

# **Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

## **Subtitle 11 MATERNAL AND CHILD HEALTH**

### **Chapter 04 Lead Poisoning Screening Program**

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

#### **.01 Purpose.**

The purpose of this chapter is to set forth requirements for conducting lead poisoning risk assessments, blood tests for lead poisoning of minor children, and the reporting of blood lead analysis in accordance with applicable State law.

#### **.02 Definitions.**

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Administer a blood test for lead poisoning" means to:

(a) Draw a blood specimen, by either venous or capillary methodology, and:

(i) Send the specimen to a medical laboratory for blood lead analysis; or

(ii) Conduct a blood lead analysis at a health care provider's office subject to licensing, certification, and approval by the Laboratories Administration of the Department; or

(b) Order a blood specimen to be drawn by a third-party health care provider, by either venous or capillary methodology, and sent to a medical laboratory for blood lead analysis.

(2) "At-risk area" means, effective March 28, 2016, any geographic area within the State that has been designated 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) "Blood lead analysis" means the analysis and determination by a medical laboratory of the blood lead level in a blood specimen.

- (4) "CDC" means the federal Centers for Disease Control and Prevention.
- (5) "Child" means an individual younger than 18 years old.
- (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 2015 Targeting Plan.
- (7) "Department" means the Department of Health and Mental Hygiene.
- (8) "Elevated blood lead level" means:
- (a) A blood lead level of 10 micrograms per deciliter or greater; or
  - (b) A blood lead level of 5 micrograms per deciliter or greater for a blood test performed after March 28, 2016.
- (9) "EPSDT" means the Early and Periodic Screening Diagnosis and Treatment program governed by COMAR 10.09.23.
- (10) "Health care provider" means a person who is licensed, certified, or otherwise authorized to provide health care services under the Health Occupations Article, Annotated Code of Maryland.
- (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 2015 Targeting Plan.
- (12) "Immunization registry" means an immunization registry established and maintained by the Department.
- (13) "Lead exposure risk questionnaire" means the set of questions used to determine an individual's risk for lead exposure and lead poisoning, as approved by the Department and based on the recommendations from the CDC.
- (14) "Local health officer" means the county health officer in each of the 23 counties of Maryland and the Commissioner of Health in Baltimore City, or their designated representative.
- (15) "Medical laboratory" means a licensed medical laboratory as defined by Health-General Article, §17-201(b), Annotated Code of Maryland.
- (16) "Nonprimary care" means health care that:
- (a) Is given or recommended by a health care provider that is not the individual's primary care provider; and
  - (b) Includes but is not limited to episodic health care for acute illness or injury or health care that is given in an emergency room or other urgent care setting.
- (17) Prekindergarten Program.
- (a) "Prekindergarten program" means a public educational or public early intervention program that enrolls or serves children below the level of kindergarten.
  - (b) "Prekindergarten program" includes:
    - (i) Programs that operate within a school and those that operate outside of a school;

- (ii) Preschool special education programs governed by COMAR 13A.05.01;
- (iii) Extended Elementary Education Programs governed by COMAR 13A.06.02.01;
- (iv) Local Infant and Toddler Programs as defined in COMAR 13A.13.01;
- (v) Head Start and Early Head Start Programs as authorized under the Head Start Act, 42 U.S.C. §9801 et seq.;
- (vi) Judith P. Hoyer Early Child Care and Education Centers established by Education Article, 5-217, Annotated Code of Maryland; and
- (vii) Any other educational or early intervention program as determined by the Department.

(18) "Primary care" means health care that:

- (a) Is continuous, comprehensive and coordinated;
- (b) Emphasizes prevention of illness and injury; and
- (c) Includes but is not limited to the following services:
  - (i) Age appropriate screenings;
  - (ii) Diagnosis and treatment of acute and chronic disorders;
  - (iii) Growth and developmental assessments;
  - (iv) Health care supervision;
  - (v) Immunizations;
  - (vi) Patient and parent health and psychosocial counseling;
  - (vii) Physical examinations; and
  - (viii) Referrals to specialty health care providers.

(19) "Primary care provider" means a health care provider that provides primary care.

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

- (a) Methodology for determining levels of risk for childhood lead poisoning;
- (b) Maps of the State designating at-risk areas;
- (c) Zip code and census tract lists indicating each zip code and census tract's designated level of risk; and
- (d) Recommendations regarding the prevention of childhood lead poisoning.

(21) "12-month visit" means a well-child evaluation by a health care provider that occurs when a child is between 12 months old and 14 months old.

(22) "24-month visit" means a well-child evaluation by a health care provider that occurs when the child is between 24 months old and 26 months old.

(23) "Well-child evaluation" means a periodic primary care assessment of a child by a primary care provider in accordance with the:

- (a) American Academy of Pediatrics' guidelines; or
- (b) Periodicity schedule established under EPSDT requirements.

### **.03 Administration of Lead Exposure Risk Questionnaire.**

A primary care provider for a child shall complete a lead exposure risk questionnaire:

- A. During the 12-month visit and again during the 24-month visit if the child does not reside in an at-risk area;
- B. If the child does not reside in an at-risk area and is 24 months old or older and younger than 6 years old, and the provider does not have documentation that a blood test for lead poisoning or a lead exposure risk questionnaire has been previously administered to, or completed on behalf of, the child;
- C. At each well-child check for a child who is 6 months old or older and younger than 6 years old, and resides in an at-risk area; and
- D. In accordance with the EPSDT requirements for a child insured under the Maryland Medicaid program regardless of the child's area of residence.

