



Fast Track Proposed Regulation Agency Background Document

Agency name	State Board of Health (Virginia Department of Health)
Virginia Administrative Code (VAC) citation	12VAC5-71
Regulation title	Regulations Governing Virginia Newborn Screening Services
Action title	Update following periodic review
Date this document prepared	February 2, 2012

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

This regulation is proposed to be amended as the result of a periodic review conducted in March 2011. The proposed changes will update names and references to programs, state regulations, and federal recommendation entities.

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 the proposed changes to 12VAC5-71, Regulations Governing Newborn Screening Services on March 23, 2012.

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.

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.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail 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 regulation needs to be amended as the result of a periodic review conducted pursuant to Executive Order (EO) 14 (2010).

The regulation is essential to protect the health of citizens as conditions identified through newborn screening can lead to death or permanent disability if left unidentified or untreated.

The regulation provides oversight for the Virginia Newborn Screening Program. The benefits of newborn screening are to identify rare genetic and heritable disorders at birth in order to reduce infant mortality and permanent disabilities which can result from unidentified and untreated disease. The proposed regulation updates names and references to programs, state regulations, and federal recommendation entities.

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?

Please note: 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 (i) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

The fast track process is being utilized as the changes to regulation are to update names and references to programs, state regulations, and federal recommendation entities. These changes are not expected to be controversial.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.) Please be sure to define any acronyms.

Definitions in Section 10 for "certified nurse midwife", "child", "hospital", "parent", "pool of funds", and "preterm infants" have been updated to be consistent with other regulations or to provide more clarity to the definition. References to "Virginia Newborn Screening Services" or "newborn screening services" have been changed to reflect the current program name, "Virginia Newborn Screening Program" throughout the regulation. In Section 30, the reference to the federal newborn screening recommended screening panel has been updated and standardized nomenclature for newborn screening condition names and abbreviations has been incorporated into the list of conditions. In Section 70, the term "from the hospital" has been added to the term "at the time of discharge" for clarity. Sections 80 and 120 have been restructured to be formatted in the correct style. In Section 90, the term "Information relative to" has been stricken to clarify information to be recorded in the record. The reference to the federal regulation for laboratories has been clarified in Section 100. In Section 160, the word protocol has been substituted for "procedure" and the term "resident adults" has been added to clarify that persons ages 19 and 20 are covered.

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 that infants in Virginia will continue to be screened for conditions as recommended by the federal government. There are no disadvantages related to the proposed changes.

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.

The federal government issues recommendations through the United States Department of Health and Human Services Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.

These are only recommendations however; there are no federal requirements for state newborn screening programs.

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.

All localities will be equally affected by the proposed regulation.

Regulatory flexibility analysis

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.

The proposed changes to the regulation will not impact small businesses. Alternative regulatory methods would not adequately protect the health of infants. Under the current regulation and proposed amendments, small businesses may not be exempted as a category because screening for all infants must be managed equitably by their providers, regardless of business size, to assure optimal outcomes.

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	There is no projected cost to the state to implement the proposed changes.
Projected cost of the <i>new regulations or changes to existing regulations</i> on localities.	There is no projected cost to localities to implement the proposed changes.
Description of the individuals, businesses or other entities likely to be affected by the <i>new regulations or changes to existing regulations</i>.	There are no projected changes that would affect newborns and their families, hospitals, primary care physicians, or others who are involved with the newborn screening program.
Agency’s best estimate of the number of such entities that will be affected. Please include an	No small businesses will be impacted by the proposed changes.

<p>estimate of the number of small businesses affected. Small business means 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.</p>	
<p>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. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. 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 regulations.</p>	<p>No projected costs will be incurred by affected individuals, businesses, or other entities.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>The proposed regulation will continue to benefit infants born in Virginia through newborn screening and early identification of rare but serious heritable diseases.</p>

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.

