Economic Impact Analysis
Virginia Department of Planning and Budget

12 VAC 5-120 – Regulations for Testing Children for Elevated Blood-Lead Levels
Department of Health
July 1, 2008

Summary of the Proposed Regulation

The State Board of Heath (Board) proposes to amend the existing Regulations for Testing Children for Elevated Blood-Lead Levels. The proposed amendments will allow the use of CDC[1]-approved and CLIA[2]-waived instruments for point of care testing[3] to screen for elevated blood-lead levels, provided that any elevated blood-lead level found through point of care testing is followed up by a venous blood-lead test performed by a qualified laboratory. The proposed regulation also requires that health care providers make information on the dangers of lead poisoning available to parents during regular well check visits for all children up to 72 months of age.

Results of Analysis

The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact

In Virginia, the main source of childhood lead poisoning is paint in homes built before 1978 (before lead paint was banned). As the paint ages, it may chip and peel, or form invisible lead dust. Lead dust can also form when painted surfaces are rubbed together, scraped, or sanded, like in a window frame or while a home is being renovated. The dust settles on places where babies and young children crawl and play. They swallow lead when they put dust-covered surfaces, like their hands and toys, in their mouths. They may also eat visible chips of paint.

[1] CDC refers to the Centers for Disease Control and Prevention.
[2] CLIA refers to for Clinical Laboratory Improvement Amendments of 1988 (42 CFR Part 493).
[3] According to the proposed regulation, "point of care testing" refers to testing by a health care provider that has a CLIA Certificate of Waiver.

The Regulations for Testing Children for Elevated Blood-Lead Levels (regulations) require that all children up to and including 72 months of age be tested for elevated blood-lead levels unless they are determined to be at low risk for elevated blood-lead levels. Currently the regulation requires that all blood-lead samples be analyzed by a qualified laboratory. The Board proposes to amend the existing regulations and allow the use of CDC-approved and CLIA-waived instruments for point of care testing to screen for elevated blood-lead levels. Any elevated blood-lead level found through point of care testing shall be confirmed by a venous blood-lead test performed by a qualified laboratory.

The use of CLIA-waived instruments for blood-lead screening test will allow children to be tested and treated for lead poisoning much easier and faster. Instead of going to a laboratory at a later time, the children can be tested in a doctor's office or clinic during their regular wellness check visits. Currently the only CDC-approved and CLIA-waived instrument for blood-lead test is LeadCare II Blood Lead Testing System made by ESA Biosciences. According to the U.S. Food and Drug Administration (FDA), the test measures lead in blood samples taken from a patient in a doctor's office or clinic, and gives results in as little as 3 minutes. If the test indicates elevated lead levels, a second sample can be obtained before the patient leaves that can be sent to a qualified laboratory for a confirmed test. Furthermore, if the result indicates high levels of lead, doctors and the parents can begin discussing treatment options immediately.

FDA reports that studies show nearly 98 percent of the values measured by the test instrument were within the Occupational Safety and Health Administration's recommendations for blood lead proficiency testing. The proposed regulations require that any elevated blood-lead level found through point of care testing be confirmed by a venous blood-lead test performed by a qualified laboratory. Therefore, the proposed regulations will provide children who need to be tested for blood-lead levels with a faster and easier screening test method without significantly affecting the accuracy of the results.

The savings of a trip to a laboratory will likely increase the lead screening rates for children younger than 3. If children under 3 years are not tested for the identification of lead hazards, they may be at risk of developmental and neurological damage that could have been prevented. The Virginia Department of Health (VDH) reports that in Fiscal Year 2007, there were approximately 119,000 children under 3 years of age enrolled in Medicaid. These children,

under the regulations, are required to be tested for blood-lead levels. However, only about 16% of the Medicaid eligible children of 3 years and younger have been tested. This proposed change will help in the detection and treatment of elevated blood-lead levels for children who need to be tested.

