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Proposed Regulation Agency Background Document

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| Agency name | Board of Dentistry, Department of Health Professions |
| Virginia Administrative Code (VAC) Chapter citation(s) | 18VAC60-30 |
| VAC Chapter title(s) | Regulations Governing the Practice of Dental Assistants |
| Action title | Elimination of direct pulp-capping as a delegable action |
| Date this document prepared | June 10, 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 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.

The Board has determined that 18VAC60-30-120 should be amended to eliminate the practice of direct pulp capping from the list of practices that can be delegated to an appropriately trained dental assistant II. Appropriately trained dental assistants II may still perform delegated tasks related to indirect pulp capping.

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.

DAII = Dental Assistant II

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the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."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 this regulatory change is concern expressed by members of the Board that the practice of pulp capping is inherently risky and should not be performed by a DAII. Because a dentist must create the exposure of a pulp (tooth nerve) that requires direct pulp capping, the Board believes a dentist should perform the resulting direct pulp capping.

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 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."

Virginia Code § 54.1-2729.01 requires the Board to promulgate regulations regarding duties dental assistants may perform.

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 protect patients in dental offices who receive services from a DAII. While dental assistants receive laboratory and clinical training in indirect pulp capping, Board members believe direct pulp capping, which requires covering a completely exposed nerve with a protective coating, should only be performed by a dentist because it presents a risk of harm to patients.

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.

Direct pulp capping is the covering of an exposed dental pulp (tooth nerve) with material to provide protection against external influences and to encourage healing. The Board has added the word "indirect"

before “pulp capping” in 18VAC60-30-120(B)(3)(a) and (b) to clarify that a DAII can only perform indirect pulp capping under supervision, rather than direct *and* indirect, as a delegable task.

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 assurance that a procedure with a high risk of harm to patients will not be performed by dental assistants. 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 regarding tasks delegable to a dental assistant. 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

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

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| <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 delegate tasks to dental assistants that create a high risk of patient harm and which should be completed by a dentist.</p> |

Impact on Localities

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

Impact on Other Entities

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| <p>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.</p> | <p>Any dental office currently using DAIs to perform direct pulp capping procedures would be affected. The Board has no information whether any dental offices currently delegate direct pulp capping to DAIs.</p> |
| <p>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.</p> | <p>Only 38 DAIs in the Commonwealth are permitted to perform any type of pulp capping. This Board action will not affect the ability of those 38 DAIs to perform direct pulp capping; however, no DAI will be permitted to perform direct pulp capping in the future. The Board has no information regarding the employment type of any registered DAI, although it is likely most are</p> |

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| | employed by independently owned and operated businesses run by licensed dentists. |
| 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. | There should be no additional costs for any individuals. This procedure is performed in dental offices by licensees, but will no longer be performed by one type of registrant with the Board. Although 38 DALLs are permitted to perform direct pulp capping, the Board has no information regarding whether any of those individuals are delegated that task by their supervising dentist. Given the invasive nature of the procedure, it is likely very few, if any, DALLs are performing direct pulp capping. |
| Benefits the regulatory change is designed to produce. | This change is intended to ensure patients receive inherently risky treatment from a licensed dentist. |

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.

Since pulp capping is currently included in section 120 among the procedures for which a dental assistant II can be trained and evaluated, an amendment to the regulation is the only alternative to its elimination. There is no cost associated with this change, therefore no less intrusive or less costly alternatives exist.

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.

1) There is no reporting requirement associated with this change. 2) There are no schedules or deadlines associated with this change. 3) This is arguably a simplification of delegated actions; no additional simplification is possible. Furthermore, this change does not create, affect, or change any reporting requirements. 4) There are no performance standards for any business, large or small, associated with this change. 5) Small businesses cannot be exempt from this change because (a) the Board does not license or regulate businesses, but practitioners, and (b) most licensees and registrants of the Board work at small or independently-owned businesses. Exempting those locations would completely negate the protection of the public the Board is trying to accomplish.

**Periodic Review and
Small Business Impact Review Report of Findings**

The 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.

Neither the agency nor the Board of Dentistry received any public comment on Town Hall or directly following publication of the NOIRA.

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, and (iii) the potential impacts 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://townhall.virginia.gov>. Comments may also be submitted by mail or email to Erin Barrett at erin.barrett@dhp.virginia.gov or at 9960 Mayland Drive, Henrico, VA 23233 or by fax at (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 this stage, and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (<https://townhall.virginia.gov>) and on the Commonwealth Calendar website (<https://commonwealthcalendar.virginia.gov/>). Both oral and written comments may be submitted at that time.

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 existing 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 and replaced, 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 | Current requirements in VAC | Change, intent, rationale, and likely impact of new requirements |
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| 30-120 | 120(B)(3)(a) and (b) list the training required to be permitted to perform specific delegable tasks as a DAII | <p>(B)(3)(a) and (b) are edited to remove an extra “and” that is unnecessary. “Indirect” is inserted before “pulp capping” in both provisions, and a parenthetical which indicates the change will not be effective until after July 1, 2022 is added to both.</p> <p>The inclusion of the word “indirect” removes direct pulp capping from a task delegable to a DAII. The Board wished to indicate that DAIIIs may have been permitted to perform direct pulp capping as a delegable task prior to the regulatory change, and wished to indicate that with the inclusion of July 1, 2022 as the date.</p> |