MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
		Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 1/8/2016

2. COMAR Codification

Title	Subtitle	Chapter	Regulation
10	11	04	02 and .04-.06

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator
Michele Phinney

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6. Check applicable items:

_ New Regulations

X- Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: September 30, 2015.

_ Repeal of Existing Regulations

_ Recodification

_ Incorporation by Reference of Documents Requiring DSD Approval

_ Reproposal of Substantively Different Text:

: Md. R

(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:

_ Yes **X-** No

8. Incorporation by Reference

_ Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

_ OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

_ OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

X- Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Claire Pierson, Assistant Attorney General, (telephone #410-767-6526) on November 24, 2015. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Van T. Mitchell

Title	**Telephone No.**
Secretary	410-767-6500

Date

December 1, 2015

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Subtitle 11 MATERNAL AND CHILD HEALTH
10.11.04 Lead Poisoning Screening Program

Authority: Education Article, §7-403; Environment Article, §6-303; and Health-General Article, §18-106; Annotated Code of Maryland

Notice of Proposed Action

[]

The Secretary of Health and Mental Hygiene proposes to amend Regulations .02, and.04—.06 under COMAR 10.11.04 Lead Poisoning Screening Program.

Statement of Purpose

The purpose of this action is to improve lead testing rates in Maryland and align regulations with the new Center for Disease Control and Prevention (CDC) guidelines. As the profile of lead exposure changes across the State, and lower levels of lead exposure are recommended by the CDC, relatively fewer children are exposed to lead in the traditional at-risk areas of older rental housing, and a higher proportion are being exposed in owner-occupied homes and from other sources of lead in the environment. Lead-exposed children can be found in every jurisdiction in the State. This proposal expands the definition of at-risk areas to include the entire State, amends lead poisoning blood testing requirements, allows the submission of alternative blood lead analysis documentation for children under certain circumstances, amends certain documentation reporting requirements, and makes general updates.

These amendments, together with the Department's new Targeting Plan, will expand the definition of at-risk area of lead poisoning to include the entire State, thus increasing the number of children tested for lead at ages 12 and 24 months. This will likely lead to an increase in the number of children tested for lead, and likely also lead to an increase in the number of children identified as having some lead exposure in an effort to prevent a number of children from ongoing lead exposure.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact.

This proposal will increase the number of children tested for lead in Maryland. The Department, the Maryland Department of the Environment (MDE), and local health departments (LHDs) will experience an indeterminate increase in expenditures related to outreach, investigation, and case management of lead-exposed children. Health care

providers may experience an increase in expenditures related to the testing and case management of children, depending on reimbursement by health care insurers. Homeowners and apartment building owners could experience an increase in expenditures for investigation and abatement of lead in their properties. Health care insurers will experience an increase in expenditures related to testing and care of children who may be found to be lead-exposed. Homeowners and apartment building owners and health care insurers could also experience cost savings by addressing lead exposures before they become lead poisoning cases and avoiding more expensive medical care. According to 2014 MDE data, the number of children 12 or 24 months of age in Maryland was 177,841, of whom 68,881 (38.7%) were tested for lead. The number untested who would require lead testing under this proposal would be approximately 108,960 children. However, ultimately the public will benefit from reduced exposure to lead hazards and earlier detection of elevated blood lead levels.

II. Types of Economic Impact.	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude
A. On issuing agency:	(E+)	Indeterminate
B. On other State agencies:	(E+)	Indeterminate
C. On local governments:	(E+)	Indeterminate

	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	(-)	Indeterminate
E. On other industries or trade groups:		
(1) Homeowners and apartment building owners	(-)	Indeterminate
(2) Insurers	(-)	Indeterminate
F. Direct and indirect effects on public:	(+)	Indeterminate

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. Medicaid will experience an increase in the number of children tested for lead and a smaller increase in the number of children identified with elevated blood lead levels. However, some of these children might have developed more severe lead poisoning except for the mandated early testing, and the costs of treating more severely lead-poisoned children would then be avoided by Medicaid due to the earlier testing.

In addition, the Environmental Health Bureau will experience a significant increase in referral calls, from parents, providers, and LHDs. In most cases, these calls will be addressed by existing staff and referred to LHDs or to MDE. There will also be an

increase in outreach by the Environmental Health Bureau that will likely continue throughout State Fiscal Year 16.

B. MDE will almost certainly experience an increase in the number of referrals related to lead exposure, primarily referrals for affected rental properties built before 1978 will require investigation and administrative follow-up for compliance with lead and rental property laws. In addition, the Childhood Lead Registry will experience an increase in the number of blood lead testing results.

C. LHDs may see a significant increase in the number of lead-exposed children and may experience an increase in the number of related inquiries. A few LHDs currently account for the bulk of the cases of lead-exposed children identified, but when the proposed changes go into effect, it is anticipated that many or all LHDs will see significantly increased numbers of lead-exposed children, especially children with low lead levels (5 – 9 micrograms/deciliter). The Department is working with LHDs to minimize an increase in expenditures, while some LHDs have agreed to funnel questions related to new cases.

