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Fast-Track Regulation Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC85-170
VAC Chapter title(s)	Regulations Governing the Practice of Genetic Counselors
Action title	Implementation of 2022 periodic review of Chapter 170
Date this document prepared	October 6, 2022; Revised April 30, 2023 Revised May 3, 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 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Pursuant to its periodic review of Chapter 170, the Board has adopted amendments to delete outdated or redundant provisions and clarify others consistent with current practice.

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

Statement of Final Agency Action

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.

The Board of Medicine voted to amend the Regulations Governing the Practice of Genetic Counselors by fast-track action on October 6, 2022.

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 the ORM procedures, “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the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part.”

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

The impetus for these amendments were the Board's 2022 periodic review of this chapter. These amendments are noncontroversial and appropriate for fast-track rulemaking because the changes delete or modify provisions that, as currently effective, are redundant of statutory requirements, are not related to the practice of genetic counseling, are outdated, or are otherwise ineffectual.

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 Medicine 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 § 54.1-2957.19 requires the Board to license and regulate genetic counselors.

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.

The rationale for the changes included in this action are the reduction of regulations, elimination of provisions redundant of statutory language, eliminations of provisions that are no longer needed, and to reduce barriers to licensure. The elimination of redundant provisions and reduction of barriers to licensure generally protect the health, safety, and welfare of citizens by ensuring a sufficient workforce of licensed genetic counselors with a reduction of barriers and reduction of redundant or outdated requirements. The goals the regulatory change is intended to solve is the elimination of redundant or outdated provisions from Chapter 170.

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.

The changes delete redundant statutory provisions or useless directions in regulation, including provisions related to: outdated definitions; public participation regulations; scope of practice provisions which are redundant of statute or nonsensical for genetic counselors based on their scope of practice in Virginia Code § 54.1-2900, which does not include providing gene therapy or authorizing the use of genetic or diagnostic testing in an emergency setting; continuing education audit provisions; provisions related to the sale, closure, or transfer of a practice that are redundant of statutory provisions; revisions related to communications to patients; and solicitation or remuneration in exchange for referral.

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) There are no primary advantages or 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.

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 applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "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

Consistent with § 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 the proposed change versus the status quo.

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>The Department of Health Professions is a Special Fund agency. All operating costs for the regulatory boards are taken from fees for licensing and renewal of regulated professions.</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 costs to other state agencies.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>There are no benefits to state agencies.</p>

Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

<p>Projected costs, savings, fees or revenues resulting from the regulatory change.</p>	<p>No impact on localities.</p>
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Benefits the regulatory change is designed to produce.	No benefit to localities.
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Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

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.	Current licensees, potential applicants by endorsement, and potential registrants for voluntary out of state licenses will be affected.
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 has no data regarding any potential applicants by endorsement or potential registrants for voluntary out of state licenses. As of June 30, 2022, there were 444 individuals licensed as genetic counselors. As of March 31, 2023, there were 593 individuals licensed as genetic counselors.
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 are no costs to individuals, businesses, or entities.
Benefits the regulatory change is designed to produce.	Fewer redundant regulations and reduced regulatory burden.

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.

These are existing regulatory requirements. To remove or change them, the Board must amend the applicable regulations. There is no alternative.

Regulatory Flexibility Analysis

Consistent with § 2.2-4007.1 B 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 are necessary to reduce burdens on applicants and remove redundant or duplicative provisions, as stated above. 1) These amendments already reduce compliance requirements. 2) The amendments already reduce reporting requirements. 3) The amendments already simplify compliance. 4) There are no design or operational standards in the regulations, and the regulations do not apply to businesses. 5) The regulations do not apply to businesses.

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.

Consistent with § 2.2-4011 of the Code of Virginia, 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.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The Board of Medicine is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency’s regulatory flexibility analysis stated in this 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://townhall.virginia.gov>. Comments may also be submitted by mail to Erin Barrett, 9960 Mayland Drive, Suite 300, Henrico, Virginia 23233; by email to erin.barrett@dhp.virginia.gov; 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.

