

# DEPARTMENT OF HEALTH AND SOCIAL SERVICES

## DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Section 122(3)t and Sections 2601-2606 (16 Del.C. §122(3)t & §§2601-2606)

16 DE Admin. Code 4459A

FINAL

ORDER

### 4459A Regulations Governing the Childhood Lead Poisoning Prevention Act for Children Between the Ages of 22 and 26 Months

#### NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("DHSS") initiated proceedings to adopt the State of Delaware Regulations Governing Childhood Lead Poisoning Prevention Act for Children Between the Ages of 22 and 26 Months. The DHSS proceedings to adopt regulations were initiated pursuant to 29 Delaware Code Chapter 101 and authority as prescribed by 16 Delaware Code, subsections 122(3)(t) and 2601-2606.

On May 1, 2023 (Volume 26, Issue 11), DHSS published in the *Delaware Register of Regulations* its notice of proposed regulations, pursuant to 29 *Del.C.* § 10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by June 8, 2023, after which time DHSS would review information, factual evidence, and public comment to the said proposed regulations. A public hearing was also held on Wednesday, May 24, 2023.

Written comments were received during the public comment period and evaluated. The results of that evaluation are summarized in the accompanying "Summary of Evidence."

#### FINDINGS OF FACT:

Some changes were made to the regulations since publication as proposed. The Department finds that the proposed regulations, as set forth in the attached copy should be adopted in the best interest of the general public of the State of Delaware.

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Regulations Governing Childhood Lead Poisoning Prevention Act for Children Between the Ages of 22 and 26 Months is adopted and shall become effective August 11, 2023 (ten days), after publication of the final regulation in the *Delaware Register of Regulations*.

7/31/2023 | 2:47 PM EDT

Date

JOSETTE D. MANNING, ESQ.

CABINET SECRETARY

#### **SUMMARY OF EVIDENCE**

##### STATE OF DELAWARE REGULATIONS GOVERNING

##### CHILDHOOD LEAD POISONING PREVENTION ACT FOR CHILDREN BETWEEN THE AGES OF 22 AND 26 MONTHS

In accordance with Delaware Law, public notices regarding proposed Department of Health and Social Services (DHSS) Regulations Governing Childhood Lead Poisoning Prevention Act for Children Between the Ages of 22 and 26 Months were published in the *Delaware Register of Regulations*. Written comments were received on the proposed regulations during the public comment period (May 1, 2023 through June 8, 2023). During this period, DHSS received four written responses, which are summarized below and are on file with DHSS along with the public hearing transcript.

Two commenters offered comments that suggested substantive and non-substantive changes including adding school nurses to the definition of "health care provider" and requiring specific methodologies for lead screening to be established. One commenter requested an update to the definition of "screening" to mean capillary or venous blood lead test, however these regulations specifically follow the definitions of "screening" and "testing" established by 16 **Del.C.** § 2601. One commenter requested the definition of "baseline screening/test" and "high risk" so insurance carriers have clarity in which screenings or tests are required to be covered under HB 222 AAB HA 1 (150th GA), however this is outside of the scope of these regulations and should be addressed through legislation.

In response to these comments, DHSS made the following non-substantive changes to the final regulation:

- **Section 1.0:** Reinstated the phrase "enforcement modalities" to reflect the Department's ability to institute penalties if these regulations are violated as a method of enforcement (Section 12.0).
- **Section 2.0:** Adds the phrase, "including a school nurse" to the definition of "Health care provider." While "including, but not limited to" implies that the health care providers specifically listed are not the only providers that meet the

definition, DHSS added school nurses specifically at the request of the written comments received during the public comment period.

- **Subsection 7.1:** At the suggestion of written comments, DHSS replaced the proposed language in subsection 7.1 with language directly from the 16 **Del.C.** § 2602(d). This change does not substantially change the meaning of this subsection.
- **Subsection 10.3:** Removed the phrase, "to the administrator of" to align with the proposed change in subsection 10.1 that requires parents or guardians to provide proof of blood lead level screening or test to a child care facility public or private nurse school, preschool, or kindergarten. Though the suggestion was to specifically add school nurses to this subsection in lieu of "administrator," DHSS determined that not all entities listed will have nurses on staff and this language allows flexibility in whom the screening/testing information is submitted to, to include school nurses.

