



townhall.virginia.gov

Periodic Review and Small Business Impact Review Report of Findings

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-71
VAC Chapter title(s)	Regulations Governing Virginia Newborn Screening Services
Date this document prepared	July 26, 2021

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the **Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code**.

Acronyms and Definitions

Define all acronyms used in this Report, and any technical terms that are not also defined in the "Definitions" section of the regulation.

RUSP – Recommended Uniform Screening Panel

VDH – Virginia Department of Health

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

The State Board of Health is authorized to make, adopt, promulgate and enforce regulations by Section

32.1-12 of the Code of Virginia.

Section 32.1-65 of the Code of Virginia requires newborn screening to be conducted on every infant born in the Commonwealth of Virginia.

Section 32.1-67 of the Code of Virginia requires the Board of Health to promulgate regulations as necessary to implement Newborn Screening Services. The regulations are required to include a list of newborn screening tests pursuant to Section 32.1-65.

Alternatives to Regulation

Describe any viable alternatives for achieving the purpose of the regulation that were considered as part of the periodic review. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving its purpose.

No viable alternatives for achieving the purpose of the existing regulations could be determined.

Public Comment

Summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency response. Be sure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. Indicate if an informal advisory group was formed for purposes of assisting in the periodic review.

VDH received one public comment following the publication of the Notice of Periodic Review. The commenter submitted the same comment via Town Hall and directly to the agency.

Commenter	Comment	Agency response
R. Brent Rawlings/Virginia Hospital & Healthcare Association	<p>Mr. Rawlings recommended that <u>“this regulation should be retained</u> and has provided suggestions for how the regulation could be further improved.”</p> <p>Mr. Rawlings provided the following recommendations:</p> <ol style="list-style-type: none"> 1. <u>Modify 12VAC5-71-30 to require listing on the RUSP as a pre-requisite for inclusion in the Newborn Screening Program.</u> 2. <u>Modify 12VAC5-71-30 to require the Commissioner to consult the Virginia Genetics Advisory Committee for any changes to the core panel of disorders for which newborn dried-blood-spot screening is conducted.</u> 	<p>VDH concurs that the regulation can be improved and has initiated the standard regulatory process to amend the regulation. A stakeholder workgroup of the Virginia Newborn Screening Advisory Committee is being established to review the regulation in its entirety and make recommendations for amendments. All of the proposed recommendations submitted by Mr. Rawlings will be put forth for consideration.</p>

	<p><u>3. Modify 12VAC5-71-30 to require the Department to provide to the Virginia Genetics Advisory Committee a fiscal impact for any changes to the core panel of disorders for which newborn dried-blood-spot screening is conducted.</u></p> <p><u>4. Modify 12VAC5-71-100 to establish the requirement to provide public information on the effectiveness and costs of laboratory tests and fees charged to and collected from health care providers.</u></p> <p><u>5. Modify 12VAC5-71-70, 12VAC5-71-100, 12VAC5-71-120, and other applicable regulations to improve electronic data exchange of testing information.</u></p> <p><u>6. Modify 12VAC5-71-100 to place reasonable limitations on the fees that may be charged to birthing hospitals and physicians for purchase of dried-blood-spot screening specimen collection kits.</u></p>	
--	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--

Effectiveness

Pursuant to § 2.2-4017 of the Code of Virginia, indicate whether the regulation meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), including why the regulation is (a) necessary for the protection of public health, safety, and welfare, and (b) is clearly written and easily understandable.

The regulations meet the criteria set out in Executive Order 14 (2018) as they are necessary for the protection of public health, safety and welfare of infants born in the Commonwealth of Virginia and their families. The regulations are clearly written and understandable.

Decision

Explain the basis for the promulgating agency’s decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).

VDH is recommending the regulations be amended to reflect current practices and updated scientific information relevant to newborn screening.

Small Business Impact

As required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (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. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

There is a continued need for the regulations because newborn screening for heritable disorders and genetic diseases in infants born in the Commonwealth of Virginia is still occurring, and these regulations establish the requirements for conducting these tests. One public comment was received. The commenter recommended that the regulations be retained but improved. The commenter identified recommendations for amending the existing regulatory language. The regulations are clearly written and easily understandable. The regulations do not duplicate or conflict with any known federal or state law or regulation; however, there is some overlap with 12VAC5-191. Regulations are evaluated on an ongoing basis and these regulations were last amended as a result of a periodic review in January 2014. The regulation was amended to add two disorders to the newborn screening panel through a final exempt regulatory action in January 2019. VDH does not anticipate that amending the regulations will have an adverse economic impact on small businesses in the Commonwealth of Virginia.