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
170-10	Contains a definition of “conscience clause.”	Deleted. The provision states that “conscious clause means the provision of § 54.1-2957.21 of the Code of Virginia.” That Code section was repealed in 2021.
170-20	Instructs individuals to review 18VAC85-11 for information regarding involvement of the public in development of regulations for the Board of Medicine.	Deleted. This is a reference to another existing chapter of the regulations of the Board of Medicine. Regulations do not need to contain a reference.
170-100(D)	(D) states that the Board shall periodically conduct random audits of active licensees to determine continuing education compliance.	This provision is deleted. The Board has only performed one or two of these audits in the last two decades, and only on two sets of its 21 types of licensees. The Board does not have staff or the ability to conduct such audits and has not for years.
170-110	Dictates general responsibility of genetic counselors.	The first sentence of this section states that “[a] genetic counselor shall engage in the practice of genetic counseling, as defined in § 54.1-2900 of the Code of Virginia.” This provision is deleted because it is ineffectual as a regulation and redundant of statute.
170-140(E)(3)	(E)(3) restates provisions of Virginia Code § 54.1-2405 regarding requirements of closing, selling, or relocating a practice.	Deleted. This is a repetition of language in statute, where the practitioner requirement is located. The language is not a full repetition of the language, however, and is therefore misleading to practitioners who would refer to the regulation rather than the statute.
170-150	Section governs communications with patients and termination of practitioner-patient relationship.	<p>(A)(3) is amended to more closely resemble interactions between patients and genetic counselors. The current language is almost identical to that for physicians in Chapter 20, except “invasive procedure” is replaced with “genetic procedure,” which is a phrase without meaning. Genetic diagnostic tests are performed by genetic counselors, not “procedures.” (A)(3) now requires genetic counselors to communicate with patients regarding diagnostic tests consistent with the standard of care.</p> <p>The remaining provisions in (A)(3) are deleted. The provisions simply do not make sense in a genetic counseling context, as demonstrated by the attempt to provide an exception for a “genetic procedure” that would need to be performed in emergency situations.</p> <p>(A)(3)(a) was an identical copy of 18VAC85-20-28(A)(3)(a). The provision related to physicians in</p>

		<p>Chapter 20 specifically refers to minors who cannot consent to medical procedures. A genetic counselor does not perform genetic testing except by consent of the patient or the legal guardian of the patient. The same consent requirements for medical <i>procedures</i> should not be enshrined in regulation for genetic counseling.</p> <p>(A)(3)(b) is copied from 18VAC85-20-28(A)(3)(b) and refers to patients receiving emergency medical procedures. Genetic counselors do not perform emergency procedures.</p> <p>(A)(3)(c) is copied from 18VAC85-20-28(A)(3)(c). The regulation governing physicians defines invasive procedure. The provision in Chapter 170 substituted “genetic” for “invasive,” creating a definition of “genetic procedure.” Genetic counselors do not perform “procedures” of any kind. Therefore this provision of the regulations is not effective and should be deleted.</p>
<p>170-160</p>	<p>This section describes general practitioner responsibilities and provide grounds for disciplinary action.</p>	<p>(A)(1) is deleted. Genetic counselors receive standardized training. Everything within the statutory scope of genetic counseling can be performed by a licensed genetic counselor. This provision is copied from license types such as physician assistants, who have a specified practice area such as endocrinology.</p> <p>(B) is amended to reflect the changed reference in the previous subdivision. (B) references A 3, but A 3 with the deletion described above is now A 2.</p>
<p>170-170</p>	<p>This section states that no practitioner of the healing arts shall knowingly and willfully solicit or receive benefits, directly or indirectly, from referring individuals to facilities or institutions as defined in Virginia Code § 37.2-100 or a hospital as defined in § 32.1-123. The regulations exclude any payments or business arrangements that are not prohibited by Title 42, Section 1320a-7b(b) of the U.S. Code or any regulations promulgated thereto.</p>	<p>This is a repeat of language already contained in Virginia Code § 54.1-2962.1. The regulation adds no requirements or information that is not already contained in statute. The statute states that the Board “shall adopt regulations as necessary to carry out the provisions of this section.” The Board only repeated the language in the statute, and does not cite this regulation in disciplinary proceedings. If such a practice was to be the subject of disciplinary proceedings, the provisions of Virginia Code § 54.1-2915 would sufficiently cover any such action. Therefore, this regulation is not “necessary to carry out the provisions of” § 54.1-2962.1 and can be deleted.</p>