### **.04 Blood Tests for Lead Poisoning.**

A. Effective March 28, 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 during the 12-month visit and again during the 24-month visit.

B. Effective March 28, 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:

- (1) Child has not previously received a blood test for lead poisoning;
- (2) Child's parent or guardian fails to provide documentation that the child has previously received a blood test for lead poisoning; or
- (3) Provider is unable to obtain the results of a previous blood lead analysis.

C. A primary care provider for a child shall administer a blood test for lead poisoning to a child if:

(1) An affirmative answer, or a response indicating that the parent or guardian does not know the answer, is given for any question on a lead exposure risk questionnaire that is completed for the child pursuant to Regulation .03 of this chapter; or

(2) The child's parent or guardian requests that the child receive a blood test for lead poisoning regardless of the child's age or area of residence.

D. If a child is insured under Maryland's Medicaid program, the child's primary care provider shall administer a blood test for lead poisoning to the child at the 12-month visit and again at the 24-month visit in accordance with EPSDT requirements regardless of the child's area of residence.

E. A primary care provider shall administer a blood test for lead poisoning, by venous methodology, if the results of a capillary blood test for lead poisoning indicate an elevated blood lead level.

F. For each blood test for lead poisoning administered by a health care provider, the provider shall provide on the lab order form the information for blood lead reporting that is required under Environment Article, §6-303, Annotated Code of Maryland, to the medical laboratory that:

(1) Draws the blood specimen; or

(2) Performs the blood lead analysis.

G. Physician offices and other point-of-care laboratories shall comply with the requirements under COMAR 10.10.03.02B(36) and C.

H. Bona Fide Religious Beliefs — At Risk.

(1) If the parent or guardian of a child who resides or has previously resided in an at-risk area that is not a high risk area 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) Counsel the parent or guardian that the blood test for lead poisoning is required by law due to the fact that their child is at risk for having an elevated blood lead level;

(b) Complete a lead exposure risk questionnaire for the child in the presence of the child and the child's parent or guardian.

(2) If an affirmative response to the questionnaire under §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) Further counsel the parent or guardian regarding the risks of lead poisoning, including the potential physical, behavioral, developmental, and intellectual effects, and again request the parent or guardian to consent to a blood test for lead poisoning;

(b) Document in the child's medical record any continued refusal by the parent or guardian to consent to a blood test for lead poisoning despite counseling, and the grounds for the parent or guardian's refusal;

(c) Write and sign an order for a blood test for lead poisoning on a medical laboratory order form; and

(d) Give the child's parent or guardian the completed order for the medical laboratory to draw a blood specimen for blood lead analysis.

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

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

(b) Complete a form issued by the Department indicating that the questionnaire was completed.

**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 §H(1) and (2) of this regulation; and

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

(2) If all the responses to the lead exposure risk questionnaire are negative, the provider shall complete the form issued by the Department indicating that the questionnaire was completed.

**J.** This regulation does not limit the duties of the child's health care provider, with respect to any child who resides or has previously resided in an at-risk area, under any other provision of the law.

**K.** A health care provider giving nonprimary care to a child may, but is not required to, administer a blood test for lead poisoning, even if a blood test for lead poisoning is not medically indicated.

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

**A.** 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 §G of this regulation, on first entry into a:

(1) Maryland public prekindergarten program; or

(2) Maryland public school system at the level of prekindergarten, kindergarten or first grade.

**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.

**C.** A health care provider shall:

(1) Document and certify by signature the dates of the blood lead analysis administered to a child pursuant to Regulation .04A of this chapter on a form developed by the Department; and

(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 §G of this regulation, in order to facilitate the Department's public health surveillance activities relating to lead poisoning.

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

(1) 20 calendar days from the 12-month visit or 24-month visit; or

(2) 20 calendar days from first entry into the program or system.

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 §C of this regulation.

F. Pursuant to Regulation .04A of this chapter, if a child has more than two blood tests for lead poisoning done between the ages of 12 months and 24 months, then only certified documentation of the two most recent blood lead analyses shall be reported.

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) Name of the child;

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

(3) The signature of the:

(a) Child's primary care provider or designee; or

(b) School health professional or designee that transcribed the information onto the form issued by the Department.

H. If a child is not required to receive a blood test for lead poisoning pursuant to Regulation .04A or B of this chapter, then the child's parent or guardian shall provide to the administrator of the child's school or program, or the administrator's designee, on a form issued by the Department, documentation that the child does not reside and has never resided in an at-risk area.

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

(1) Take their child to a primary care provider for the provider to complete a lead poisoning risk assessment questionnaire; and

(2) Submit to the administrator of the child's school or program, or the administrator's designee, a written, signed statement of exemption on a form issued by the Department.

J. Notice Required.

(1) The program or school shall give notice in accordance with §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 §G of this regulation; or

(b) A signed statement of exemption.

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

## **.06 Blood Lead Analysis Reporting Requirements.**

A. Notwithstanding §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.

B. A medical laboratory that performs blood lead analysis shall report the results of all blood tests for lead poisoning, performed pursuant to Regulation .04 of this chapter for a child who resides in Baltimore City, to the Commissioner of the Baltimore City Health Department in accordance with Article-Health, §4-607, Baltimore City Revised Code.

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

D. The Department may report the results of blood lead analysis to an immunization registry developed by the Department.

E. The Department of the Environment may report the results of blood lead analysis to an immunization registry developed by the Department.

### Administrative History

*Effective date: May 12, 2003 (30:9 Md R. 614)*

Regulation .02B amended as an emergency provision effective September 1, 2003 (30:20 Md. R. 1445); amended permanently effective December 22, 2003 (30:25 Md. R. 1845)

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