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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Dentistry, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC60-21
VAC Chapter title(s)	Regulations Governing the Practice of Dentistry
Action title	Training requirements for botulinum toxin injections for cosmetic purposes
Date this document prepared	December 8, 2023

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 the subject matter, intent, and goals of this 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 or changes. If applicable, generally describe the existing regulation.

This action creates training requirements for dentists to administer botulinum toxin injections for cosmetic purposes as required by Ch. 413 of the 2023 Acts of Assembly. This action is an emergency regulatory action due to language included in Item 301 of the amended budget bill passed in the 2023 Special Session.

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.

N/A

Mandate and Impetus (Necessity for Emergency)

Explain why this rulemaking is an emergency situation in accordance with § 2.2-4011 A and B of the Code of Virginia. In doing so, either:

a) *Indicate whether the Governor's Office has already approved the use of emergency regulatory authority for this regulatory change.*
b) *Provide specific citations to Virginia statutory law, the appropriation act, federal law, or federal regulation that require that a regulation be effective in 280 days or less from its enactment.*

As required by § 2.2-4011, also describe the nature of the emergency and of the necessity for this regulatory change. In addition, delineate any potential issues that may need to be addressed as part of this regulatory change.

This action is an emergency regulatory action under Virginia Code § 2.2-4011(B) due to language included in Item 301 of the amended budget bill passed in the 2023 Special Session. That language stated that "the regulations the Board of Dentistry is required to promulgate pursuant to Chapter 413, 2023 Acts of Assembly, shall be promulgated to be effective within 280 days of its enactment." *See* Item 301, HB6001, 2023 Special Session. The agency and the Board of Dentistry are not aware of any healthcare emergency requiring this action, but are responding to the requirements of the legislature pursuant to Virginia Code § 2.2-4011(B).

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 or Acts and 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 § 54.1-2711.2 requires the Board to determine training requirements for the administration of botulinum toxin injections for cosmetic purposes.

Purpose

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

The agency has been directed to determine training requirements for dentists to administer botulinum toxin injections for cosmetic purposes. To state such requirements, the Board must promulgate regulations. A workgroup of stakeholders and the Board felt that the training delineated in the proposed regulatory language constituted the minimum requirements necessary to ensure safety of patients and the public.

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.

A new section, 18VAC60-21-55, lists the training requirements for dentists to administer botulinum toxin injections for cosmetic purposes. 18VAC60-21-350 is amended as required by Ch. 413 of the 2023 Acts of Assembly.

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 advantages to the public are ensuring that dentists administering botulinum toxin injections are appropriately trained. 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. 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.

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.

There is no alternative to regulation. The Board was directed to amend its regulations by emergency action.

Periodic Review and Small Business Impact Review Announcement

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

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. In addition, as required by § 2.2-4007.02 of the Code of Virginia describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

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 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

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 emergency 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-	New chapter-section	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements

section number	number, if applicable		
	21-55	None.	Subsection A requires that prior to administering botulinum toxin injections for cosmetic purposes, a dentist must complete 12 hours of training in subjects listed in C. The training must include a minimum of four hours of clinical, in-person training on at least two live patients. The training must include follow up post-procedure. Eight of the 12 hours may be didactic (rather than clinical) and may be either online or in person. The stakeholder workgroup and the Board felt that four hours of in-person training on two patients was the minimum requirement to ensure the dentist was fully trained to administer botulinum toxin injections for cosmetic purposes. Both groups likewise believed that training on at least two live patients, with post-procedure follow up care included, was necessary to ensure competence. The workgroup and the Board felt that 12 total hours of training in the subjects listed in subsection C was necessary to protect the public. Subsection B states that the training required in the section must be provided by a dental program or advanced dental education program accredited by CODA (the Commission on Dental Accreditation), the ADA (American Dental Association) or its constituent or branch associations, or the Academy of General Dentistry. This requirement is to ensure public safety by verifying that training is provided by individuals and entities recognized by national accrediting and training organizations as providing rigorous and beneficial education. Subsection C lists the topics that must be covered by the training described in subsections A and B. Although C lists ten individual subjects, there is no requirement that the subjects be covered individually. Members of the workgroup familiar with training in the topics listed in C stated that some will likely be combined. The workgroup and the Board determined which topics to include after discussion among Board members and experts in the field and reviewing training used in other states.
21-350		For oral and maxillofacial surgeons to receive certification to perform aesthetic or cosmetic procedures by application of	The existing language of B 9 is deleted and replaced with “[a]dministration of dermal filler.” Other actions that fell under the deleted language of B 9 were botulinum toxin injections for cosmetic purposes. Those will now be covered by 18VAC60-21-55 and do not require

		injectable medication or material for the purpose of treating extra-oral cosmetic conditions, the OMS must demonstrate appropriate education, training, and experience.	an OMS certification to perform. Dermal fillers will still be performed by OMS only and will still require a certificate pursuant to subsection B.