DHSS is appreciative of these comments and greatly appreciates the thoughtful input given.

## **4459A Regulations Governing the Childhood Lead Poisoning Prevention Act for Children Between the Ages of 22 and 26 Months**

### **1.0 General Provisions. Provisions**

#### **1.1 Preamble.**

- 1.1.1 These regulations are adopted by the Secretary of Delaware Health and Social Services pursuant to 16 **Del.C.**, §122(3)(t) and ~~§ 2602 §§2601-2606~~. These regulations establish standards for blood lead level screening and testing of children between 22 12 and 26 24 months of age who are at high risk of lead poisoning. These regulations also establish a record retention policy, ~~enforcement modalities,~~ **enforcement modalities,** and penalties for violators.

### **2.0 Definitions. Definitions**

For purposes of this chapter, the following definitions shall apply:

**"Administer a blood lead level screening or test"** means to draw a blood specimen, by either capillary or venous methodology, and:

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

(b) Conduct a blood lead analysis at a health care provider's office; or

(c) 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.

**"Blood lead analysis"** means the analysis and determination by a medical laboratory of the blood lead level in a blood specimen.

**"Blood lead registry"** means the database maintained by the Department that includes the results of all blood lead ~~screening and testing reported to the Department.~~

**"Blood lead testing"** means ~~taking a capillary or venous sample of blood for point of care testing using a Clinical Laboratory Improvement Act of 1988 (CLIA) licensed or waived test or sending it to a laboratory to determine the level of lead in the blood.~~

**"Capillary"** means a blood sample taken from the capillaries in the finger or heel for lead analysis.

**"Child care facility"** means any facility licensed by the Office of Child Care Licensing to provide child care services in Delaware.

**"Division"** means the Delaware Division of Public Health.

**"Department"** means the Delaware Department of Health and Social Services.

**"Health care provider"** means ~~the~~ a licensed practitioner individual that generally provides medical care to a child including, but not limited to, a physician, a ~~physician's assistant~~ physician assistant, or a **[nurse nurse, including a school nurse]**.

**"High risk"** means ~~a child between the ages of 22 and 26 months who meets any of the following conditions:~~

- ~~Is suspected by a parent or a health care provider to be at risk for lead exposure or to exhibit the symptoms of lead poisoning.~~
- ~~Has a sibling or frequent playmate with lead poisoning.~~
- ~~Is a recent immigrant, refugee, or foreign adoptee.~~
- ~~Has a household member who uses traditional, folk, or ethnic remedies or cosmetics or who routinely eats food imported informally (e.g., by a family member) from abroad.~~
- ~~Lives in or regularly visits a house or day care center (including out buildings) built before 1978.~~

- Lives with an adult whose job or hobby involves exposure to lead (e.g. construction, welding, pottery, mechanic, jeweler, plumber, renovator, firing range enthusiast, stained glass maker)–
- Lives near an active lead smelter, battery recycling plant, or other industry likely to release lead.
- Lives in, attends day care in, or visits any of the following zip code areas at least 6 hours a week or 60 hours a year:
  - ~~197XX~~: 01, 02, 03, 06, 09, 11, 13, 20, 33
  - ~~198XX~~: 01, 02, 03, 04, 05, 06, 08, 09, 10
  - ~~199XX~~: 01, 04, 33, 34, 38, 39, 40, 41, 43, 45, 46, 47, 50, 52, 53, 56, 58, 60, 62, 63, 66, 68, 71, 73, 75, 77.

“**Laboratory**” means a laboratory certified to perform either waived or non-waived blood lead analysis according to the federal Clinical Laboratory Improvement Act of 1988 (CLIA).

“**Low Risk**” means a child between the ages of 22 and 26 months who does not meet any of the conditions listed in the definition for “**High Risk**”.

“**Parent or guardian**” means an individual acting in a primary custodial capacity.

“**Reference value**” means the most current blood lead reference value as determined by the Centers for Disease Control and Prevention.

