Virginia Regulatory Town Hall

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Notice of Intended Regulatory Action (NOIRA) 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	September 1, 2013

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 *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 reporting and disease control. The *Regulations for Testing Children for Elevated Blood Lead Levels* prescribe the criteria and schedule for testing children to identify those who have been exposed to environmental lead.

The agency intends to amend several disease-specific sections of the disease reporting regulations. Cancer reporting requirements will be updated to require the use of electronic means of reporting. The section on testing of gamete donors will be amended to align state requirements with those of the federal Food and Drug Administration (FDA). The agency also proposes to incorporate the testing and risk determination criteria for identifying children with elevated blood lead levels into 12VAC5-90 and to repeal 12VAC5-120, the existing regulation pertaining to blood lead

testing of children. The Virginia Department of Health may propose additional changes that reflect changing practices in the field of communicable disease control and emergency preparedness that are needed to protect the health of the residents of Virginia.

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.

Chapter 2 of 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 Regulations for Disease Reporting and Control. Specifically, § 32.1-35 directs the Board of Health to promulgate regulations specifying which diseases occurring in the Commonwealth must be reported to the health department and the method by which they are to be reported. Further, § 32.1-42 of the *Code of Virginia* authorizes the Board of Health to promulgate regulations and orders to prevent a potential emergency caused by a disease dangerous to public health. §32.1-70 et seq authorizes the Board of Health to promulgate regulations pertaining to the statewide cancer registry; §32.1-45.3 requires the Board to establish procedures for testing gamete donors; and §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*.

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.

The amendment is necessary in order to ensure that the regulations comply with current public health practices and recommendations of national public health organizations. The proposed changes improve the ability of the Virginia Department of Health to conduct surveillance and implement disease control for conditions of public health concern and position the agency to better detect and respond to these illnesses to protect the health of the public. The incorporation of lead testing requirements in with the regulations that pertain to the reporting of lead test results is logical and should minimize confusion and lead to efficiencies for the regulated community.

Substance

Please detail any changes that will be proposed. Be sure to define all acronyms. 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.

- Update cancer reporting requirement to require electronic reporting in accordance with standards established by the Centers for Disease Control and Prevention;
- Incorporate the testing schedule and criteria for identifying children with elevated blood lead levels into the disease reporting regulations while simultaneously repealing separate regulations that accomplish the same purpose;
- Update the section on testing gamete donors for human immunodeficiency virus (HIV) to align the requirements with those of the FDA;
- Renumber sections to increase internal consistency within the regulations;
- Propose other changes necessary to conform with disease surveillance and control processes that are necessary to protect the health of residents of the Commonwealth.

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.

In light of the clear, specific and mandatory authority of the State Board of Health to promulgate the proposed amendments to the regulations and a history of effective implementation of the regulations, no alternatives are advisable.

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.

Please also indicate pursuant to your Public Participation Guidelines whether a panel will be appointed to assist in the development of the proposed regulation. Please state one of the following: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

The agency is seeking comments on this regulatory action, including but not limited to 1) ideas to be considered in the development of this 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) the probable effect of the regulation on affected small businesses, and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to Diane Woolard, PhD, MPH, Director, Division of Surveillance and Investigation, Virginia Department of Health, PO Box 2448 Suite 516E, Richmond, VA 23218; fax (804) 864-8139; or email at 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 day of the public comment period.

A panel will not be used to assist in the development of the proposed regulation and a public hearing will not be held following the publication of the proposed stage of this regulatory action.

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 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.