Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency name	Virginia Department of Health (State Board of Health)
Virginia Administrative Code (VAC) citation	12 VAC 5 -120
Regulation title	Regulations for Testing Children for Elevated Blood-Lead Levels
Action title	Amend to conform with Code of Virginia Requirements
Date this document prepared	May 8, 2008

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.*

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

There are two substantive changes proposed. One will permit the use of CLIA-waived instruments for point of care testing to screen for elevated blood-lead levels, provided any elevated blood-lead level is followed up with a venous blood-lead test performed by a qualified laboratory. The second change requires health care providers to make information on the dangers of lead poisoning, along with a list of available resources, to parents as part of regular well check visits for all children up to 72 months of age.

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., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

The legal authority to promulgate the regulation is § 32.1-46.1 of the Code of Virginia, which requires health care providers to make available information on the dangers of lead poisoning, along with a list of

available resources, to parents as part of regular well check visits for all children. The promulgating entity is the State Board of Health.

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 amended regulation is needed to require physicians to provide information to parents on the dangers of lead poisoning, hopefully reducing childhood exposure to lead in the environment; this amendment will bring the regulations into compliance with the requirements of the Code of Virginia. Another amendment will provide health care providers with an additional option for screening children for elevated blood-lead levels.

Substance

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

The addition of language to approve CLIA-waived instruments for administering screening tests provides additional tools for screening for elevated blood-lead levels. The language requiring health care providers to provide information on the dangers of lead poisoning to parents during well check visits increases the awareness of the dangers and should aid in the detection and treatment of elevated blood-lead levels.

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 so indicate.

The proposed changes provide for an additional screening method and provide more educational material to parents on the dangers of lead poisoning. Both are advantages associated with implementing these changes.

There are no disadvantages to the public or the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which are 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.

No applicable 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.

All localities will be affected equally.

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 by mail, email or fax to Gary L. Hagy, Virginia Department of Health, 109 Governor Street, Richmond, Virginia 23219, **gary.hagy@vdh.virginia.gov**, 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 date of the public comment period.

A public hearing will be held and notice of the public hearing may appear 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.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

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	None.
Projected cost of the regulation on localities	None.

Description of the individuals, businesses or other entities likely to be affected by the regulation	Health care providers.
Agency's best estimate of the number of such entities that will be affected. Please include an 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.	Approximately 5,800 health care providers in the Commonwealth list their primary practice as either pediatrics or family medicine. (Source: VIPnet) Approximately 35 (and growing) currently using some type of CLIA-waived instrument.
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	No cost to health care providers. The use of CLIA-waived instruments is optional, not required. There may be a savings to the citizens as the use of a CLIA-waived instrument may save a trip to a laboratory for testing. The information on the dangers of lead poisoning is already available and in use by most health care providers.

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.

Regulations are mandated by Code of Virginia. No alternative exists.

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.

No other alternative method exists. The regulations are mandated by the Code of Virginia and the regulations reflect the minimum standards specified in the Code.

Public comment

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

No comments received.

Commenter	Comment	Agency response

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.

Proposed amendments will provide parents with additional information on the dangers of lead poisoning.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12 VAC 5-120-10		Definitions	Adds new term, "Point of care testing." Adds the acronym "CLIA" in the definition of "Qualified laboratory" and cites the pertinent CFR.
12 VAC 5-120-30		Requires all blood-lead samples to be analyzed by a qualified laboratory.	Adds permissive language to permit the use of CLIA-waived instruments by Point of Care users for screening for elevated blood-lead levels.
None	12 VAC 5-120-35	Does not require blood-lead testing for children determined by health care provider to be at low risk for elevated blood-levels.	Adds requirements for health care provider to provide parents with information on the dangers of lead poisoning along with a list of available resources.