



## Virginia Department of Planning and Budget **Economic Impact Analysis**

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**18 VAC 85-170 Regulations Governing the Practice of Genetic Counselors**  
**Department of Health Professions**  
**Town Hall Action/Stage: 6114/9833**  
June 5, 2023

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The Department of Planning and Budget (DPB) 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 19. The analysis presented below represents DPB’s best estimate of these economic impacts.<sup>1</sup>

### **Summary of the Proposed Amendments to Regulation**

The Board of Medicine (Board) proposes to delete outdated or redundant provisions and clarify some provisions to be consistent with current practice.

### **Background**

As a result of a 2022 periodic review, the Board seeks to amend the regulation to remove outdated language and references to the Code of Virginia that are redundant, and to update certain provisions so that they accurately reflect current practice.<sup>2</sup> The most substantive changes are summarized as follows:

- The definition of “conscience clause” is based on a provision in the Code of Virginia that was repealed in 2021; thus, this definition would be removed.
- Section 170-100(D) currently states that the Board shall periodically conduct random audits. The Board reports that it does not have the staff or the ability to conduct such

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<sup>1</sup> Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the analysis 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.

<sup>2</sup> See <https://townhall.virginia.gov/l/ViewPReview.cfm?PRid=2158>.

audits and has only performed one or two such audits in the last two decades and seeks to delete this provision. The Department of Health Professions (DHP) noted that the Board does investigate and respond to complaints against practitioners, and that removing this provision in the regulation would not increase the risk to the public since the Board has not conducted such an audit in many years.

- Section 150 governing communications with patients currently contains language copied over from corresponding sections in the regulation for physicians, which does not reflect the work and responsibilities of genetic counselors. For instance, A(3) contains requirements for informed consent for “genetic procedures” with specific requirements for minors and in emergency situations. This language is identical to 18 VAC 85-20-28 A(3), which governs practitioner-patient communication for physicians, except that Section 150 uses the term “genetic procedure” instead of “surgery or invasive procedure.”<sup>3</sup>

However, the Board reports that the scope of practice for genetic counselors is very different from that of physicians, and thus the language should not apply to genetic counselors. The Board notes that a genetic counselor’s involvement with patients is limited to consultation after examining test results and that the risks involved in such consultation are minimal. In addition, the Board reports that a genetic counselor would not be involved in an “emergency intervention,” and thus the person who would be subject to obtaining informed consent or being exempted in that situation is the physician.<sup>4</sup>

To the extent that this occurs in practice, the impact of this change would be minimal. However, to the extent that a genetic counselor also advises on the type of tests to administer and the potential consequences of testing, including in emergency interventions, the impact would be greater. The actual extent of the impact cannot be determined based upon available information. The proposed language would still require

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<sup>3</sup> See <https://law.lis.virginia.gov/admincode/title18/agency85/chapter20/section28/> for the corresponding language governing physicians in Chapter 20.

<sup>4</sup> Email from DHP dated May 1, 2023. DHP further notes that the language being repealed was initially included in this regulation “for consistency” with 18 VAC 85-20 and that although this intent is understandable, “in practice this does not translate to usable regulations for many professions regulated by the Board. Those professions need individual provisions that reflect the realities of their professions and practices.”

genetic counselors to obtain documented informed consent in accordance with the policies of the health care entity and consistent with the standard of care.

- The remaining changes would be to remove references to other chapters of the Virginia Administrative Code or to remove language that is redundant of statute.<sup>5</sup>

### **Estimated Benefits and Costs**

Since the proposed changes would not change the practice of genetic counseling as it is currently practiced, and largely serves to update the regulatory text, neither genetic counselors, nor their employers or clients are likely to incur any benefits or costs other than those benefits that result simply from ensuring the regulatory text is clear and up-to-date. However, to the extent that behavior analysts or the public rely upon the regulation for references to the Code, the proposed changes that would remove these references may decrease clarity regarding the requirements applicable to this profession. No information exists with which to determine the extent to which this reliance occurs.

### **Businesses and Other Entities Affected**

DHP reports that there are 593 licensed genetic counselors as of March 31, 2023. The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.<sup>6</sup> An adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined. Since the proposed amendments would not result in an increase in net costs for any entity, an adverse impact is not indicated.

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<sup>5</sup> See the Agency Background Document, pp. 7-8 for the specific references that would be removed: [https://townhall.virginia.gov/L/GetFile.cfm?File=26\6114\9833\AgencyStatement\\_DHP\\_9833\\_v3.pdf](https://townhall.virginia.gov/L/GetFile.cfm?File=26\6114\9833\AgencyStatement_DHP_9833_v3.pdf).

<sup>6</sup> Pursuant to Code § 2.2-4007.04(D): 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. Statute does not define “adverse impact,” state whether only Virginia entities should be considered, nor indicate whether an adverse impact results from regulatory requirements mandated by legislation.

**Small Businesses<sup>7</sup> Affected:<sup>8</sup>**

The proposed amendments would not impact small businesses.

**Localities<sup>9</sup> Affected<sup>10</sup>**

The proposed amendments do not disproportionately affect any particular localities or create costs for local governments.

**Projected Impact on Employment**

The proposed amendments would not affect the employment of genetic counselors, or have any impact on employment in general.

**Effects on the Use and Value of Private Property**

The proposed amendments are unlikely to affect the value of private property. Real estate development costs would not be affected.

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<sup>7</sup> 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.”

<sup>8</sup> 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.

<sup>9</sup> “Locality” can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

<sup>10</sup> Code § 2.2-4007.04 defines “particularly affected” as bearing disproportionate material impact.