Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Department of Health (State Board of)
VAC Chapter Number:	12 VAC 5-120
Regulation Title:	Regulations for Testing Children for Elevated Blood-Lead Levels
Action Title:	Adopt regulations to implement a program for testing children to determine those who have elevated blood-lead levels as required by 2000 legislation
Date:	May 7, 2001

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form, Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The intended regulations will establish a protocol for testing children for elevated blood-lead levels and reporting all laboratory blood-lead test results to the Virginia Department of Health. The intended protocol is based on guidelines published by the Centers for Disease Control and Prevention in 1997 to assure a sound scientific basis for effective and efficient identification of elevated blood-lead levels that will protect the health of citizens.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Section 32.1-46.1 of the Code of Virginia directs the Board of Health to promulgate regulations establishing a protocol for the identification of children at risk for elevated blood-level levels which shall provide (i) for blood-lead level testing at appropriate ages and frequencies, when indicated, and (ii) for criteria for determining low risk for elevated blood-lead levels and when such blood-lead level testing is not indicated. The protocol may also address follow-up testing for children with elevated blood-lead levels, dissemination of the protocol and other information to relevant health care professions, appropriate information for parents, and other means of preventing lead poisoning among children.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

The Commonwealth of Virginia has recognized the need for early identification of children with elevated blood-lead levels to alert parents and guardians to the need for intervention to prevent developmental, behavioral, and learning problems associated with elevated blood lead levels. The purpose of this chapter is to provide a protocol for identifying children with elevated blood-lead levels

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

The intended regulations will establish a protocol for testing children for elevated blood-lead levels. The intended protocol is based on guidelines published by the Centers for Disease Control

and Prevention in 1997 to assure a sound scientific basis for effective and efficient identification of elevated blood-lead levels that will protect the health of citizens.

Article 1 of the intended regulations (sections 10 through 50) contains provisions that define key terms and set forth general information relating to the protocol for testing children for elevated blood-lead levels. These provisions include a statement of the general policy, purpose and administration of the regulations.

Article 2 (sections 60 through 100) of the intended regulations sets forth the protocol for identifying children with elevated blood-lead levels. The protocol includes the ages and frequencies of testing, time limits for confirming screening tests, criteria for determining low risk for elevated blood-lead levels and when blood testing is not indicated, and provisions for providing guidelines for follow-up testing and appropriate information to parents and health care professionals.

No potential issues have been identified that may need to be addressed as a permanent final regulation is developed.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 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 include a sentence to that effect.

The emergency regulations established a protocol for testing children for elevated blood-lead levels. The protocol is based on guidelines published by the Centers for Disease Control and Prevention in 1997 to assure a sound scientific basis for effective and efficient identification of elevated blood-lead levels that will protect the health of children. The protocol gives health care providers a standard for determining if children are at risk of exposure to lead and should be tested or not at risk and not tested. The judgement of the provider takes precedent in the decision to perform a blood-lead test or testing may also be done upon request of the parents or guardian.

A number of private laboratories are now reporting test results to the Lead-Safe Virginia program on a voluntary basis. The program will consult with laboratories not reporting at this time to determine the most efficient means to accommodate reporting through existing computer database formats.

The Commonwealth benefits from the more comprehensive reporting of blood-lead test results to the program. This will give Lead-Safe Virginia the ability to conduct a more complete analysis of who and where tests are being conducted. It will improve surveillance, epidemiologic applications and reporting. The program will be better able to identify target populations and geographic areas for intervention. The regulations will allow the program to more specifically

focus resources into high-risk populations and geographic target areas within the Commonwealth.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

The rules will require the development of a web-based laboratory-reporting page. The anticipated one time cost is $45,000 in FY 02 and $45,000 in FY 03 to further expand the system to exchange information between VDH and the local health departments. System maintenance is estimated as an ongoing cost with a range of between $12,000 to $18,000 per year. Support for this project has been requested from the Center for Disease Control and Prevention, Childhood Lead Poisoning Prevention Program grant and may be further additionally support by funding from the Title V Maternal & Child Health grant.

There are no anticipated direct additional costs to localities.

The regulations have an impact on clinical laboratories required to report all blood-lead test results to the Lead-Safe Virginia program. At this time 12 laboratories are reporting test results to Lead-Safe Virginia. Six laboratories report on a continuous basis and six intermittently. It is projected that the rules will impact on a range of 15 to 18 facilities. For clinical laboratories reporting blood-lead results to Lead-Safe Virginia now, the fiscal impact is minimal. The implementation of an electronic reporting system and web-based reporting page may result in a cost benefit for laboratories now submitting paper test results to the program. For laboratories not now reporting the cost estimate to implement this reporting requirement might range from $500 to $3,500 per year. The lower the volume of tests performed the less cost involved.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

None

Alternatives

Please describe the specific 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.

In light of the clear, specific, and mandatory authority of the State Board of Health to promulgate the intended regulations, the Board has not considered any alternatives to the intended regulations. The Board has, however, carefully drafted the intended regulations to ensure that they embody the most appropriate, least burdensome, and least intrusive protocol for effectively identifying children with elevated blood-lead levels. The Board considered the guidelines of the Centers for Disease Control and Prevention and the recommendations of a state advisory group consisting of private physicians, public health professionals, and parents of lead-poisoned children.

In drafting the intended regulations, the Board considered alternatives that would have required testing of all children without regard to risk status, annual testing to age six years, and testing of venous bloodonly. In all cases the Board accepted the recommendations of the state advisory group for less burdensome and less intrusive alternatives for achieving the essential purpose of the regulations. The intended regulations exempt low risk children from testing, require testing after two years of age only if the child was not previously tested, and allow for testing of capillary blood. The Board chose to address follow-up testing for children with elevated blood-lead levels, dissemination of the protocol and other information to relevant health care professions, appropriate information for parents, and other means of preventing lead poisoning among children through guidance documents rather than regulation.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

No comments were received by the Lead-Safe Virginia program.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The agency strived to draft these regulations to be understandable to health care providers and the general public.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable

regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

The Board of Health will review/re-evaluate the regulations no later than thirty-six (36) months from implementation.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which 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.

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1. The intended regulations will strengthen the authority of parents in the supervision of their children by providing a protocol for parents to use with health care providers to ensure that children receive appropriate testing for elevated blood-lead levels. Early identification of children with elevated blood-lead levels will alert parents and guardians to the need for intervention to prevent physical, developmental, behavioral, social, and learning problems associated with elevated blood lead levels in children.

2. The intended regulations will encourage economic self-sufficiency for one's children. Children with elevated blood-lead levels have been shown to suffer the adverse effects of decreased intelligence, behavioral disturbances, and developmental disabilities. Lead has lasting effects on the health of children that reach well into their adult years.

3. The intended regulations will neither strengthen nor erode the marital commitment.

4. The intended regulations will decrease disposable family income in the short term for those families with children not covered by health insurance for blood-lead level testing. The intended regulations will increase disposable family income in the long term for those families with children with elevated blood-lead levels if the source of lead poisoning is identified and controlled before medical treatment is needed or the lead significantly effects the developing brain and nervous system. Such effects can be associated with increased medical and social costs over a person's lifetime.