“**Screening**” means a capillary blood lead level test, including where a drop of blood is taken from a finger or heel of the foot.

“**Testing**” means a venous blood lead level test where blood is drawn from a vein.

“**Venous**” means a blood sample taken from a vein in the arm for lead analysis.

### 3.0 Requirement. Requirement for Blood Lead Level Screenings and Tests

- 3.1 ~~The Pursuant to 16 Del.C. § 2602(a), a primary health care provider of for a child between the ages of 22 and 26 months shall determine if said child is at high risk of lead poisoning. If the child is determined to be at high risk, the health care provider shall perform or cause to be performed a blood lead shall administer a blood screening or test for lead when the child is between 9 and 15 months of age and again between 21 and 27 months of age. Screenings or tests administered from 15 through 18 months of age shall be considered a 12-month screening or test, and from 18 through 21 months of age shall be considered a 24-month screening or test.~~
- 3.2 Unless a child's parent or guardian requests a blood lead level screening or test, a primary health care provider for a child who is 28 months old or older and younger than 6 years old shall administer a blood screening or test for lead in the following circumstances:
  - 3.2.1 If the child has not previously received a blood lead level screening or test;
  - 3.2.2 If the child's parent or guardian fails to provide documentation that the child has previously received a blood lead level screening or test; or
  - 3.2.3 If the health care provider is unable to obtain the results of a previous blood lead analysis.
- 3.3 A health care provider shall administer a blood lead level test, by venous methodology, if the results of a capillary screening indicate a blood lead level result greater than or equal to the reference value.
- 3.4 A health care provider giving non-primary care to a child may administer a blood lead level screening or test, even if a blood lead level screening or test is not medically indicated.
- 3.5 If a child is insured under Delaware's Medicaid program, the child's primary health care provider shall administer a blood lead level screening or test to the child at the 12-month visit and again at the 24-month visit in accordance with Early and Periodic Screening, Diagnosis and Treatment (EPSDT) requirements.
- 3.6 In addition to the blood lead level screening and testing requirements in this section, a health care provider may order a lead screening or test at their discretion and these results must be reported to DPH pursuant to Section 7.0.

### 4.0 Applicability. [Reserved.]

- 4.1 ~~The blood lead testing requirement specified in these regulations applies to all children 22 to 26 months of age except those determined not to be at high risk.~~
- 4.2 ~~Blood lead testing is not required on a child between the ages of 22 and 26 months when said child is determined by the health care provider to be at low risk for elevated blood lead levels. If a health care provider determines that a child is low risk, the health care provider will keep the completed risk assessment questionnaire (with all “NO” responses) in the child's chart for at least three years.~~

### 5.0 Religious exemption. Exemption

A religious exemption may be granted to a child if the blood lead level screening or testing conflicts with a genuine and sincere religious belief and not a belief based merely on philosophical, scientific, moral, personal, or medical opposition to blood lead level screening or testing. ~~A certificate~~ The DPH affidavit of blood lead level screening or testing exemption for religious reasons ~~beliefs~~ shall be signed and dated by the child's parent or guardian, notarized, and kept in the child's medical chart.

## 6.0 **Time line for valid blood lead testing. Timeline for Valid Blood Lead Level Screening and Testing**

To be valid, a blood lead level screening or test shall be performed, as required by these regulations, on a child ~~after completion of a risk assessment questionnaire when the child is between the ages of 22 and 26 months~~ when the child is from 9 through 15 months of age and again from 21 through 27 months of age, pursuant to subsection 3.1. Children ~~that test~~ with blood lead levels above the level-of-concern reference value established by the Centers for Disease Control ("CDC"), which is currently 10 µg/dl, will and Prevention must have a venous confirmation by a laboratory prior to intervention blood test if the original analysis was conducted through capillary screening.