The proposed regulations will likely shift some of the blood-lead testing businesses from the qualified laboratories to the 5,800 health care providers or clinics that list their primary practice as pediatrics, family medicine, or general practice. According to VDH, currently four large laboratories are accredited to do lead testing in Virginia, including the Virginia Division of Consolidated Laboratory Services, the Medical College of Virginia, Children's Hospital King's Daughters, and Norfolk Department of Public Health Laboratory. One large national lab also has a small accredited location in the Commonwealth and performs some lead testing. Some large laboratories may have drawing sites in Virginia but send the samples to their main facilities out of the Commonwealth for lead tests. Among the health care providers that list their primary practice as pediatrics, family medicine, or general practice, 11 of them are currently using some type of CLIA-waived instruments. These health care providers would be the potential point-of-care users. The approximate 5,789 health care providers who are not currently using any type of CLIA-waived instruments may have to apply for a Certificate of Waiver if they opt to use the blood-lead test instruments. The application fee will be $150 every two years.

The Board also proposes to require health care providers to provide information on the dangers of lead poisoning to parents as part of regular well check visits for all children up to 72 months of age. This proposed change will increase the awareness of the dangers and will help in the detection and treatment of elevated blood-lead levels. VDH states that the information on the dangers of lead poisoning is already available and in use by most health care providers. Therefore, this proposed change will likely not cause any significant costs to the health care providers.

Businesses and Entities Affected

According to VDH, currently there are approximately 5,800 health care providers in the Commonwealth that list their primary practice as pediatrics, family medicine, or general practice. Among them, approximately 11 are currently using some type of CLIA-waived instruments. These health care providers would be the potential point-of-care users. The 2000 Census shows

that there were 276,483 children under 72 months of age in the Commonwealth. The 2007 data shows that there were 221 confirmed elevated blood lead levels for children under 3 years of age in 2007. According to VDH, only the Virginia Division of Consolidated Laboratory Services, the Medical College of Virginia, Children's Hospital King's Daughters, Norfolk Department of Public Health Laboratory, and a small location of a national lab are accredited to do lead testing in Virginia. Some large laboratories have drawing sites in Virginia but conduct lead tests outside of the Commonwealth. VDH reports that currently 8 out of state labs report to VDH on a regular basis. This number may vary from time to time.

Localities Particularly Affected

The proposed amendments will affect all of the localities in the Commonwealth, especially the areas that are listed as high-risk zip code areas in guidelines issued by VDH. These areas have 27% or more of the housing built before 1950 or 12% or more of the children with elevated blood-lead levels based on current available data.

Projected Impact on Employment

Allowing the use of CDC-approved and CLIA-waived instruments for blood-lead screening tests will likely increase the hours worked for the potential point-of-care users. On the other hand, laboratories that conduct lead testing and those that have blood-drawing stations in Virginia may experience reduction in their business, which may adversely affect the hours worked and the number of people employed in those laboratories.

Effects on the Use and Value of Private Property

Allowing children to be tested for blood-lead levels in a doctor's office or clinic will likely increase the profits of the doctors and the clinics, which will have a positive effect on the value of their property. The qualified laboratories may see reduction in their lead testing business, which may adversely affect their profits and the value of their property. Among the private entities, currently only one large national lab has a small accredited location in the Commonwealth and performs some lead testing. Since lead testing is not a major component of its business, the impact will likely not be substantive. Some laboratories that only have drawing sites in Virginia may also see a slight reduction in their business, which may adversely affect the value of their property.

Small Businesses: Costs and Other Effects

Allowing the use of CDC-approved and CLIA-waived instruments for blood-lead screening tests may increase the profits of the potential users. There are approximately 5,800 health care providers in the Commonwealth that list their primary practice as pediatrics, family medicine, or general practice. Most of them are small businesses. The qualified laboratories may experience reduction in their lead testing businesses, which may adversely affect their profits. Among the private entities, currently only one large national lab has a small accredited location in the Commonwealth and performs some lead testing. Since lead testing is not a major component of its business, the impact will likely not be substantive. Some laboratories that only have drawing sites in Virginia may also see a slight reduction in their business. Currently there are 8 out of state laboratories reporting to VDH on a regular basis.

Small Businesses: Alternative Method that Minimizes Adverse Impact

Doctor's offices and small clinics will likely benefit from the proposed regulations. Small laboratories may experience slight reduction in their lead testing business. There is no alternative method that will generate lower adverse impact.

Legal Mandate

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.H of the Administrative Process Act and Executive Order Number 21 (02). Section 2.2-4007.H requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, Section 2.2-4007.H requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a

description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.