Virginia Regulatory Town Hall

Final 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:	March 28, 2002

Please refer 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* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

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.

Changes Made Since the Proposed Stage

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

There are only four substantive changes that the Department proposes to make to the regulation in response to the public comment received.

The first change is to amend 12 VAC 5-120-20, the Statement of general policy. To facilitate that blood- lead testing be conducted for all children in the Commonwealth where low risk cannot be established and to clarify that there is not a perception of dual standards for parents and health care providers, the following statement is proposed to be added at the end of 12 VAC 5-120-20:

The Department encourages health care providers, parents and guardians to exercise reasonable, but liberal judgement and discretion in implementing and applying the protocol set forth in this chapter, so that the health of all Virginia's children may be protected from lead poisoning.

The second change is to add a fourth criteria to 12 VAC 5-120-30. In order to be consistent with 12 VAC 5-120-50, Risk factors requiring testing, and to reiterate the parent or guardian's right to request testing, the fourth criteria is proposed to be added to 12 VAC 5-120-30:

4. Children should be tested at the request of a parent or guardian due to any suspected exposure.

The third change amends 12 VAC 5-120-60. To encourage providers to consider potential exposure besides the factors listed in 12 VAC 5-120-50 in determining low risk and to facilitate providers exercising the greatest latitude in ordering blood-lead testing, the second sentence in 12 VAC 5-120-60 is proposed to be expanded to read in full as:

A health care provider may determine a child to be at low risk for elevated blood-lead level if the child meets none of the criteria listed in 12 VAC 5-120-50, but is encouraged to cause a child to be tested if, in the exercise of discretion and in consideration of the various means by which exposure to lead may occur, such exposure cannot be clearly ruled out.

The fourth change addresses the comment regarding that follow up testing for children be addressed in the regulations. The original 12 VAC 5-120-80 does direct the Department of Health to establish guidelines for follow-up testing for children with confirmed elevated blood-lead levels. In addition, the last sentence of 12 VAC 5-120-80 is proposed to be:

The Department encourages health care professionals to conduct whatever follow-up testing as is indicated or warranted in the exercise of medical or clinical judgement and discretion.

The proposed revision does not change the intent of the proposed regulation.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

The State Board of Health adopted the final Regulations for Testing Children for Elevated Blood-Lead Levels on February 8, 2002.

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, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final 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 final 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 of the regulatory action's detail.

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 final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the 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 regulations establish 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.

There are no disadvantages to the public or the Commonwealth.

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

One member of the public submitted comments on December 21,2001. The comments and responses are:
Comment:
1. The regulations do not address the dissemination of the protocol to health care professionals and parents.
Agency Response:
The regulations do require dissemination of guidelines to parents and health care professionals per 12 VAC 5-120-80.
Comment:
2. The regulations do not address follow-up of the children.
Agency Response:
The regulations do require the agency to develop guidelines for follow-up testing per 12 VAC 5-120-80.
Comment:
3. The legislation specifically states that the parents “shall cause such a child to be tested for elevated. .". However, when physicians “should test all children up to and ..”, it leaves the parents in conflict if the physicians do not order testing for which the child is a suitable candidate. The proposed regulations do not address this “dual standard” and parents could be guilty of not following the legislation.
Agency Response:
Physicians are required to test all children according to the schedule set forth in 12 VAC 5-120-30, unless they are determined to be at low risk per the agency’s guidelines. This does not create a situation where the parents are guilty of not following the regulation; if the physician does not

order testing because the child is low-risk, parents can seek an explanation of this determination from the provider.
Comment:
4. The regulations sets forth multiple standards of care for children with EBL when Medicaid (EPSDT) requires that all children who are on Medicaid be tested and the remaining children are either at the mercy of their parents' insurance or are just simply are not tested.
Agency Response:
The nature of lead poisoning is a matter of degree – both screening and treatment must be performed in accordance with the degree of risk. Because children eligible for Medicaid are presumed to be at high risk – based on considerable national data - this triggers the testing requirement. This does not create multiple standards of care because all children at high risk are to be tested regardless of insurance status.
Comment:
5. Further, the regulation does not set forth any mandatory evaluation of the children so that a clinically sound judgment can be made.
Agency Response:
Again, the purpose of the regulation is not to interfere with the physician-patient relationship nor to preclude the agency adjusting its guidelines as additional information becomes available. The patient is evaluated, but it would be inappropriate for a regulation to define that evaluation in place of the clinician's judgment for each child.
Comment:
6. That mandatory evaluations be required for ALL children.
Agency Response:
We concur with what we understand to be the intent of the suggestion, which is to provide for an expansion in evaluations. A regulatory mandate for all children, however, would go against federal recommendations from the Centers for Disease Control and Prevention. Screening must be targeted to achieve efficient use of limited resources and to avoid invasive testing of low-risk children.
Comment:
7. That those determined to be at risk "shall" be tested.
Agency Response:
The definition of "at-risk" is tiered with respect to lead poisoning because different levels trigger different actions. Each child's history must be taken into account so that an informed decision regarding testing can be made by the physician. Changing "should" to "shall" could interfere unduly with the physician-patient relationship.
Comment:
8. That provisions for dissemination of information be included in the regulations.
Agency Response:
Part II of the regulation requires the Virginia Department of Health to establish guidelines for follow-up testing and appropriate information to parents and health care professionals. Allowing this decision to be left to the department, as it permits flexibility in revising the guidelines as best practices continue to emerge, without having to seek a change in the Code of Virginia for each revision.
Comment:
9. That provisions for follow-up be included in the regulations, as well.
Agency Response:

See response to comment 8, above.

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 crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.

These regulations are similar to emergency regulations adopted earlier in response to statutory madate. They have been amended, as discussed above, in response to public comment.

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the 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.

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.