Virginia Regulatory Town Hall

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Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-71
Regulation title	Regulations Governing Virginia Newborn Screening Services
Action title	Amend regulation as a result of periodic review
Date this document prepared	March 28, 2011

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.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The Virginia Department of Health conducted a periodic review of 12VAC5-71 "Regulations Governing Virginia Newborn Screening Services" pursuant to Executive Order (EO) 14 (2010). As a result of this review, the Virginia Department of Health plans to begin the regulatory process to amend these regulations. It is necessary to amend these regulations to make corrections to outdated citations and to update the current list of conditions for which newborns are screened.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

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

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

Section 32.1-65 of the Code of Virginia mandates the necessity of newborn screening to protect the public health of all infants born in Virginia. This Code section states that newborn screening is necessary "in order to prevent mental retardation and permanent disability or death".

Section 32.1-66 of the Code of Virginia requires the Commissioner of Health to notify the attending physician and to "perform or provide for additional testing required to confirm or disprove the diagnosis" whenever a result indicates suspicion of a possible disorder as screened for pursuant to § 32.1-65.

The need for the regulation is required under § 32.1-67 of the Code of Virginia.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

The changes proposed to 12VAC5-71 will revise Section 30 listing the specific disorders for which screening is conducted as part of the "core panel". Currently, the Division of Consolidated Laboratory Services (DCLS) analyzes biological markers that may be indicative of 28 certain disorders that constitute the "core panel". Section 32.1-67 of the Code of Virginia requires that this list be in the regulation. Other conditions may be identified and reported to attending physicians. However, the screening is not conducted to search specifically for these other conditions; rather, they are by-products of the primary testing methods and often referred to as secondary conditions. As the scientific evidence on specific analytes indicating certain conditions has evolved in the past few years, it has changed the laboratory requirement for primary screening for Tyrosinemia. After the expansion of newborn screening evolved across the country, it was discovered that the marker originally thought to detect Tyrosinemia type I (tyrosine) was not actually an indicator of that condition. This marker is actually an indicator of Tyrosinemia type II/type III. The marker that must be used to screen for Tyrosinemia type I (tyrosine) is succinyl acetone. The DCLS is not currently testing for this marker. To add this marker would require changes and the DCLS does not have a time frame for adding this marker. Tyrosinemia type II/type III are reported out as secondary conditions and are not appropriate to have in the core panel. Therefore, it will be recommended that Tyrosinemia be deleted from the core panel of screened disorders.

In addition, certain references to state regulations, the program name, and the federal body which issues recommendations for newborn screening will be updated.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

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.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website, www.townhall.virginia.gov, or by mail, email, or fax to Nancy Ford, 109 Governor Street, 8th Floor, Richmond, Virginia 23220, phone (804) 864-7691 or e-mail Nancy.Ford@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by the last day of the public comment period.

A public hearing will not be held.

Participatory approach

Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, regulatory advisory panels) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

The Virginia Department of Health has formed a regulatory advisory panel to assist in the periodic review and development of the amendments to these regulations.

Family impact

Assess the potential 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.

The proposed amendments to the regulation will not strengthen or erode the rights of parents in the education, nurturing, and supervision of their children. Parents have the right to refuse newborn screening for religious reasons. Parents also have the right to seek additional newborn screening testing outside of the state program if desired.

The proposed amendments will not encourage or discourage economic self-sufficiency, self-pride, or the assumption of responsibility for oneself, one's spouse, one's children and/or elderly parents.

The proposed amendments will not strengthen or erode marital commitment.

The proposed amendments will not increase or decrease disposable family income.

Periodic review

Per Executive Order 14 (2010), each existing regulation shall be reviewed ***at least once every four years****.*

If this NOIRA is <u>not</u> the result of a periodic review of the regulation, please delete this entire section.

If this NOIRA <u>is</u> the result of a periodic 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.

Commenter	Comment	Agency response

No public comments were received following the publication of the Notice of Periodic Review. The public comment period was held from February 28, 2011 through March 22, 2011.

The regulation meets the criteria that it is necessary for the protection of public health as it requires newborn screening in order to prevent mental retardation and permanent disability or death.

Small business impact review

Pursuant to § 2.2-4007.1 E and F each existing regulation shall be reviewed ***at least once every five years*** *to ensure that it minimizes the economic impact on small businesses.*

If this NOIRA will not include a review of the entire regulation for small business impact, please delete this entire section.

If this NOIRA will include a review of the entire regulation for small business impact, 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 complexity of the regulation; (3) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) 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, include a discussion of the agency's determination whether the regulation should be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact of regulations on small businesses.

This regulation is required by § 32.1-67 of the Code of Virginia.

This regulation primarily impacts birthing hospitals that would not be classified as a small business using the definition of less than 500 FTES or less than $6 million annually in revenue. The majority of births (99%) occur within the hospital setting.

This regulation impacts small business practitioners who deliver infants outside of the birthing hospital setting which would include births that are delivered through a birthing center or through a licensed professional midwife. Approximately 500-700 out of over 100,000 births in the Commonwealth occur within these settings. There are approximately 42 licensed certified professional midwives practicing outside of the hospital setting and five birthing centers in Virginia.

This regulation is of moderate complexity. The complexity of the regulation involves explicit instructions in how to handle the timing and responsibility of newborn screening for infants who have certain medical conditions (e.g. requiring a blood transfusion); who are transferred between facilities; and who are born outside a hospital setting.

The regulation, however, is written in a clear format that specifies necessary actions and responsibilities for differing circumstances.

The regulation is consistent with federal recommendations for newborn screening. The federal government does not issue regulations for newborn screening. Newborn screening regulations are handled at the state level.

The regulation was last changed in 2007 following legislative action directing newborn screening to expand the number and type of disorders on the core panel. Science and technology continue to impact newborn screening and will be a significant factor in maintaining the list of conditions for which newborn screening occurs.