D. Blood lead testing will likely increase across the Maryland population, both for children enrolled in Medicaid, and for children covered by private insurance. The increased expenditures by health care providers will likely be greater for children enrolled in private health insurance since Medicaid children are all supposed to be tested at ages 12 and 24 months already (current testing rates are probably in the 60% range for this population). By contrast, many children enrolled in private health insurance will not be living in areas previously defined as at-risk, so they would not previously have been tested. It is anticipated that testing will be covered by health insurance in virtually all locations and practices. There will be costs associated with follow-up of positive tests.

E(1). Homeowners and apartment building owners may see an increase in expenses if additional homes and/or rental units are identified with lead hazards. Homeowners and apartment building owners would experience additional expenditures in order to abate the lead hazard. However, some cases of lead exposure will be identified and addressed before they become lead poisoning cases, which will result in savings by avoiding more expensive medical care.

E(2). As testing increases, health care insurers will experience an increase in expenditures related to testing and care of children who may be found to be lead-exposed. It is anticipated that some cases of lead exposure will be identified and addressed before they become lead poisoning cases, which will also result in savings to insurers by avoiding more expensive medical care.

F. Members of the public will benefit from earlier recognition of lead poisoning and follow-up. There will, however, be some cases in which the initial results may be elevated, then drop after the elevated tests are confirmed with venous testing.

Economic Impact on Small Businesses

The proposed action has a meaningful economic impact on small business. An analysis of this economic impact follows.

Some property owners who meet the criteria of small businesses could be affected if

children in their properties are identified as having lead exposure. This could result in additional expenditures to investigate and abate lead sources in their properties.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through February 8, 2016. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2016
B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?
Yes
C. If 'yes', state whether general, special (exact name), or federal funds will be used:
General Funds
D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 11 MATERNAL AND CHILD HEALTH

10.11.04 Lead Poisoning Screening Program

Authority: Education Article, §7-403; Environment Article, §6-303; and Health-General Article, §18-106; Annotated Code of Maryland

10.11.04 (Downloaded 9/30/15)

.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1) (text unchanged)

(2) "At-risk area" means, *effective January 1, 2016,* any geographic area within the State that has been designated **[**as high-risk, moderate-risk, or low-risk for lead poisoning by the Department in the current Targeting Plan.**]** *by the Department as at-risk for lead exposure:*

(a) For individuals born on January 1, 2015 or later in the 2015 Targeting Plan for Areas at Risk for Childhood Lead Poisoning; or

(b) For individuals born before January 1, 2015 in the 2004 Targeting Plan for Areas at Risk for Childhood Lead Poisoning.

(3)—(5) (text unchanged)

(6) "Child at high-risk" means a child who resides, or has previously resided, in an area within the State that has been designated as high-risk for lead poisoning by the Department in the **[**current **]** *2015* Targeting Plan.

(7) (text unchanged)

(8) "Elevated blood lead level" means:

(a) A blood lead level of **[**10**]** *5* micrograms per deciliter or greater; or

(b) (text unchanged)

(9) "EPSDT " means the Early and Periodic Screening Diagnosis and Treatment program governed by COMAR 10.09.23.

(10) (text unchanged)

(11) "High-risk area" is an area within the State that has been designated by the Department as high-risk for lead poisoning according to the **[**current**]** *2015* Targeting Plan.

(12)—(16) (text unchanged)

(17) Prekindergarten Program.

(a) (text unchanged)

(b) "Prekindergarten program" includes:

(i)—(v) (text unchanged)

(vi) Judith P. Hoyer Early Child Care and Education Centers established by Education Article, **[**§5-215**]** *§5-217*, Annotated Code of Maryland; and

(vii) (text unchanged)

(18)—(19) (text unchanged)

(20) "Targeting Plan" means the **[**current**]** *2015* Targeting Plan for Areas at Risk for Childhood Lead Poisoning developed by the Department that includes but is not limited to:

(a)—(d) (text unchanged)

(21)—(23) (text unchanged)

.04 Blood Tests for Lead Poisoning.

A. **[**A**]** *Effective January 1, 2016, a* primary care provider for a child who resides, or who is known to have previously resided, in an at-risk area shall administer a blood test for lead poisoning **[**:

(1) During**]** *during* the 12-month visit and again during the 24-month visit **[**; and.

(2) To a child who is 24 months old or older and younger than 6 years old, if:**]**.

B. Effective January 1, 2016, a primary care provider for a child who is 24 months old or older and younger than 6 years old who resides, or who is known to have previously resided, in an at-risk area as defined in the 2004 Targeting Plan for Areas at Risk for Childhood Lead Poisoning, shall administer a blood test for lead poisoning if the:

(a) **[**The child**]** *Child* has not previously received a blood test for lead poisoning;

(b) **[**The child's**]** *Child*'s parent or guardian fails to provide documentation that the child has previously received a blood test for lead poisoning; or

(c) **[**The provider**]** *Provider* is unable to obtain the results of a previous blood lead analysis.

[B.**]** *C.*—**[**F.**]** *G.* (text unchanged)

[G.**]** *H.* Bona Fide Religious Beliefs — At Risk.

