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## Revised Proposed Regulation Agency Background Document

<b>Agency name</b>	Board of Dentistry, Department of Health Professions
<b>Virginia Administrative Code (VAC) Chapter citation(s)</b>	18VAC60-21
<b>VAC Chapter title(s)</b>	Regulations Governing the Practice of Dentistry
<b>Action title</b>	Training and supervision of digital scan technicians by dentists in the practice of teledentistry
<b>Date this document prepared</b>	August 6, 2022

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), 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.

This action previously completed Executive Branch review and was published for public comment as a proposed action. The proposed regulatory language synced from the Virginia Register was a previous draft of the amendments, not the draft approved by the Board on June 11, 2021. Therefore, the Board has withdrawn the previous proposed stage and is resubmitting with the correct draft of the amended language and this revised Agency Background Document.

### 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.

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N/A

### Mandate and Impetus

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously reported information, include a specific statement to that effect.

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The impetus for this action is found in Ch. 37 and Ch. 220 of the 2020 Acts of 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.

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Regulations of the Board of Dentistry are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Virginia Code § 54.1-2400(6) specifically states that the general powers and duties of health regulatory boards shall be "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system."

The specific legislative authority for this action can be found in [Ch. 37](#) and [Ch. 220](#) of the 2020 Acts of Assembly, which established requirements for the practice of teledentistry and the taking of dental scans for use in teledentistry by dental scan technicians, and clarified requirements related to the use of digital work orders for dental appliances in the practice of teledentistry. The legislation specifically made the Board responsible for approving programs of training for digital scan technicians.

### 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 is intended to solve.

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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.*

Ch. 37 and Ch. 220 of the 2020 Acts of Assembly define a digital scan technician used in teledentistry and required 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.
- 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. Any restraint on competition as a result of promulgating these regulations is a foreseeable, inherent, and ordinary result of the statutory obligation of the Board to protect the safety and health of citizens of the Commonwealth and of the statutory directive to implement regulations consistent with approving training programs of digital scan technicians and setting out responsibilities of a dentist practicing teledentistry. The Board is authorized under § 54.1-2400 “[t]o 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.” The promulgated regulations do not conflict with the purpose or intent of Chapters 1 or 25 of Title 54.1.

**Requirements More Restrictive than Federal**

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously reported information, include a specific statement to that effect.

There are no requirements more restrictive than federal requirements.

**Agencies, Localities, and Other Entities Particularly Affected**

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities particularly affected by the regulatory change. If there are no changes to previously reported information, include a specific statement to that effect.

Other State Agencies Particularly Affected - None Localities

Particularly Affected - None

Other Entities Particularly Affected - None

**Economic Impact**

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding all specific economic impacts (costs and/or benefits) anticipated to result from the regulatory change. If there are no changes to previously reported information, include a specific statement to that effect. If any information previously provided on the ORM Economic Impact form has changed, upload a new ORM form.

**Impact on State Agencies**

<p><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.</p>	<p>There are no expected costs, savings, fees, or revenues to the agency from this regulatory change.</p>
<p><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.</p>	<p>There are no expected costs, savings, fees, or revenues to other state agencies from this regulatory change.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>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.</p>

**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; 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.	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.  In addition to receiving training from a sponsor organization, the regulations require digital scan technicians to receive training by the manufacturer. Many manufacturers of intraoral scanners offer free training videos online.
Benefits the regulatory change is designed to produce.	The regulatory changes will ensure that members of the public can be confident that their safety 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.

**Alternatives to Regulation**

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. If there are no changes to previously reported information, include a specific statement to that effect.

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**

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding 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. If there are no changes to previously reported information, include a specific statement to that effect.

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

**Public Comment**

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. 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
<b>Comments received via Town Hall</b>		
Albert L. Kelling DDS	Intra-oral scans need to be verified for accuracy. Recommends that digital scan technicians work only under the direct supervision of a dentist.	The Board acknowledges the comment and concerns expressed. However, 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

		<p>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.</p>
<p>Julie Staggers</p>	<p>Objects to allowing scans to be done outside a dental office. Urges the Board to restrict scanning to licensed or supervised personnel only.</p>	<p>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 teledentistry.” 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.</p> <p>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.</p>
<p>Paul Supan, DDS, MA, MPH Diplomate, American Board of Orthodontics</p>	<p>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.</p>	<p>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.</p> <p>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.”</p> <p>Va. Code § 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</p>

