DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

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

16 **DE Admin. Code** 4459A

PROPOSED

PUBLIC NOTICE

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

Pursuant to 16 **Del.C.** §122(3)(t) and §§ 2601-2606, the Health Systems Protection Section of the Division of Public Health, Department of Health and Social Services, is proposing revisions to the Regulations Governing the Childhood Lead Poisoning Prevention Act for Children Between the Ages of 22 and 26 Months. On May 1, 2022, the Division of Public Health plans to publish as "proposed" revisions to the Regulations Governing the Childhood Lead Poisoning Prevention Act for Children Between the Ages of 22 and 26 Months regulations. The revisions include:

- Renamed regulation to remove outdated reference;
- Updated and added new definitions;
- Updated requirements for blood lead testing, including age requirements and documentation and reporting requirements; and
- Technical corrections.

These revisions are required by House Bill 222 as amended by House Amendment 1 (151st GA).

Copies of the proposed regulations are available for review in the May 1, 2022 edition of the *Delaware Register of Regulations*, accessible online at: http://regulations.delaware.gov or by calling the Division of Public Health at (302) 744-4951.

Any person who wishes to make written suggestions, testimony, briefs, or other written materials concerning the proposed regulations must submit them by Wednesday, June 1, 2022, at:

Division of Public Health
417 Federal Street
Dover, DE 19901
Email: DHSS_DPH_regulations@delaware.gov
Phone: (302) 744-4951

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 testing of children between ~~22~~ 12 and ~~26~~ 24 months of age ~~who are at high risk of~~ to test for lead poisoning. These regulations also establish a record retention policy, enforcement ~~modalities~~ modalities, and penalties for violators.

2.0 ~~Definitions.~~ Definitions

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

"**Administer a blood test for lead**" means to draw a blood specimen, by either venous or capillary 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 Level of Concern**" means a concentration of lead in whole venous blood greater than or equal to 3.5 micrograms per deciliter in a child younger than six years old. Blood Lead Level of Concern shall be used for surveillance and outreach for children at risk of lead poisoning.

"Blood lead registry" means the database maintained by the Department that includes the results of all blood lead 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.

"Division" means the Delaware Division of Public Health.

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

"**Elevated blood lead level**" means an elevated blood lead level defined by the Division of Public Health to be potentially detrimental to the health, behavioral development, or cognitive potential of a child.

"Health care provider" means ~~the~~ an individual that generally provides medical care to a child including~~, but not limited to,~~ a physician, a physician's ~~assistant~~ assistant, or a 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 leve**l" means the revised blood lead reference level as determined by the Centers for Disease Control and Prevention.

"Venous" means a blood sample taken from a vein ~~in the arm~~ for lead analysis.

3.0 ~~Requirement.~~ Requirement for Blood Tests for Lead Poisoning

3.1 ~~The~~ 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 test~~ shall administer or order a blood test for lead when the child is at or around 12 months of age and again at or around 24 months of age.

3.2 A primary health care provider for a child who is 24 months old or older and younger than six years old shall administer a blood test for lead in the following circumstances:

3.2.1 If the child has not previously received a blood test for lead;

3.2.2 If the child's parent or guardian fails to provide documentation that the child has previously received a blood test for lead;

3.2.3 If the health care provider is unable to obtain the results of a previous blood lead analysis; or

3.2.4 If the child's parent or guardian requests that the child receive a blood test for lead regardless of the child's age or area of residence.

3.3 A primary health care provider shall administer or order a blood test for lead, by venous methodology, if the results of a capillary blood test for lead poisoning indicate an elevated blood lead level result greater than or equal to 3.5 micrograms per deciliter in a child younger than six years old.

3.4 A health care provider giving non-primary care to a child may, but is not required to, administer a blood test for lead, even if a blood test for lead 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 test for lead 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 regardless of the child's area of residence.

4.0 ~~Applicability.~~ Applicability

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~~ under six years of age (younger than 72 months of age).

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 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 testing. A certificate of blood lead 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~~ Timeline for valid blood lead ~~testing.~~ testing

To be valid, a blood lead 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 at or around 12 months of age and again when the child is at or around 24 months of age. Children ~~that test~~ with blood lead levels above the level of concern established by the ~~Centers for Disease Control ("CDC"), which is currently 10 µg/dl, will~~ Division must have a venous confirmation ~~by a laboratory prior to intervention~~ blood test.

7.0 ~~Documentation.~~ Blood Lead Testing Documentation and Reporting Requirements

7.1 A health care provider and a laboratory performing a blood lead test required by these regulations shall ensure that the results of the blood lead test are reported to the Division.

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 draws a blood specimen from a child 18 years old or younger for a blood lead level test 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.

7.3.1 The facility that draws a blood specimen shall:

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

7.3.1.2 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 test under this regulation shall report the blood lead level 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 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" test results, the limit of detection for the laboratory.

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 of 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 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 test result of greater than or equal to the reference level;

8.3.2 Five business days of receiving the message for a blood lead level test result of less than the reference level.

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 of 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 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 test before submitting the information to the Division in accordance with this regulation.

8.5.2 A laboratory shall report to the Division the missing information collated pursuant to this regulation:

8.5.2.1 Concurrently with the blood lead level test result, if the reporting time frame for a blood lead level 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 test record, if reporting the missing information after the initial blood lead level 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 test to:

9.1.1 The health care provider that ordered the blood lead level 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 test to the Division by electronic system, facsimile or other manner required by the Division within the following time frames:

9.2.1 By the close of business of the next business day following a final blood lead level test result of greater than or equal to the reference level; and

9.2.2 Within two weeks of a final blood lead level test result of less than the reference level.

9.3 A laboratory that uses an electronic system for tracking blood lead level 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 administrator of a child care facility, public or private nursery school, preschool, or kindergarten proof from their child's primary health care provider that the child received a blood test (screening) for lead poisoning.

10.2 Except in the case of enrollment in kindergarten, the screening 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 a blood test (screening) for lead poisoning;

10.3.2 A certificate signed by the parent or guardian stating that the blood test (screening) 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 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.

10.5 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.

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.

~~9.0~~ 11.0~~Severability.~~ 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.

~~10.0~~ 12.0~~Penalty~~. Penalty

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

14 DE Reg. 570 (12/01/10)
25 DE Reg. 1006 (05/01/22) (Prop.)