgate regulations. The legislation does not authorize or mandate registration, certification, or licensure of digital scan technicians.

## **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:

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 legislative authority for this regulatory action is:

#### **CHAPTER 37**

An Act to amend and reenact §§ 54.1-2700, 54.1-2711, and 54.1-2719 of the Code of Virginia and to amend the Code of Virginia by adding in Article 2 of Chapter 27 of Title 54.1 a section numbered 54.1-2708.5, relating to teledentistry.

[H 165] Approved March 2, 2020

Be it enacted by the General Assembly of Virginia:

1. That §§ <u>54.1-2700</u>, <u>54.1-2711</u>, and <u>54.1-2719</u> of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Article 2 of Chapter 27 of Title 54.1 a section numbered <u>54.1-2708.5</u> as follows:

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#### § <u>54.1-2700</u>. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Appliance" means a permanent or removable device used in a plan of dental care, including crowns, fillings, bridges, braces, dentures, orthodontic aligners, and sleep apnea devices.

"Board" means the Board of Dentistry.

"Dental hygiene" means duties related to patient assessment and the rendering of educational, preventive, and therapeutic dental services specified in regulations of the Board and not otherwise restricted to the practice of dentistry.

"Dental hygienist" means a person who is licensed by the Board to practice dental hygiene.

"Dentist" means a person who has been awarded a degree in and is licensed by the Board to practice dentistry.

"Dentistry" means the evaluation, diagnosis, prevention, and treatment, through surgical, nonsurgical, or related procedures, of diseases, disorders, and conditions of the oral cavity and the maxillofacial, adjacent, and associated structures and their impact on the human body.

"Digital scan" means digital technology that creates a computer-generated replica of the hard and soft tissues of the oral cavity using enhanced digital photography.

"Digital scan technician" means a person who has completed a training program approved by the Board to take digital scans of intraoral and extraoral hard and soft tissues for use in teledentistry.

"Digital work order" means the digital equivalent of a written dental laboratory work order used in the construction or repair of an appliance.

"License" means the document issued to an applicant upon completion of requirements for admission to practice dentistry or dental hygiene in the Commonwealth or upon registration for renewal of license to continue the practice of dentistry or dental hygiene in the Commonwealth.

"License to practice dentistry" means any license to practice dentistry issued by the Board.

"Maxillofacial" means pertaining to the jaws and face, particularly with reference to specialized surgery of this region.

"Oral and maxillofacial surgeon" means a person who has successfully completed an oral and maxillofacial residency program, approved by the Commission on Dental Accreditation of the American Dental Association, and who holds a valid license from the Board.

"Store-and-forward technologies" means the technologies that allow for the electronic transmission of dental and health information, including images, photographs, documents, and health histories, through a secure communication system.

"Teledentistry" means the delivery of dentistry between a patient and a dentist who holds a license to practice dentistry issued by the Board through the use of telehealth systems and electronic technologies or media, including interactive, two-way audio or video.

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- § <u>54.1-2708.5</u>. Digital scans for use in the practice of dentistry; practice of digital scan technicians.
- A. No person other than a dentist, dental hygienist, dental assistant I, dental assistant II, digital scan technician, or other person under the direction of a dentist shall obtain dental scans for use in the practice of dentistry.
- B. A digital scan technician who obtains dental scans for use in the practice of teledentistry shall work under the direction of a dentist who is (i) licensed by the Board to practice dentistry in the Commonwealth, (ii) accessible and available for communication and consultation with the digital scan technician at all times during the patient interaction, and (iii) responsible for ensuring that the digital scan technician has a program of training approved by the Board for such purpose. All protocols and procedures for the performance of digital scans by digital scan technicians and evidence that a digital scan technician has complied with the training requirements of the Board shall be made available to the Board upon request.

