



## Final Regulation Agency Background Document

<b>Agency name</b>	Department of Health
<b>Virginia Administrative Code (VAC) citation</b>	12 VAC 5-120
<b>Regulation title</b>	Regulations for Testing Children for Elevated Blood-Lead Levels
<b>Action title</b>	Amendment
<b>Date this document prepared</b>	February 13, 2009

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

*Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.*

There are two substantive changes to the regulations. One will permit the use of CLIA-waived instruments for point of care testing for lead, 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.

### Statement of final agency action

*Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.*

On February 13, 2009, the State Board of Health adopted amendments to the Regulations for Testing Children for Elevated Blood-Lead Levels (12 VAC 5-120).

## 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 numbers, 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.*

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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 up to 72 months of age. The promulgating entity is the State Board of Health.

## Purpose

*Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.*

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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 testing children for elevated blood-lead levels.

## Substance

*Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.*

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The addition of language to approve CLIA-waived instruments for lead testing provides an additional and more convenient option for health care providers. 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 there are no disadvantages to the public or the Commonwealth, please indicate.*

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The amended regulations provide for an additional testing method and provide more educational material to parents on the dangers of lead poisoning. Both are advantages that will be realized by parents of young children.

There are no disadvantages to the public or the Commonwealth.

**Changes made since the proposed stage**

*Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar’s office, please put an asterisk next to any substantive changes.*

No changes were made.

**Public comment**

*Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.*

Commenter	Comment	Agency response

One public hearing was held on the regulations. The Department did not receive any comments during the public comment period and no one attended the public hearing.

**All changes made in this regulatory action**

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

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		Requires all blood-lead	Adds permissive language to permit the use

5-120-30		samples to be analyzed by a qualified laboratory.	of CLIA-waived instruments by Point of Care users for testing 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.

**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.

**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. It also provides for a new method of testing for elevated blood-lead levels in children which should reduce cost for most individuals by negating the need for more expensive laboratory testing. If a CLIA-waived instrument is used, then additional laboratory testing will be necessary only when the test indicates an elevated blood-lead level. If elevated, immediate follow-up can begin while the child is still in the provider’s office. This saves the family time and money and also provides more efficient health care.