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Fast-Track Regulation Agency Background Document

| Agency name | Board of Medicine, Department of Health Professions | |
|---|---|--|
| Virginia Administrative Code (VAC) citation(s) | 18VAC85-110 | |
| Regulation title(s) | Regulations Governing the Practice of Licensed Acupuncturists | |
| Action title | Periodic review | |
| Date this document prepared | 10/24/18 | |

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 (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

Brief Summary

Please 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.

Pursuant to its periodic review of Chapter 110, the Board has adopted amendments to update the name of a required examination and to the use the more inclusive term of "dietary supplements" to include herbs and herbal supplements that acupuncturists are allowed to use and recommend.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On October 18, 2018, the Board of Medicine amended 18VAC85-110-10 et seq., Regulations Governing the Practice of Licensed Acupuncturists.

Mandate and Impetus

Please 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, board decision, etc.). 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."

As required by Virginia Code § 2.2-4012.1, please also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

As required by Executive Order 14 (2018), the Board of Medicine conducted a periodic review of this chapter. The amendments are clarifying or intended for consistency with current practice. There are no substantive changes, so the amendments are not expected to be controversial.

Legal Basis

Please identify (1) the agency or other promulgating entity, 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 of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity'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 Medicine 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 (§ <u>54.1-100</u> et seq.) and Chapter 25 (§ <u>54.1-2500</u> et seq.) of this title. ...

Purpose

Please 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.

It is necessary to retain the current chapter because licensure and regulation of acupuncturists under the Board of Medicine is a requirement of statute. The provisions of this chapter protect the health and safety of patients who received acupuncture treatments from a licensed acupuncturist. The regulatory changes are consistent with the principle that regulations should be clearly written and easily understandable.

Substance

Please 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.

Pursuant to its periodic review of Chapter 110, the Board has adopted amendments to update the name of a required examination and to the use the more inclusive term of "dietary supplements" to include herbs and herbal supplements that acupuncturists are allowed to use and recommend.

Issues

Please 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) There are no substantive changes to the regulation so there are no real advantages or disadvantages to the public. The amendments are technical and clarifying.
- 2) There are no advantages or disadvantages to the agency or the Commonwealth.
- 3) There are no other pertinent matters of interest. 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 which are reasonable and necessary to administer effectively the regulatory system.*"

The proposed amendments are a foreseeable result of the statute requiring the Board to protect the health and safety of citizens of the Commonwealth.

Requirements More Restrictive than Federal

Please 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 is no applicable federal requirement.

Agencies, Localities, and Other Entities Particularly Affected

Please 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, please 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. Please 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 projected costs or savings resulting from the change. As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; The agency will incur no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. |
|---|---|
| <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. | None |
| <i>For all agencies:</i> Benefits the regulatory change is designed to produce. | None |

Impact on Localities

| Projected costs, savings, fees or revenues resulting from the regulatory change. | No costs |
|--|----------|
| Benefits the regulatory change is designed to produce. | None |

Impact on Other Entities

| Descriptions of the field description of | |
|--|--|
| Description of the individuals, businesses, or | Licensed acupuncturists |
| other entities likely to be affected by the | |
| regulatory change. If no other entities will be | |
| affected, include a specific statement to that | |
| effect. | |
| Agency's best estimate of the number of such | There are 529 persons who hold a license as an |
| entities that will be affected. Please include an | acupuncturist in Virginia. |
| estimate of the number of small businesses | |
| affected. Small business means a business | All acupuncturists operate small businesses, but |
| entity, including its affiliates, that: | the proposed changes would not affect any such |
| a) is independently owned and operated and; | business. |
| b) employs fewer than 500 full-time employees or | |
| has gross annual sales of less than \$6 million. | |
| All projected costs for affected individuals, | None |
| businesses, or other entities resulting from the | |
| regulatory change. Please 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. | |
| Benefits the regulatory change is designed to | Regulations are that consistent and updated. |
| produce. | S |
| | |

Alternatives

Please 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 amendments do not change the substance of the chapter; there are no alternatives that meet the essential purpose of licensing and regulating acupuncturists.

One comment from the Notice of Periodic Review requested an amendment in section 178 on practitioner responsibility that would include a scope of practice somewhat different from the statutory definition of the "practice of acupuncture." Accordingly, the Board did not revise the section.

Regulatory Flexibility Analysis

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Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

There are no alternative regulatory methods for clarifying or updating the language of a regulation other than promulgating a regulatory action.

Public Participation

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Detail of Changes

| Current section number | New section number, if applicable | Current requirement | Change, intent, rationale, and likely impact of new requirements |
|------------------------------|---|--|---|
| 80 | | Sets out requirements for licensure examinations | The section is amended to update the name of the current point location examination. |
| 180 | | Sets out the requirements for recommendations of supplements | The section is amended to delete "vitamins, minerals or food supplements" and inserting the term "dietary supplements" to clarify that recommendations may also include herbs or herbal supplements. The Food and Drug Administration uses the term "dietary supplements" to be inclusive of all – vitamins, minerals, herbs, and food supplements. The Advisory Board on Acupuncture recommended use of the more inclusive term in regulation, and the Board of Medicine concurred. |