#### § <u>54.1-2711</u>. Practice of dentistry.

- A. Any person shall be deemed to be practicing dentistry who (i) uses the words dentist, or dental surgeon, the letters D.D.S., D.M.D., or any letters or title in connection with his name, which in any way represents him as engaged in the practice of dentistry; (ii) holds himself out, advertises, or permits to be advertised that he can or will perform dental operations of any kind; (iii) diagnoses, treats, or professes to diagnose or treat any of the diseases or lesions of the oral cavity, its contents, or contiguous structures,; or (iv) extracts teeth, corrects malpositions of the teeth or jaws, takes or causes to be taken digital scans or impressions for the fabrication of appliances or dental prosthesis, supplies or repairs artificial teeth as substitutes for natural teeth, or places in the mouth and adjusts such substitutes. Taking impressions for mouth guards that may be self-fabricated or obtained over-the-counter does not constitute the practice of dentistry.
- B. No person shall practice dentistry unless a bona fide dentist-patient relationship is established in person or through teledentistry. A bona fide dentist-patient relationship shall exist if the dentist has (i) obtained or caused to be obtained a health and dental history of the patient; (ii) performed or caused to be performed an appropriate examination of the patient, either physically, through use of instrumentation and diagnostic equipment through which digital scans, photographs, images, and dental records are able to be transmitted electronically, or through use of face-to-face interactive two-way real-time communications services or store-and-forward technologies; (iii) provided information to the patient about the services to be performed; and (iv) initiated additional diagnostic tests or referrals as needed. In cases in which a dentist is providing teledentistry, the examination required by clause (ii) shall not be required if the patient has been examined in person by a dentist licensed by the Board within the six months prior to the initiation of teledentistry and the patient's dental records of such examination have been reviewed by the dentist providing teledentistry.
- C. No person shall deliver dental services through teledentistry unless he holds a license to practice dentistry in the Commonwealth issued by the Board and has established written or electronic protocols for the practice of teledentistry that include (i) methods to ensure that patients are fully informed about services provided through the use of teledentistry, including obtaining informed consent; (ii) safeguards to ensure compliance with all state and federal laws and regulations related to the privacy of health information; (iii) documentation of all dental services provided to a patient through teledentistry, including the full name, address, telephone number, and Virginia license number of the dentist providing such dental services; (iv) procedures for providing in-person services or for the referral of patients requiring dental services that cannot be provided by teledentistry to another dentist licensed to practice dentistry in the Commonwealth who actually practices dentistry in an area of the Commonwealth the patient can readily access; (v) provisions for the use of appropriate encryption when transmitting patient health information via teledentistry; and (vi) any other provisions required by the Board. A dentist who delivers dental services using teledentistry shall, upon request of the patient, provide health records to the patient or a dentist of record in a timely manner in accordance with § 32.1-127.1:03 and any other applicable federal or state laws or

regulations. All patients receiving dental services through teledentistry shall have the right to speak or communicate with the dentist providing such services upon request.

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D. Dental services delivered through use of teledentistry shall (i) be consistent with the standard of care as set forth in § 8.01-581.20, including when the standard of care requires the use of diagnostic testing or performance of a physical examination, and (ii) comply with the requirements of this chapter and the regulations of the Board.

E. In cases in which teledentistry is provided to a patient who has a dentist of record but has not had a dental wellness examination in the six months prior to the initiation of teledentistry, the dentist providing teledentistry shall recommend that the patient schedule a dental wellness examination. If a patient to whom teledentistry is provided does not have a dentist of record, the dentist shall provide or cause to be provided to the patient options for referrals for obtaining a dental wellness examination.

F. No dentist shall be supervised within the scope of the practice of dentistry by any person who is not a licensed dentist.

§ 54.1-2719. Persons engaged in construction and repair of appliances.

A. Licensed dentists may employ or engage the services of any person, firm, or corporation to construct or repair an appliance, extraorally, prosthetic dentures, bridges, or other replacements for a part of a tooth, a tooth, or teeth in accordance with a written or digital work order. Any appliance constructed or repaired by a person, firm, or corporation pursuant to this section shall be evaluated and reviewed by the licensed dentist who submitted the written or digital work order, or a licensed dentist in the same dental practice. A person, firm, or corporation so employed or engaged shall not be considered to be practicing dentistry. No such person, firm, or corporation shall perform any direct dental service for a patient, but they may assist a dentist in the selection of shades for the matching of prosthetic devices when the dentist sends the patient to them with a written or digital work order.

B. Any licensed dentist who employs the services of any person, firm, or corporation not working in a dental office under-his the dentist's direct supervision to construct or repair, an appliance extraorally, prosthetic dentures, bridges, replacements, or orthodontic appliances for a part of a tooth, a tooth, or teeth, shall furnish such person, firm, or corporation with a written or digital work order on forms prescribed by the Board, which shall, at minimum, contain: (i) the name and address of the person, firm, or corporation; (ii) the patient's name or initials or an identification number; (iii) the date the work order was written; (iv) a description of the work to be done, including diagrams, if necessary; (v) specification of the type and quality of materials to be used; and (vi) the signature and address of the dentist.

