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Fast-Track Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12 VAC 5-90-230 through 12 VAC 5-90-270
Regulation title(s)	Regulations for Disease Reporting and Control
Action title	Repeal Sections Pertaining to HIV Testing of Gamete Donors
Date this document prepared	6/30/2017

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

This regulatory action is necessary to comply with a change in the Code of Virginia, and no agency discretion is involved. The law that formerly charged the Board of Health with promulgating regulations to establish a testing protocol for gamete donors (§ 32.1-45.3) was repealed in 2015. Thus, the related regulations, which are currently contained in 12VAC5-90-230, 12VAC5-90-240, 12VAC5-90-250, 12VAC5-90-260, and 12VAC5-90-270, are no longer necessary and are being repealed in this regulatory action.

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.

No acronyms have been used in this Agency Background Document.

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.

The State Board of Health approved these amendments to the Regulations for Disease Reporting and Control (12VAC5-90) at its regular quarterly meeting on September 7, 2017.

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.

§§ 32.1-12 and 32.1-35 of the Code of Virginia authorizes the Board of Health to promulgate regulations and empowers the Board of Health to adopt such regulations as are necessary to carry out provisions of laws of the Commonwealth administered by the Commissioner of the Department of Health.

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 section of the Code of Virginia that promulgated the regulations in this action has been repealed. Therefore, the sections of regulations contained in this regulatory action are no longer authorized, necessary, or applicable.

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?

As the section of the Code of Virginia has already been repealed, the repeal of the regulation is noncontroversial. This regulatory action aligns regulations with the Code, and no agency discretion is involved.

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.

Not applicable; regulatory language is being repealed, in compliance with Code, and no new provisions are being proposed.

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.

The primary advantage to the public is the removal of potentially confusing regulatory language that no longer applies. This is also the primary advantage to the agency. No disadvantages or other pertinent matters have been identified as this action simply removes these sections of the regulations because they are no longer authorized by the Code of Virginia.

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.

Not applicable; the section of the Code of Virginia has been repealed and this action repeals the corresponding sections of the Regulations for Disease Reporting and Control.

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.

No locality is disproportionately affected by this action.

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.

Not applicable; the section of the Code of Virginia has been repealed and thus corresponding sections of the regulations also need to be repealed.

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.

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	None.
Projected cost of the new regulations or changes to existing regulations on localities.	None.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	None.
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.	None.
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	None.

regulations.	
Beneficial impact the regulation is designed to produce.	None.

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.

No viable alternatives exist.

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.

Any public comments may be submitted to Diane Woolard, Director, Division of Surveillance and Investigation, Virginia Department of Health at diane.woolard@vdh.virginia.gov or via the regulatory Town Hall.

Periodic review and small business impact review report of findings

If this fast-track is the result of a periodic review/small business impact review, use this form to report the agency's findings. Please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review and (2) indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Commenter	Comment	Agency response

Not applicable.

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.

This action is not anticipated to have an 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.

For changes to existing regulation(s), please use the following chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-90-230 through 12VAC5-90-270	N/A		These sections are to be repealed in order to comply with changes to the Code of Virginia.

If an existing regulation or regulations (or parts thereof) are being repealed and replaced by one or more new regulations, please use the following chart:

Current chapter-section number	Proposed new chapter-section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements

If a new regulation is being promulgated, that is not replacing an existing regulation, please use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements

If the proposed regulation is intended to replace an emergency regulation, and the proposed regulation is identical to the emergency regulation, please choose and fill out the appropriate chart template from the choices above. In this case “current section number” or “current chapter-section number” would refer to the **pre-emergency** regulation.

If the proposed regulation is intended to replace an emergency regulation, and the proposed regulation includes changes since the emergency regulation, please create two charts: 1) a chart describing changes from the **pre-emergency** regulation to the proposed regulation as described in the paragraph above, and 2) a chart describing changes from the **emergency** regulation to the proposed regulation. For the second chart please use the following title: “Changes from the Emergency Regulation.” In this case “current section number” or “current chapter-section number” would refer to the **emergency** regulation.