

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

12 VAC 5-90 Regulations for Disease Reporting and Control
Virginia Department of Health
Town Hall Action/Stage: 4908 / 8053
October 23, 2017

Summary of the Proposed Amendments to Regulation

Pursuant to Chapter 301 of the 2015 Acts of Assembly (Chapter 301),¹ the State Board of Health (Board) proposes to repeal regulatory text concerning HIV testing of gamete² donors.

Result of Analysis

The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact

Prior to 2015, § 32.1-45.3 of the Code of Virginia required that the Board promulgate regulations establishing an HIV testing protocol for donors of gametes used to treat patients for infertility. Chapter 301 repealed this requirement. Regulations of the U.S. Food and Drug Administration³ require testing and other measures to prevent transmission of HIV and other infections when assisted reproductive technology, including donated gametes, are used to treat infertility and related problems. These federal regulations are more comprehensive than the existing state regulations. Thus the proposed repeal of text from the Virginia Regulations for

¹ See <http://leg1.state.va.us/cgi-bin/legp504.exe?151+ful+CHAP0301>

² Gametes are either sperm or ova.

³ CFR 21, Chapter 1, Part 1271-Human Cells, Tissues, and Cellular and Tissue-Based Products
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1271>

Disease Reporting and Control would have no impact, beyond potentially reducing confusion, since the federal regulations already apply.

Businesses and Entities Affected

Beyond potentially reducing confusion among readers of the regulation, the proposed repeal of text does not affect any businesses or entities. The subject matter concerns practitioners who treat infertility, their medical practices, and potential donors of gametes.

Localities Particularly Affected

The proposed amendments do not disproportionately affect particular localities.

Projected Impact on Employment

The proposed amendments do not affect employment.

Effects on the Use and Value of Private Property

The proposed amendments do not affect the use and value of private property.

Real Estate Development Costs

The proposed amendments do not affect real estate development costs.

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

The proposed amendments do not affect costs for small businesses.

Alternative Method that Minimizes Adverse Impact

The proposed amendments do not adversely affect small businesses.

Adverse Impacts:**Businesses:**

The proposed amendments do not adversely affect businesses.

Localities:

The proposed amendments do not adversely affect localities.

Other Entities:

The proposed amendments do not adversely affect other entities.

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.