The person, firm, or corporation shall retain the original written work order or an electronic copy of a digital work order, and the dentist shall retain a duplicate of the written work order or an electronic copy of a digital work order, for three years.

C. If the person, firm, or corporation receiving receives a written or digital work order from a licensed dentist engages a subcontractor to perform services relative to the work order, a written disclosure and subwork order shall be furnished to the dentist on forms prescribed by the Board, which shall, at minimum, contain:—(i) the name and address of the person, firm, or corporation and subcontractor; (ii) a number identifying the subwork order with the original work order; (iii) the date the any subwork order was written; (iv) a description of the work to be done and the work to be done by the subcontractor, including diagrams or digital files, if necessary; (v) a specification of the type and quality of materials to be used; and (vi) the signature of the person issuing the disclosure and subwork order.

The subcontractor shall retain the subwork order, and the issuer shall retain a duplicate of the subwork order, which shall be attached to the work order received from the licensed dentist, for three years.

D. No person, firm, or corporation engaged in the construction or repair of appliances shall refuse to allow the Board or its agents to inspect the files of work orders or subwork orders during ordinary business hours.

The provisions of this section shall not apply to a work order for the construction, reproduction, or repair, extraorally, of prosthetic dentures, bridges, or other replacements for a part of a tooth, a tooth, or teeth, done by a person, firm or corporation pursuant to a written work order received from a licensed dentist who is residing and practicing in another state.

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#### **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.

Provisions of Chapter 37 of the 2020 Acts of the Assembly set out the safeguards that must be in place for the practice of teledentistry, including the training and supervision of a digital scan technician if used in the practice. The purpose of the regulation is to specify the responsibility of the dentist for such training and supervision in order to protect the safety and health of patients receiving dental care via teledentistry.

#### **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.

HB 165 and SB122 of the 2020 General Assembly defines a digital scan technician used in teledentistry and requires the Board to promulgate the education and training for them to practice under the direction and supervision of a dentist licensed in Virginia. The proposed regulations will:

- Establish requirements for a "training program approved by the Board to take digital scans of intraoral and extraoral hard and soft tissues for use in teledentistry"
- Set out the responsibilities of the dentist for the practice of teledentistry and the training and supervision of a digital scan technician
- Establish requirements records that may be requested by the Board.

#### **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 private citizens is that digital scan technicians will be required to have board-approved training prior to performing digital scans on a patient, thereby

ensuring the safety of patients who receive digital dental scans outside of a dentist's office. There are no disadvantages to the public.

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- 2) There are no primary 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. 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." Any restraint on competition as a result of promulgating this regulation is a foreseeable result of the statutory obligation of the Board to protect the safety and health of clients/patients 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 requirements more restrictive than federal requirements.

## 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** 

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	There are no expected costs, savings, fees, or revenues to the agency from this regulatory change.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no expected costs, savings, fees, or revenues to other state agencies from this regulatory change.
For all agencies: Benefits the regulatory change is designed to produce.	The primary benefits to agencies is the ability to hold dentists accountable for ensuring they do not work with persons taking digital scans without Board-approved training.

# Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no expected costs, savings, fees or revenues to localities from this regulatory change.
Benefits the regulatory change is designed to produce.	There are no expected benefits to localities from this regulatory change.

# **Impact on Other Entities**

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Dentists who utilize digital scan technicians in the practice of teledentistry.
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 does not have information on the number of entities that are likely to be affected by the regulatory change. The 2020 legislation requires a Virginia license for any dentist who directs the taking of a digital scan via teledentistry, but there is no identifiable license for teledentistry. While we do not have specific data on dentists practicing by teledentistry, we do know there was a substantial increase in the number of applicants for licensure from out-of-state in FY2021. In FY2020, there were 184 applicants from out-of-state; in FY2021 there were 259 such applicants.  Most dentists who are affected would likely be employees of a national corporation such as Smile Direct Club.
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;	The Board currently does not have an estimate on what the training could cost. The Board has approved entities for continuing education, and those entities are approved to offer training for digital scan technicians.

b) specify any costs related to the development of In addition to receiving training from a sponsor real estate for commercial or residential purposes organization, the regulations require digital scan that are a consequence of the regulatory change; technicians to receive training by the c) fees: manufacturer. Many manufacturers of intraoral d) purchases of equipment or services; and scanners offer free training videos online. e) time required to comply with the requirements. Benefits the regulatory change is designed to The regulatory changes will ensure that members of the public can be confident that their safety produce. and well-being are not risked by receiving digital scans outside of a dental office. Therefore, the regulatory changes ensure that dental labs and other entities working with digital scan technicians can continue to assist dental offices in the practice of teledentistry.