There are no alternatives which would comply with the current § 32.1-67 of the Code of Virginia. This section would need to be amended through the legislative process to make promulgation of these regulations optional. This is not a viable or desired alternative.

Periodic review/small business impact review result

If this fast-track regulation is not the result of a periodic review/small business of the regulation, please delete this entire section.

If this fast-track regulation is the result of a periodic review/small business impact review, 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 14 (2010), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, please include, pursuant to § 2.2-4007.1 E and F, 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
Cholesterol Objawy	Generic comment of support	Comment noted
Bob Watkins	Generic comment of support	Comment noted
Leslie	Comment on proposed abortion regulations	DPB notified regarding comment placement
Belle Noneya	Comment on proposed abortion regulations	DPB notified regarding comment placement
Mark	Comment on proposed abortion regulations	DPB notified regarding comment placement
Eric Sampo	Generic comment of support	Comment noted
Heather Strang, Peditrix Audiology Services	Comments on Proposed Newborn Hearing Guidelines	Comment is on guidance document related to newborn hearing screening which is handled under separate section (12VAC5-80). This comment is not applicable to this regulatory action.

Note: Town Hall web site states that four comments will be hidden due to violation of Town Hall policy.

The regulation is essential to protect the health of citizens as conditions identified through newborn screening can lead to death or permanent disability if left unidentified or untreated. The regulation is required by Section 32.1-67 of the Code of Virginia. No complaints or comments specific to newborn screening services have been received regarding the regulation. The regulation is of moderate complexity. The federal government does not mandate state newborn screening programs. No federal regulations exist which are applicable. Scientific advances and technology will continue to increase the capability of newborn screening programs. The regulation will continue to be periodically reviewed as required and the list of screened conditions will be reviewed every two years as stated in the regulation.

Family impact

Please assess the impact of the proposed 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.

Although the testing is mandated by the Code of Virginia, provisions remain in the statute for parents to refuse newborn screening if the test conflicts with their religious practices or tenets. Because parents retain the right to refuse testing, the regulation does not erode the authority or rights of parents.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. 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 list separately (1) all differences between the *pre-emergency regulation* and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulation(s), use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, rationale, and consequences
10		Definition of “Certified nurse midwife”	Update citation to applicable state regulations
10		Definition of “Child”	Update definition to be consistent with other regulations
10		Definition of “Hospital”	Update definition to be consistent with other regulations
10		Definition of “Parent”	Update definition to be consistent with other regulations
10		Definition of “Pool of Funds”	Grammatical change
10		Definition of “Preterm infant”	Grammatical changes
10, 30, 100, 120, 130, 140, 150, 170, 180, 190		References to “Virginia Newborn Screening Services” or “newborn screening services”	References changed where appropriate to “Virginia Newborn Screening Program” or “the newborn screening program” to reflect correct reference and current program name
20		Administration of chapter	Repealed as this section is no longer necessary in regulation
30		Reference to “recommendations for screening by the American College of Medical Genetics in its 2005 report Newborn Screening: Toward a Uniform Screening Panel and System”	Updated reference to “United States Department of Health and Human Services Secretary’s Recommended Uniform Screening Panel” to reflect change in how federal recommendations are issued
30		Listing of conditions by name and abbreviation	Updates multiple condition names and abbreviations using national standardized nomenclature. List is re-alphabetized.
70		Use of term “at the time of discharge”	Phrase “from the hospital” added throughout section for consistency and clarity
80		Restructured subsection D to include subsections E and F	To correct style and structure of text
90		Strike “Information relative to” in number 4 and substitute “The”	Clarification of information to be recorded
100		Addition of words “federal and “regulations” with use of term “Clinical Laboratory Improvement Amendments”	Clarification of reference

120		Restructure subsection D to include subdivisions 1 and 2	To correct style and structure of text
160		Removal of word "procedure" in subsection A and substitution of word "protocol"	Grammatical change
160		In subsections C and D, addition of term "resident adults"	Clarifies that subsections apply to those persons ages 19 and 20.