Virginia Regulatory Town Hall

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Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-120
Regulation title	Regulations for Testing Children for Elevated Blood-Levels
Action title	Amend the current regulations for clarity and to include new statutory requirements.
Date this document prepared	June 21, 2007

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) 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.

Amend the Regulations for Testing Children for Elevated Blood-Levels to update the definition of a qualified laboratory, add a limited exemption to the requirement for blood-lead samples to use a qualified laboratory and add a new statutory requirement for health care providers to make information on the dangers of lead poisoning available to parent.

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.

Title 32.1-46.1 of the Code of Virginia requires the Board of Health to promulgate regulations establishing a protocol for the identification of children at risk for elevated blood-lead levels. Chapter 691 of the Acts of Assembly, 2007, requires the regulations to include a requirement that physicians make available to parents information on the dangers of lead poisoning, along with a list of available resources, as part of regular well check visits for all children.

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.

Chapter 691 of the Acts of the Assembly requires the Board's regulations to include a requirement for physicians to provide parents with information on the dangers of lead poisoning along with a list of available resources as part of a regular well check for children. This information will better educate parents regarding the health of their child.

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 definition of "qualified laboratory" will be amended for clarity by adding the acronym "CLIA" for Clinical Laboratory Improvement Act, which is a common acronym used by laboratories.

The regulations will also provide a limited exemption to the requirement that all blood-lead samples be analyzed by a qualified laboratory. This exemption will permit the use of CLIA waived a LeadCare II instrument approved by Point of Care users for screening tests only. Any positive tests must be followed by a venous blood test performed by a qualified laboratory.

Language will be included to require physicians to provide parents with information on the dangers of lead poisoning and a list of available resources as part of a regular well check visit.

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.

These regulations are mandated. No alternative exists.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include 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 written comments may do so by mail, email or fax to Nancy VanVoorhis, **nancy.vanvoorhis@vdh.virginia.gov**, Virginia Department of Health, 109 Governor Street, 5th Floor, Richmond, Virginia 23219, 804-864-7694, fax 804-864-7475. 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 be held and notice of the hearing may be found on the Virginia Regulatory Town Hall website (**www.townhall.virginia.gov**) and can be found in the Calendar of Events section of the Virginia Register of Regulations. Both oral and written comments may be submitted at that time.

Participatory approach

Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, technical advisory committees) 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 agency will not be using the participatory approach in this process.

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.

This action will not impact families and family stability.