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## **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 training and practice of a digital scan technician are dependent on regulations promulgated by the Board; there are no alternatives to a regulatory change.

# **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.

The amendments to regulations are necessary to accomplish the objectives of applicable law.

# 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.

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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 the 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 NOIRA is not being used to announce a periodic review or a small business impact review.

#### **Public Comment**

<u>Summarize</u> 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.

A public comment period was held from March 1, 2021 through March 31, 2021. During that time, 12 comments were received in total. Ten comments were received on the Regulatory Town Hall, but one of those comments was misplaced and directed towards a different regulatory action. Two were received by letters directed to the Board of Dentistry.

Commenter	Comment	Agency response
Comments		
received via		
Town Hall:		
Albert L. Kelling DDS	Intra-oral scans need to be verified for accuracy. Recommends that digital scan technicians work only under the	The Board acknowledges the comment and concerns expressed. However,
	direct supervision of a dentist.	The Board cannot require that digital scan technicians work under the <b>direct</b> supervision of a dentist. By definition, digital scan technicians are persons who have "completed a training program approved by the Board to take digital scans of intraoral and extraoral hard and soft tissues for use in <b>teledentistry</b> ." Direct supervision means the dentist is immediately available in the office, which is contrary to the definition of teledentistry.
		The proposed regulations require that the directing dentist remain accessible and available for communication and
		consultation with a digital scan technician while such digital scan technician is working

		under the direction of the dentist in accordance with a valid work order.
Julie Staggers	Objects to allowing scans to be done outside a dental office. Urges the Board to restrict scanning to licensed or supervised personnel only.	By definition, digital scan technicians are persons who have "completed a training program approved by the Board to take digital scans of intraoral and extraoral hard and soft tissues for use in <b>teledentistry</b> ." Thus, the Virginia legislature intended that digital scan technicians work remotely to allow dentists access to teledentistry services, and regulations of the Board cannot limit digital scans to dental offices.
		The Board cannot restrict scanning to licensed personnel. The Virginia Code authorizes the Board only to select appropriate training for digital scan technicians. The digital scan technicians will be supervised, at least remotely, meaning that the dentist must remain accessible and available for communication and consultation in the practice of teledentistry.
Paul Supan, DDS, MA, MPH Diplomate, American Board of Orthodontics	Supports the comment from Julie Staggers. Requests that a dentist be a necessary part of the training and supervision process and be required to perform a final check prior to the customer/patient receiving an appliance.	The proposed regulations require a dentist to ensure that the digital scan technician has received Board-approved training, which includes training in prepping the patient, taking and evaluating the quality of a digital scan, safety protocols, and dental terminology given by an approved sponsor and in-office training by the manufacturer on the proper operation of the digital scanner.
		The proposed regulations reiterate that the directing dentist is ultimately responsible for "communicating with the patient or his representative the specific treatment the patient will receive, which aspects of treatment will be delegated to qualified personnel, and the direction required for such treatment, in accordance with the Regulations Governing the Practice of Dentistry and the Code of Virginia and for documenting such communication in the patient record."
		The Code of Virginia (§ 54.1-2719 (A)) also requires that any appliance constructed or repaired pursuant to a digital work order be "evaluated and reviewed by the licensed dentist who submitted the written or digital work order, or a licensed dentist in the same dental practice."
Herb Hughes	Concerned about the potential danger to patients working with digital scan technicians if there is no in-person exam or x-ray	The Board does not have the statutory authority to require an in-person exam of the patient.