(1) (text unchanged)

(2) If an affirmative response to the questionnaire under **[**§G(1)(b)**]** *§H(1)(b)* of this regulation, or a response indicating that the parent or guardian does not know the answer, is entered for any question on the lead exposure risk questionnaire for the child, the provider shall:

(a)—(d) (text unchanged)

(3) If all the responses to the lead exposure risk questionnaire are negative, the provider shall:

(a) Follow procedures set forth in **[**§G(2)(b)**]** *§H(2)(b)* of this regulation; and

(b) (text unchanged)

[H.**]** *I.* Bona Fide Religious Beliefs — High Risk.

(1) If the parent or guardian of a child at high risk refuses to consent to a blood test for lead poisoning due to the parent or guardian's stated bona fide religious beliefs and practices, a primary care provider shall:

(a) Follow the procedures set forth in **[**§G(1)**]** *§H(1)* and (2) of this regulation; and

(b) **[**Make a determination whether the child**]** *If a provider determines that a child* is at a substantial risk of harm from lead exposure **[**and**]**, *the provider shall* follow applicable law if the child's parent or guardian continues to refuse to have the child tested.

(2) (text unchanged)

[I.**]** *J.*—[J.] *K.* (text unchanged)

.05 Documentation Requirements on Entry into a Prekindergarten Program, Kindergarten Program, or First Grade.

A. **[**Beginning not later than September 2003, the**]** *The* parent or guardian of a child who currently resides, or has previously resided, in an at-risk area shall provide to the administrator of the child's school or program, or the administrator's designee, certified documentation of the child's blood lead analysis, as specified in **[**§F**]** *§G* of this regulation, on first entry into a:

(1)—(2) (text unchanged)

B. An electronic report of the child's blood lead analysis from a health care provider to the administrator of the child's school or program, or the administrator's designee, may serve as an acceptable alternative to the documentation required in §A of this regulation.

[B.**]** *C.* A health care provider shall:

(1) (text unchanged)

(2) Upon request by the child's public school or program administrator, or the administrator's designee, for a child who resides or has previously resided in an at-risk area, provide to the school or program the certified documentation of the child's blood lead analysis, as specified in **[**§F**]** *§G* of this regulation, in order to facilitate the Department's public health surveillance activities relating to lead poisoning.

[C.**]** *D.* The child's parent or guardian shall provide certified documentation of the child's blood lead analysis, as specified in **[**§F**]** *§G* of this regulation, administered in connection with the 12-month visit and 24-month visit to a Maryland public prekindergarten program **[**or Maryland public school**]** not later than:

(1)—(2) (text unchanged)

[D.**]** *E.* Pursuant to Regulation .04A of this chapter, if the child's first blood test for lead poisoning was administered after the child is 24 months old, then only certified documentation of the most recent blood lead analysis is required to be reported pursuant to **[**§B**]** *§C* of this regulation.

[E.**]** *F.* (text unchanged)

[F**]** *G.* The information sent to or received by a program or school pursuant to §A of this regulation shall be recorded and certified by a health care provider's signature on a form issued by the Department that includes the following:

(1) (text unchanged)

(2) Date *and result* of the blood lead analysis; and

(3) (text unchanged)

[G.**]** *H.* (text unchanged)

[H.**]** *I.* If a parent or guardian does not consent to a blood test for lead poisoning pursuant to Regulation **[**.04F**]** *.04H* of this chapter, the child's parent or guardian shall:

(1)—(2) (text unchanged)

[I.**]** *J.* Notice Required.

(1) The program or school shall give notice in accordance with **[**§I(2)**]** *§J(2)* of this regulation to the parent or guardian of a child who resides or has resided in an at-risk area who does not provide:

(a) The certified documentation of the child's blood lead analysis, as specified in **[**§F**]** *§G* of this regulation; or

(b) (text unchanged)

(2) The notice required under this section shall state that the parent or guardian is required by law to provide the information under **[**§I(1)(a) or (b)**]** *§J(1)* of this regulation at the time of enrollment.

.06 Blood Lead Analysis Reporting Requirements.

[A. Beginning not later than September 2003, for a child for whom certified documentation of blood lead analysis is not provided in accordance with Regulation .05A of this chapter, an administrator of a school or program, or the administrator's designee, shall report to the local health department in the jurisdiction in which the child resides:

(1) The child's name;

(2) The child's last known address; and

(3) The name and phone number of child's parent or guardian.**]**

[B.**]** *A.* Notwithstanding **[**§C**]** *§B* of this regulation, a medical laboratory shall report, to the Department of the Environment, the information required under Environment Article, §6-303, Annotated Code of Maryland.

[C.**]** *B.* (text unchanged)

[D.**]** *C.* The Commissioner of the Baltimore City Health Department may report the information received under **[**§C**]** *§B* of this regulation to the Baltimore Immunization Registry Program.

[E.**]** *D.*—**[**F.**]** *E.* (text unchanged)

VAN T. MITCHELL

Secretary of Health and Mental Hygiene