		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 requirements. Asserts that they have seen several grossly negligent orthodontic cases which were misdiagnosed and mistreated by aligner companies.	<p>The Board does not have the statutory authority to require an in-person exam of the patient. Under, Va. Code § 54.1-2711(B), 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 <b>or store-and-forward technologies.</b>”</p> <p>Va. Code § 54.1-2700 defines store-and-forward technologies as “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.”</p>
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. 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.”	<p>Va. Code § 54.1-2719(A) states that “[a]ny 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.”</p> <p>The Board does not have authority to alter the establishment of a dentist-patient relationship because it is specifically set out in Va. Code § 54.1-2711(B). This statute allows the 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.”</p>
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.	<p>The Board does not have the authority to alter the definitions set out in the Virginia Code, such as “digital scan technician.”</p> <p>Va. Code § 54.1-2700 defines digital scan technician as “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.”</p>
Dr. Frank Iuorno, DDS, President,	The VDA proposed very specific regulatory language, including definitions for “Appliance,” “Digital	The terms for which the VDA proposed definitions are already defined in the Code of Virginia. The Board has added those in



<p>Virginia Dental Association (VDA)</p>	<p>Work Order,” and “Teledentistry.” Suggested a new Chapter for Regulating the practice of digital scan technicians. Suggested creating a new part in the regulations to govern the practice of digital scan technicians and standards of conduct for digital scan technicians.</p>	<p>the proposed regulatory language to reference the Virginia Code.</p> <p>The Board does not have the statutory authority to license, certify, or register digital scan technicians. The Code requires the Board to approve training and does not grant authority to regulate digital scan technicians.</p> <p>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.</p> <p>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 nor the Virginia component be listed.</p> <p>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.</p>
<p>Bao Vu</p>	<p>Supports the definition of digital scan technician proposed by the VDA.</p>	<p>See above.</p>
<p>Danielle Robb</p>	<p>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.</p>	<p>See above.</p>
<p>Dr. A B Hammond III Orthodontist</p>	<p>Supports the VDA proposed definition of digital scan technician.</p>	<p>See above.</p>
<p>Peter Horkan, Vice President,</p>	<p>Suggested the same specific regulatory language suggested by the VDA.</p>	<p>See above.</p>

Government Affairs, SmileDirectClub		
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**

*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 providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, (iii) the potential impacts of the regulation, and (iv) the agency’s regulatory flexibility analysis stated in that section of the background document.

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 Erin Barrett, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or [erin.barrett@dhp.virginia.gov](mailto:erin.barrett@dhp.virginia.gov) or by fax to (804) 915-0382. 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.

**Detail of Changes Made Since the Previous Stage**

*List all changes made to the text since the previous stage was published in the Virginia Register of Regulations. 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. \* Put an asterisk next to any substantive changes.*

As a general note, these changes reflect the version of the proposed regulations approved by the Board at its June 11, 2021 meeting. These are not changes that were made by the Board. Instead, this submission is the correct version of what the Board approved in 2021. Following a review of minutes of the regulatory committee and Board meetings leading to the approved version, it is not always clear why a change was made from the original draft of these regulations, which it should be noted was drafted by staff of the agency and Board, and never actually approved by the Board.

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
21-10	N/A	No new requirement.	In definition of "direction," removal of requirement that ordering dentist must be licensed in Virginia. Inclusion of remote supervision removed from definition.	Requirement of licensed Virginia dentist was not necessary or useful in definition of "direction."  Remote supervision inclusion was redundant of later definition.
21-60	N/A	No new requirement.	Removal of delegation of digital scans only to qualified personnel from requirements of dentists to public.  Removal of other changes to this section which amended "he" and "his" to "dentist."	Likely removed because the inclusion was unnecessary.  Other changes to 60 were unnecessary.
	21-165	No new requirements. Rather the previous requirements are listed to be the responsibility of the licensed dentist and some requirements are reordered.	Requirements generally are not removed, only reorganized and clearly assigned to licensed dentist rather than unregulated digital scan technicians.  The only requirement removed is to produce "all" written work orders for digital scans to the Board upon request.	A is different from the previous submission. The requirement to comply with the regulations is placed on the licensed dentist to ensure training of digital scan technicians.  B is slightly different as well. This subdivision is changed to a list of written protocols for teledentistry, digital cans, and written work orders for scans.  C 3 had previously stated that the dentist and the patient (or patient's representative) would determine course of treatment. The approved language was that the dentist is responsible for patient communication of treatment.  D 3 removed the word "all" before written orders used for digital scans. Requiring a dentist to produce "all"

				work orders to the Board on request would have been overly burdensome.
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