	requirements. Asserts that they have seen several grossly negligent orthodontic cases which were misdiagnosed and mistreated by aligner companies.	Under, § 54.1-2711(B) of the Code of Virginia, a dentist is required to perform or caused to be performed "an appropriate examination of the patient, either physically, through use of instrumentation and diagnostic equipment through which digital scans, photographs, images, and dental records are able to be transmitted electronically, or through use of face-to-face interactive two-way real-time communications services or store-and-forward technologies."
		Under § 54.1-2700 of the Code of Virginia: ""Store-and-forward technologies" means the technologies that allow for the electronic transmission of dental and health information, including images, photographs, documents, and health histories, through a secure communication system."
Trey Lawrence, Vice President, Advocacy and General Counsel, American Association of Orthodontists (AAO)	Requests regulatory language that ensures that appliances fabricated pursuant to digital scans are verified in-person by the dentist to prevent harm to patients that could be caused by patients receiving appliances based on inaccurate images.	Under § 54.1-2719 (A), "Any appliance constructed or repaired by a person, firm, or corporation pursuant to this section shall be evaluated and reviewed by the licensed dentist who submitted the written or digital work order, or a licensed dentist in the same dental practice."
	Requests that a dentist-patient relationship be established only through a face-to-face encounter. Requests specific language, "No person, other than a dentist, shall obtain digital scans for use during the practice of dentistry unless the patient has or will be seen in person by a dentist within six months of the scan."	The Board does not have authority to alter the establishment of a dentist-patient relationship because it is specifically set out in the Virginia Code in § 54.1-2711 subsection (B). This language allows dentist-patient relationship to be established through the "use of face-to-face interactive two-way real-time communications services or store-and-forward technologies".
Michael Holbert	Supports comments made by AAO and the definitions and training protocols the VDA proposed to the Board. Recommends that a dentist be required to verify scans for accuracy and verify the fit of appliances prior to delivery to the patient.	The Board does not have the authority to alter the definitions set out in the Virginia Code, such as "digital scan technician". The definition of "digital scan technician" is set in § 54.1-2700 of the Code of Virginia: ""Digital scan technician" means a person who has completed a training program approved by the Board to take digital scans of intraoral and extraoral hard and soft tissues for use in teledentistry."
Dr. Frank Iuorno, DDS, President, Virginia Dental Association (VDA)	The VDA proposed very specific regulatory language, including definitions for "Appliance," "Digital Work Order," and "Teledentistry." Suggested a new Chapter for Regulating the practice of digital scan technicians. Suggested creating a new part in the	The definitions proposed by the VDA are already set in the Virginia Code. The Board has added those in the proposed regulatory language to reference the Virginia Code.  The Board does not have statutory authority to license, certify, or register digital scan technicians. The Code requires the Board to

	Regulations to govern the practice of digital scan technicians and standards of conduct for digital scan technicians.	approve training and does not grant authority to regulate digital scan technicians.
		The proposed regulations include most of the sponsors suggested by the VDA as acceptable sponsors for training digital scan technicians. The proposed regulations add that digital scan technicians shall be trained by the manufacturer of a digital scan machine in addition to receiving training from a sponsor organization.
		The Board did not comply with the VDA recommendation that the AAO be added as a sponsoring organization because the representative of the AAO spoke to the Regulatory Committee and requested that neither the AAO or the Virginia component be listed.
		The Virginia Code authorizes the Board to approve training programs for digital scan technicians and to require dentists to ensure that technicians have received appropriate training. The proposed regulations are consistent with requirements for practice by teledentistry in the Virginia Code.
Bao Vu	Supports the definition of digital scan technician proposed by the VDA.	See above.
Danielle Robb	Supports the comments made by the AAO and the definitions and training protocols the VDA proposed to the board. Recommends that a dentist be required to verify scans for accuracy and verify the fit of appliances prior to delivery to the patient.	See above.
Dr. A B Hammond III Orthodontist	Supports the VDA proposed definition of digital scan technician.	See above.
Peter Horkan, Vice President, Government Affairs, SmileDirectClub	Suggested the same specific regulatory language suggested by the VDA.	See above.
William G. Horbaly, D.D.S., M.S., M.D.S., LTD.	This comment was misplaced and refers to a different regulation.	N/A

## **Public Participation**

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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 <a href="https://www.townhall.virginia.gov">https://www.townhall.virginia.gov</a>. 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 <a href="mailto:elaine.yeatts@dhp.virginia.gov">elaine.yeatts@dhp.virginia.gov</a> 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 (<a href="http://www.townhall.virginia.gov">http://www.townhall.virginia.gov</a>) and on the Commonwealth Calendar website (<a href="https://www.virginia.gov/connect/commonwealth-calendar">https://www.virginia.gov/connect/commonwealth-calendar</a>). Both oral and written comments may be submitted at that time.