## 7.0 **Documentation. Blood Lead Level Screening and Testing Documentation and Reporting Requirements**

7.1 ~~[A health care provider and a laboratory performing a blood lead level screening or test required by these regulations shall ensure that the results of the blood lead level screening or test are reported to the Division. All laboratories and health-care providers involved in blood lead level analysis, including screening and testing, shall participate in a universal reporting system as established by the Division of Public Health.]~~

7.2 ~~Proof of blood lead testing will be verified through the Blood Lead Registry and by auditing a child's medical charts. The laboratory, health care provider's office, or other facility that administers a blood lead level screening or test for a child younger than 18 years old shall obtain the information required by this regulation at the time of drawing the blood specimen.~~

7.3 A laboratory that performs blood lead analysis shall provide a referral form of paper or electronic requisition that specifies the required information for use by a laboratory, a health care provider's office, or another facility that draws a blood specimen. The facility that draws a blood specimen shall:

7.3.1 Record the information required under this regulation on the laboratory's referral form or similar form; and

7.3.2 Forward the required information concurrently with the blood specimen to the laboratory that performs blood lead analysis.

7.4 A laboratory required to report a blood lead level screening or test under this regulation shall report the blood lead level screening or test in the format approved by the Division and shall include the following information:

7.4.1 The child's demographic information, including:

7.4.1.1 First name, middle initial, and last name;

7.4.1.2 Date of birth;

7.4.1.3 Country of birth;

7.4.1.4 Sex;

7.4.1.5 Race and ethnicity;

7.4.1.6 Master Client Index (MCI) number if the child is enrolled in Medicaid or a Delaware children's health program;

7.4.1.7 Complete home address at the time the blood specimen was drawn, including house or apartment number, street, city or town, county, zip code, and state;

7.4.1.8 Telephone number; and

7.4.1.9 Parent's or guardian's name.

7.4.2 Type of blood specimen, venous or capillary, and the blood draw date;

7.4.3 The health care provider's name, office name, address, telephone number, and national provider identifier (NPI);

7.4.4 If the draw site is different from the health care provider's office, the laboratory's or other facility's name, address, telephone number, and NPI;

7.4.5 All of the following information about the laboratory performing the blood lead analysis:

7.4.5.1 Laboratory name, address, telephone number, and clinical laboratory improvement amendment number (CLIA);

7.4.5.2 Laboratory method used to analyze the blood specimen;

7.4.5.3 The limit of detection for the method used to analyze the blood specimen; and

- 7.4.5.4 If reporting a "no result" screening or test result, the limit of detection for the laboratory method.
- 7.4.6 Blood lead level in micrograms per deciliter expressed with a numeric results comparator of:
  - 7.4.6.1 Equal, if the blood lead level is an exact measurement; or
  - 7.4.6.2 Less than or greater than, if a blood lead level reading is below or above a certain level that a device used to analyze a blood specimen can accurately record.
- 7.4.7 Additional information as may be required by the Division.

## **8.0 Records.**

~~A completed risk assessment questionnaire, including the determination of the child's risk of lead poisoning, shall be maintained in a child's medical chart for at least three years. The Division will conduct scheduled and impromptu chart audits to monitor compliance.~~

## **8.0 Missing Information**

- 8.1 A laboratory that receives a blood specimen from a laboratory, a health care provider's office, or another facility without all the required information listed in Section 7.0 included on the referral form required under subsection 7.3 shall:
  - 8.1.1 Within three business days of receipt of the blood specimen, send to the facility that provided the blood specimen a written or electronic message citing the requirements of this regulation, requesting that all the required missing information be forwarded to the laboratory; and
  - 8.1.2 Upon receipt of the required information, collate and transmit the information to the Division within the time frames set forth in this regulation.
- 8.2 When the laboratory reports a blood lead level screening or test result to the Division with one or more of the requirements listed in Section 7.0 omitted, the laboratory shall concurrently provide the name and address of the facility that:
  - 8.2.1 Drew the blood specimen; and
  - 8.2.2 Failed upon request to forward the required information to the laboratory.
- 8.3 The facility that drew the blood specimen shall respond to a written or electronic message from a laboratory that did not receive all of the required information listed in Section 7.0 by providing the information to the laboratory within:
  - 8.3.1 One business day of receiving the message regarding a blood lead level screening or test result of greater than or equal to the reference value;
  - 8.3.2 Five business days of receiving the message for a blood lead level screening or test result of less than the reference value.
- 8.4 A laboratory not permitted to perform a blood lead analysis that accepts a blood specimen from a health care provider for referral to another laboratory for blood lead analysis shall ensure that:
  - 8.4.1 The requisition record includes all the information that is required under this regulation; and
  - 8.4.2 The required information is transmitted to the laboratory performing the blood lead analysis along with the blood specimen.
- 8.5 Reporting a blood lead level screening or test result with missing information:
  - 8.5.1 A laboratory shall collate information required under Section 7.0 that is collected to complete a previously incomplete requisition record for a blood lead level screening or test before submitting the information to the Division in accordance with this regulation.
  - 8.5.2 A laboratory shall report the missing information collated to the Division pursuant to this regulation:
    - 8.5.2.1 Concurrently with the blood lead level screening or test result, if the reporting time frame for a blood lead level screening or test result established in subsection 8.3 has not concluded; or
    - 8.5.2.2 In a manner indicating that there has been a change in the blood lead level screening or test record, if reporting the missing information after the initial blood lead level screening or test result was reported to the Division.

