

Adverse impact notification sent to Joint Commission on Administrative Rules, House Committee on Appropriations, and Senate Committee on Finance (COV § 2.2-4007.04.C): Yes Not Needed

If/when this economic impact analysis (EIA) is published in the *Virginia Register of Regulations*, notification will be sent to each member of the General Assembly (COV § 2.2-4007.04.B).



Virginia Department of Planning and Budget Economic Impact Analysis

18 VAC 85-170 – Regulations Governing the Practice of Genetic Counselors
Department of Health Professions
Town Hall Action/Stage: 4254/7475
May 27, 2016 (revised to reflect additional analysis on June 30, 2016)

Summary of the Proposed Amendments to Regulation

As mandated by Chapter 10 of the 2014 Acts of the Assembly, the Board of Medicine (Board) proposes to promulgate rules for new licensure of genetic counselors.

Result of Analysis

The Board's proposed amendments satisfy statutory requirements. A different design would likely yield the same benefits at lower cost for at least one proposed change.

Estimated Economic Impact

Currently, genetic counselors are not licensed. In 2014, the General Assembly passed legislation¹ that: 1) directed the Board to adopt regulations governing the practice of genetic counselors that meets specific criteria,² 2) made it unlawful for individuals to practice, or hold

¹ Chapter 10 of the 2014 Acts of Assembly (<http://leg1.state.va.us/cgi-bin/legp504.exe?141+ful+CHAP0010>) and the identical Chapter 266.

² §54.1-2957.18 (A) requires that Board regulations on this matter: 1) set forth requirements for licensure to practice genetic counseling, 2) provide for appropriate application and renewal fees, 3) include requirements for licensure renewal and continuing education, 4) 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 5) allow for independent practice.

themselves out as practicing, genetic counseling³ without a valid Board license, 3) specified that applicants for licensure in genetic counseling have a master's degree from a genetic counseling education program that is accredited by the accreditation Council of Genetic Counseling, and 4) specified that applicants hold a current, valid certificate issued by the American Board of Genetic Counseling or American Board of Medical Genetics to practice counseling. The General Assembly made provision in this legislation for the Board to waive the educational requirements above for individuals who 1) apply for licensure before July 1, 2016,⁴ 2) have at least 20 years of documented work experience practicing genetic counseling, 3) submit two letters of recommendation (one from a genetic counselor and one from a physician), 4) have completed at least 25 hours of continuing education and 5) comply with the Board's regulations relating to the National Society of Genetic Counselors Code of Ethics. The General Assembly also made provision for the Board to grant temporary licenses to applicants for licensure who have been granted Active Candidate status by the American Board of Genetic Counseling and who are practicing under the supervision of a licensed genetic counselor or physician.

Finally, the General Assembly included a conscience clause (Code of Virginia §54.1-2057.20) in the legislation that states:

“Nothing in this chapter shall be construed to require any genetic counselor to participate in counseling that conflicts with their deeply-held moral or religious beliefs, nor shall licensing of any genetic counselor be contingent upon participation in such counseling. Refusal to participate in counseling that conflicts with the counselor's deeply-held moral or religious beliefs shall not form the basis for any claim of damages or for any disciplinary or recriminatory action against the genetic counselor, provided the genetic counselor informs the patient that he

³ The General Assembly provides exemptions to this provision for physicians practicing within their scopes of practice (so long as he does not use the title “genetic counselor”), students who are performing genetic counseling under supervision as a part of a course of studies and employees of rare disease organizations who are certified by the American Board of Genetic Counseling or the American Board of Medical Genetics who provide genetic counselling for fewer than 10 days per year.

⁴Board staff reports that no individuals will be able to apply to be grandfathered in to licensure before the required deadline because there are currently no regulations in effect under which to apply. Legislation would have to be introduced to change this date in order for any individual to qualify to have the legislatively required master's degree waived. Board staff reports that only one genetic counselor in the state does not already have a master's degree.

will not participate in such counseling and offers to direct the patient to the online directory of licensed genetic counselors maintained by the Board.”

