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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)	18VAC85-170-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Genetic Counselors
Action title	Clarification of temporary licensure
Date this document prepared	6/5/18

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The purpose of the proposed regulatory action is to clarify that if a person fails the licensure examination for genetic counseling, his active candidate status is terminated and he is no longer eligible for a temporary license. However, if an applicant passes the examination, he may continue to practice with his temporary license until his permanent license has been issued.

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.

ABGC = American Board of Genetic Counseling

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 February 15, 2018, the Board of Medicine adopted amendments to 18VAC85-170-10 et seq., Regulations Governing the Practice of Genetic Counseling.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person'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 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...*

The specific Code section relating to licensure of genetic counselors is:

§ 54.1-2957.19. Genetic counseling; regulation of the practice; license required; licensure; temporary license.

A. The Board shall adopt regulations governing the practice of genetic counseling, upon consultation with the Advisory Board on Genetic Counseling. The regulations shall (i) set forth the requirements for licensure to practice genetic counseling, (ii) provide for appropriate application and renewal fees, (iii) include requirements for licensure renewal and continuing education, (iv) be consistent with the American Board of Genetic Counseling's current job description for the profession and the standards of practice of the National Society of Genetic Counselors, and (v) allow for independent practice.

B. It shall be unlawful for a person to practice or hold himself out as practicing genetic counseling in the Commonwealth without a valid, unrevoked license issued by the Board. No

unlicensed person may use in connection with his name or place of business the title "genetic counselor," "licensed genetic counselor," "gene counselor," "genetic consultant," or "genetic associate" or any words, letters, abbreviations, or insignia indicating or implying a person holds a genetic counseling license.

C. An applicant for licensure as a genetic counselor shall submit evidence satisfactory to the Board that the applicant (i) has earned a master's degree from a genetic counseling training program that is accredited by the Accreditation Council of Genetic Counseling and (ii) holds a current, valid certificate issued by the American Board of Genetic Counseling or American Board of Medical Genetics to practice genetic counseling.

D. The Board shall waive the requirements of a master's degree and American Board of Genetic Counseling or American Board of Medical Genetics certification for license applicants who (i) apply for licensure before December 31, 2018, or within 90 days of the effective date of the regulations promulgated by the Board pursuant to subsection A, whichever is later; (ii) comply with the Board's regulations relating to the National Society of Genetic Counselors Code of Ethics; (iii) have at least 20 years of documented work experience practicing genetic counseling; (iv) submit two letters of recommendation, one from a genetic counselor and another from a physician; and (v) have completed, within the last five years, 25 hours of continuing education approved by the National Society of Genetic Counselors or the American Board of Genetic Counseling.

E. The Board may grant a temporary license to an applicant who has been granted Active Candidate Status by the American Board of Genetic Counseling and has paid the temporary license fee. Temporary licenses shall be valid for a period of up to one year. An applicant shall not be eligible for temporary license renewal upon expiration of Active Candidate Status as defined by the American Board of Genetic Counseling. A person practicing genetic counseling under a temporary license shall be supervised by a licensed genetic counselor or physician.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the regulatory action is clarity and consistency in interpretation of the law and regulation related to issuance of temporary licenses in genetic counseling. A person who passes the national examination and receives certification, as required for licensure, no longer has "Active Candidate Status." The regulation, as currently written, appears to terminate a temporary license when Active Candidate Status is terminated, resulting in placing a qualified genetic counselor who is employed and seeing patients in a limbo period between passage of the examination and issuance of a permanent license. The amendment is necessary to ensure continuation of the temporary license until a permanent license is issued, so there is no disruption in patient care. Likewise, the regulation is amended to clarify that failure of the examination results in termination of Active Candidate Status and the temporary license, so patient health and safety is not at risk by receiving care from an applicant who has not demonstrated minimal competency.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

Upon recommendation of the Advisory Board on Genetic Counseling, the Board voted in February to adopt an amendment by a fast-track action. Subsequently, it was decided that § 54.1-2957.19 should be amended, so the regulatory action was not submitted at that time. The Advisory Board is concerned that the statutory change may not occur in 2019 and has requested that the agency proceed with the fast-track regulatory action.

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.

The amendment to section 60 will clarify that if a person fails the licensure examination for genetic counseling, his active candidate status is terminated and he is no longer eligible for a temporary license. However, if an applicant passes the examination, he may continue to practice with his temporary license until his permanent license has been issued.

Issues

Please identify the issues associated with the proposed regulatory action, 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, please indicate.

- 1) The advantage to the public is continuation of genetic counseling services without interruption if those services are being provided by a person with a temporary license who passes the examination and been certified but has not yet received a permanent license issued by the Board. There are no disadvantages; if a person fails the examination, he can no longer practice with a temporary license.
- 2) There are no 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. The Board is authorized under § 54.1-2400 to "*To 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.*" There is no restraint on competition as a result of promulgating this regulation. To the contrary, it clarifies the issuance of a temporary license under which a genetic counselor may see patients.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include 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 statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Regulatory flexibility analysis

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) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of 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 proposed regulation.

There are no alternative regulatory methods; the proposed regulation clarifies the intent of temporary licensure.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

<p>Projected cost to the state to implement and enforce the proposed regulation, including: a) fund source / fund detail; and b) a delineation of one-time versus on-going expenditures</p>	<p>There is no cost for implementation or enforcement.</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>There are no costs to localities.</p>

<p>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</p>	<p>The individuals affected will be genetic counselors with temporary licenses.</p>
<p>Agency’s best estimate of the number of such entities that will be affected. Please 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>There are 5 pending applications for temporary licensure; 147 persons hold a current Virginia license as a genetic counselor. Since this is a newly licensed profession, there was a one-year “grace period” for persons to become licensed; that period expires on June 14, 2018. There is no estimate of the number of small businesses because genetic counselors generally practice in large medical institutions/hospital systems.</p>
<p>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	<p>There are no costs.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>Facilitation of practice by genetic counselors who have passed the licensure examination.</p>

Alternatives

Please describe 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. 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 regulation.

Since this is a regulation that solves a problem for applicants for genetic counselor licensure, there are no alternatives that meet the essential purpose of the action.

Public participation notice

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.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no impact on the family and family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

Current section number	Proposed new section number, if applicable	Proposed change, intent, rationale, and likely impact of proposed requirements
60	Sets out the licensure requirements for genetic counselors, including the issuance of a temporary license to persons who have active candidate status by the ABGC.	Subsection C on temporary licenses is amended to delete “upon expiration of active candidate status” to “upon failure of the ABGC certification examination.” <i>Once a person has taken the certification examination, he no longer has “active candidate status” from ABGC. That is not problematic if the person has failed the examination because he should not be practicing with a temporary license. However, if a person has passed the examination and received certification, he should be able to continue practicing with a temporary license until a permanent license is issued. As currently written, the regulation would not allow continuation with a temporary license, and technically, the licensee should not be practicing for the period of time it takes to issue a permanent license (up to 30 days). The proposed amendment will clarify the regulation and resolve the problem it has created.</i>