## **9.0 Additional Reporting Requirements**

- 9.1 In addition to the reporting requirements set forth in Section 7.0, a laboratory shall report the result of a blood lead level screening or test to:
  - 9.1.1 The health care provider that ordered the blood lead level screening or test; and
  - 9.1.2 Another entity as required by State, federal, or local statutes or regulations, or in accordance with accepted standards of practice.

- 9.2 A laboratory shall report the result of a blood lead level screening or test to the Division by electronic system, facsimile, or other manner required by the Division within two weeks of a final blood lead level screening or test result.
- 9.3 A laboratory that uses an electronic system for tracking blood lead level screening or test results shall report a result to the Division electronically in a manner consistent with the technical specifications established by the Division.

#### **10.0 Proof of Documentation Requirements Prior to Child Care or School Enrollment**

- 10.1 Upon first admission or continued enrollment, the parent or guardian of a child 12 months of age or older shall provide to the child care facility, public or private nursery school, preschool, or kindergarten proof that the child received a blood lead level screening or test.
- 10.2 Except in the case of enrollment in kindergarten, the blood lead level screening or test may be done within 60 calendar days of the date of enrollment.
- 10.3 A child's parent or guardian must provide one of the following to ~~the administrator of~~ a child care facility, public or private nursery school, preschool, or kindergarten:
- 10.3.1 A statement from the child's primary health care provider that the child has received the required screenings or tests for lead; or
- 10.3.2 The DPH affidavit signed by the parent or guardian stating that the blood lead level screening or test is contrary to the parent's or guardian's religious beliefs; or
- 10.3.3 Certified documentation of the child's blood lead analysis, as specified in this regulation, administered in connection with the 12-month visit and 24-month visit to the child's health care provider not later than:
- 10.3.3.1 30 calendar days from the 12-month visit or 24-month visit; or
- 10.3.3.2 30 calendar days from first entry into the program or system.
- 10.4 If the child's first blood lead level screening or test was administered after the child is 28 months old, then only certified documentation of the most recent blood lead analysis is required to be reported.
- 10.5 If a child has more than two blood lead level screenings or tests administered from the ages of 9 months through 27 months then only certified documentation of the two most recent blood lead analyses shall be reported.
- 10.6 The information sent to or received by a program or school shall be recorded and certified by a health care provider's signature on a form that includes the following:
- 10.6.1 Name of the child;
- 10.6.2 Date of the blood lead analysis; and
- 10.6.3 The signature of the child's primary health care provider or designee.
- 10.7 This Section shall apply to all children born after June 30, 2021.

#### **9.0 Severability. 11.0 Severability**

If any provision or application of any provision of these regulations is held invalid, that invalidity shall not affect the validity of other provisions or applications of these regulations.

#### **40.0 Penalty. 12.0 Penalty**

Violators are subject to sanctions pursuant to 16 ~~Del.C.~~, Del.C. §107 for each violation of the requirements established in these regulations.

14 DE Reg. 570 (12/01/10)

27 DE Reg. 109 (08/01/23) (Final)