A Regulatory Advisory Panel will not be used. Proposed regulations will be 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.

If an <u>existing</u> VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed <u>and replaced</u>, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter- section number	New chapter- section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
Chapter 21, section 10		Sets out the definitions for words and terms used in the chapter	Subsection (A) adds the following terms to the list of terms defined by the Code of Virginia: "Appliance," "Digital scan," "Digital scan technician," "Digital work order," and "Teledentistry" to comply with § 54.1-2700.
			Subsection (C) adds to the definition of "direction" the specific application of the term in the context of directing a digital scan technician. Direction means the written or electronic instructions provided to a digital scan technician in the form of a work order for a digital scan of a patient and the dentist's specified availability to consult with a digital scan technician while the scan is taken.  The Code specifies that a digital scan technician obtains dental scans for use in teledentistry under the direction of a dentistry. Teledentistry, as defined in 54.1-2700, does not include a requirement for an in-person patient encounter.  Subsection (C) also adds to the definition of "remote supervision" the specific application of the terms in the context of supervision of a digital scan technician The directing dentist is required by
			statute to be accessible and available for communication and consultation in the practice of teledentistry."
N/A	18VAC60-21- 165	N/A	New section 165 sets out the requirements for dentists using digital scan technicians.
			Subsection A requires that a dentist ensure that a digital scan technician has Board-approved training, which includes:  1. Training in prepping the patient, taking and evaluating the quality of a digital scan, safety protocols, and dental terminology given by a sponsor approved for continuing education as set forth in subsection C of 18VAC60-21-250; and  2. In-office training by the manufacturer on the proper operation of the digital scanner that includes orientation to the process and protocols for taking and evaluating digital scans for

fabrication of a restoration or an appliance.

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The Code (§54.1-2700) implicitly instructs the Board to approve appropriate training for digital scan technicians: "Digital scan technician" means a person who has completed a training program approved by the Board to take digital scans of intraoral and extraoral hard and soft tissues for use in teledenitstry.

The Board has determined that it is necessary that a digital scan technician have appropriate training related to the dental anatomy and proper care of a patient in addition to training by the manufacturer of the digital scanning machine they intend to operate while scanning a patient.

Subsection B specifies the written or electronic documents that a dentist shall create and maintain to direct a digital scan technician to take digital scans, including protocols and procedures for digital scan technicians, protocols and procedures for teledentistry, and work orders for digital scans.

The Code (§54.1-2708.5) requires that dentists create and maintain protocols and procedures for the performance of digital scans by digital scan technicians. The Code (§ 54.1-2711) also has specific requirements for what should be included in the dentist's written protocols and procedures for teledentistry.

The Code (§§ 54.1-2708.5(A) and 54.1-2719 (A)) requires that digital scan technicians only operate under the direction of a dentist and that persons engaged in the construction and repair of appliances work pursuant to a digital or written work order.

Subsection C reiterates the requirements set out in the Code of Virginia that are specific to dentists directing digital scan technicians to take digital scans.

The Code (§ 54.1-2708.5 (B)) requires that dentists directing digital scan technicians be (i) licensed by the Board

to practice dentistry in the Commonwealth, (ii) accessible and available for communication and consultation with the digital scan technician at all times during the patient interaction, and (iii) responsible for ensuring that the digital scan technician has a program of training approved by the Board for such purpose.

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The Regulations Governing the Practice of Dentistry (18VAC60-21-120) already require dentists to assume ultimate responsibility for determining with the patient or his representative the specific treatment the patient will receive, which aspects of treatment will be delegated to qualified personnel, and the direction required for such treatment.

Subsection D specifies the documents which a dentist is required to make available to the Board upon request.

The Code (§ 54.1-2708.5 (B)) specifies that "All protocols and procedures for the performance of digital scans by digital scan technicians and evidence that a digital scan technician has complied with the training requirements of the Board shall be made available to the Board upon request.

The Code (§ 54.1-2719 (D)) also prohibits anyone engaged in the construction or repair of appliances from prohibiting the Board from inspecting the files of work orders or subwork orders during ordinary business hours.