The Board now proposes to promulgate this regulation for licensure of genetic counselors that mirrors legislative requirements for initial licensure and grandfathering. The Board proposes to set fees for initial licensure (\$130), temporary licensure (\$50), biennial renewal of active licenses (\$135) and inactive licenses (\$70), late renewal (\$50 added to the renewal fee), license reinstatement (\$180), license reinstatement after revocation pursuant to §54.1-2408.2 (\$2,000) and verification letters (\$10). The Board additionally proposes to charge the same fees for duplicate licenses (\$5), duplicate wall certificates (\$15) and returned checks (\$35) as they do for all Board licensure programs.

This proposed regulation will also require licensees to complete 50 hours of continuing education (CE) every two years (30 hours of Category 1 training⁵ and 20 hours of Category 2 training⁶ or professional activity). The Chair of the Genetic Counseling Advisory Board reports that costs for CE can vary widely; some CE would likely be free and some opportunities can cost as much as several hundred dollars (plus travel costs and cost of time spent) for national conferences. Genetic counselors will incur costs for pursuing and maintaining licensure that include paying licensure fees, paying for CE (when there is a cost attached) and costs for time spent on these activities (including travel time).

The Board also proposes to set requirements for the exercise of the legislation’s conscience clause that include: 1) requirements for informing patients in a timely fashion if the genetic counselor has a religious or deeply held moral belief that precludes the provision of services (including informing the patient, prior to taking them on as a patient, if there are any limitations on the services that the genetic counselor will be willing to provide), 2) a requirement to direct the patient to an online directory and 3) a requirement to offer to refer the patient to another licensed health care professional. The

⁵ Activities approved by the American Board of Genetic Counselors, the American Board of Medical Genetics or the National Society of Genetic Counselors.

⁶ Category 2 training can include consultation with another genetic counselor, independent research or reading, authorship, clinical supervision, volunteer leadership in the profession, preparation for a presentation or other such experiences that promote continued learning.

last requirement appears to have been added in response to public comment from individuals concerned that there was not currently an online list for patients to access, and that patient care would be delayed and suffer on account of this.

Businesses and Entities Affected

These proposed regulatory changes will affect all genetic counselors in the Commonwealth. The Genetic Counseling Advisory Board estimates that there are 35 to 40 genetic counselors in the Commonwealth.

Localities Particularly Affected

No locality will be disproportionately affected by these proposed regulatory changes.

Projected Impact on Employment

Absent a legislative change to change the end date for grandfathering, the one genetic counselor who has practiced in the Commonwealth (presumably for many years) without a master's degree will either have to stop practicing or incur likely large costs to gain the required education.

Effects on the Use and Value of Private Property

These proposed regulatory changes are unlikely to affect the use or value of private property in the Commonwealth.

Real Estate Development Costs

These proposed regulatory changes are unlikely to affect real estate development costs in the Commonwealth.

Small Businesses:

Definition

Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as “a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.”

Costs and Other Effects

Genetic counselors who are in private practice will incur the costs listed above for licensure and CE.

Alternative Method that Minimizes Adverse Impact

The American Board of Genetic Counseling offers the option of either examination or CE to satisfy the requirements of certification. Permitting licensees to satisfy the Virginia CE requirements for licensure renewal by passing the American Board of Genetic Counseling recertification examination could potentially save individuals who have on their own kept up-to-date on relevant knowledge a significant amount of time. Passing this exam would also be a more concrete indicator that the licensee has understanding of recent relevant developments in genetics and genetics counseling than would attending CE events. Learning may occur at CE sessions, but attendance in of itself does not imply comprehension. Passing an exam does imply comprehension.

Adverse Impacts:

Businesses:

Genetic counselors who are in private practice will incur the costs listed above for licensure and CE.

Localities:

Localities in the Commonwealth are unlikely to see any adverse impacts on account of these proposed regulatory changes.

Other Entities:

No other entities are likely to be adversely affected by these proposed changes.

Legal Mandates

General: The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order Number 17 (2014). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5) the impact on the use and value of private property.

Adverse impacts: Pursuant to Code § 2.2-4007.04(C): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.