Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) citation	12VAC5-90 and 12VAC5-120
Regulation title	Regulations for Disease Reporting and Control and Regulations for Testing Children for Elevated Blood Lead Levels
Action title	Updating Disease Reporting Regulations and Repealing Lead Testing Regulation
Date this document prepared	August 13, 2014

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

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

The *Regulations for Disease Reporting and Control* provide information about the process and procedures for reporting diseases to the Virginia Department of Health, including what diseases must be reported, who must report them and other details related to public health reporting and disease control. The Virginia Department of Health is proposing an amendment to the regulations in order to bring them into compliance with recent changes in the field of environmental disease control that are needed to protect the health of the residents of Virginia.

The agency proposes to incorporate the testing and risk determination criteria for identifying children with elevated blood lead levels into 12VAC5-90 and to repeal the 12VAC5-120, the existing regulation pertaining to blood lead testing of children.

The amendments to the cancer reporting and gamete donor testing requirements that were included in the Notice of Intended Regulatory Action will not be pursued at this time.

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 are used without being defined in context.

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.

Title 32.1 of the *Code of Virginia*, §§ 32.1-12 and 32.1-35 through 32.1-73, contains mandatory language authorizing the State Board of Health to promulgate the proposed regulations. Specifically, § 32.1-35 directs the Board of Health to promulgate regulations specifying which diseases occurring in the Commonwealth are to be reportable and the method by which they are to be reported. §32.1-46.1 authorizes the Board to establish a protocol for the identification of children with elevated blood lead levels. The Board of Health is empowered to adopt such regulations as are necessary to carry out provisions of laws of the Commonwealth administered by the state health commissioner by § 32.1-12 of the *Code of Virginia*.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

The proposed amendment will improve the ability of the Virginia Department of Health to conduct surveillance and implement disease control for detectable blood lead levels in children. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)

The section on testing children to determine their blood lead levels is new to the Regulations for Disease Reporting and Control but reflects minor amendments to existing requirements that are currently included in another set of agency regulations, 12VAC5-120. The agency decided it was a logical and efficient change to incorporate the lead testing requirements into the set of regulations that addresses the

reporting of elevated blood lead levels. Having one set of regulations on this topic should reduce confusion among the regulated community.

12VAC5-120, the existing regulation pertaining to the identification of children with elevated blood lead levels, is being repealed as its content is being incorporated into 12VAC5-90. Some changes to the requirements are proposed as well. The changes simplify and clarify the requirements, remove unnecessary references to guidelines and non-mandatory actions, and reflect current Centers for Disease Control and Prevention recommendations. The proposed amendment to 12VAC5-90 pertaining to blood lead levels in children reflects a similar schedule of testing, risk factors for testing, criteria for determining low risk, and need for confirmatory testing as is currently provided in 12VAC5-120.

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 the regulatory action poses no disadvantages to the public or the Commonwealth, please indicate.

The primary advantages to the public will be clearer rules for testing children for exposure to lead and less confusion that is inherent in maintaining two sets of regulations pertaining to the same subject and procedures.

The primary advantages to the agency are the same as for the public. That is, elimination of the confusion caused by needing to track multiple sets of regulations or the potential for inconsistent requirements in different regulations.

No disadvantages or other pertinent matters of interest to the regulated community have been identified.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale 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.

None of these requirements is more restrictive than federal requirements.

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.

The impact of these changes is anticipated to be similar for all localities.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is 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 written comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email or fax to Diane Woolard, Director, Division of Surveillance and Investigation, Virginia Department of Health, P.O. Box 2448, Room 516E, Richmond VA 23218; phone 804-864-8141; fax 804-864-8139; email diane.woolard@vdh.virginia.gov . Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last date of the public comment period.

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. Please keep in mind that we are looking at the impact of the proposed changes to the status quo.

Description of the individuals, businesses or other entities likely to be affected (positively or negatively) by this regulatory proposal. Think broadly, e.g., these entities may or may not be regulated by this board	The proposed amendment regarding testing children's blood lead levels pertain to physicians and other medical care providers and are anticipated to have minimal impact on their practices or procedures.
Agency's best estimate of the number of (1) entities that will be affected, including (2) small businesses affected. Small business means a business, including affiliates, that is independently owned and operated, employs fewer than 500 full-time employees, or has gross annual sales of less than $6 million.	Any physician who diagnoses or treats children could be affected by the lead regulation. This would include 1,200 pediatricians and 3,300 family practitioners in Virginia.
Benefits expected as a result of this regulatory proposal.	Proposed changes to the lead testing requirement clarifies existing language and consolidates two regulations pertaining to the same topic into one regulation.
Projected cost to the state to implement and enforce this regulatory proposal.	No costs are anticipated.
Projected cost to localities to implement and enforce this regulatory proposal.	No costs are anticipated.
All projected costs of this regulatory proposal for affected individuals, businesses, or other entities. Please be specific and include all costs,	No costs are anticipated.

including projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses, and costs related to real estate development.	

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.

In light of the clear, specific and mandatory authority of the State Board of Health to promulgate the proposed amendments to the regulations, no alternatives have been considered, nor are there any that are advisable.

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.

No lessening of testing requirements is advisable given the need to detect elevated blood lead levels in children. The proposed changes do not increase the extent of existing requirements, the requirements are as necessary and as simple as possible, and the impact on small businesses is expected to be minimal.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
None	No comments were received following the publication of the NOIRA	

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.

The proposed changes will indirectly protect and improve the health of the people of the Commonwealth. No adverse impacts on the institution of the family or on family stability are anticipated.

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) or regulations that are being repealed and replaced, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-120		Regulations for testing children for elevated blood lead levels	Repealed and replaced with the new regulation, cited below.

If a new regulation is being promulgated, use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
12VAC5-90-215	Testing children at 12 and 24 months of age for blood lead levels if they meet any of a list of criteria; confirming tests indicating elevated levels if the test was not a standard confirmatory test performed by a certified laboratory; providing test results to parents or guardians.	Similar requirement exists in 12VAC5-120, which is being repealed within this same regulatory action.	Physicians will need to assess children and determine if they meet criteria for testing for blood lead levels and provide the results and educational materials to parents/guardians for any laboratory results that indicate the child was exposed to lead. This is already a standard of practice for clinicians and a recommendation of the Centers for Disease Control and

			Prevention. Similar requirements are in effect in an existing agency regulation, except that the blood lead level that indicates that exposure to lead has occurred has been lowered so action will be necessary for children testing at a level lower than previously, which is again an existing standard of practice.