DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Section 122(3)t (16 **Del.C.** §122(3)t)
16 **DE Admin. Code** 4459A

FINAL

ORDER

4459A Regulations Governing the Childhood Lead Poisoning Prevention Act

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("DHSS"), Division of Public Health ("DPH") initiated proceedings to publish 4459A Regulations Governing the Childhood Lead Poisoning Prevention Act. These proceedings were initiated pursuant to 29 **Del.C.** Ch. 101 and the authority as prescribed by 16 **Del.C.** §122(3)t).

DHSS initially published the proposed amendments to this regulation in the December 2023 issue of the *Delaware Register of Regulations* ("*Register*") (27 **DE Reg.** 409 (12/01/23). Substantive changes were made to the regulation because of the public comment received (between December 1, 2023, and January 8, 2024). DHSS/DPH published the re-proposed regulation which included the additional revisions in the February 1, 2024, issue of the *Register* (27 **DE Reg.** 570). DHSS requested that written materials and suggestions from the public concerning the re-proposed regulation be delivered to DHSS by March 4, 2024, after which time DHSS would review information, factual evidence, and public comment to the said proposed regulations.

SUMMARY OF EVIDENCE:

No comments were received during the public comment period (of February 1, 2024, through March 4, 2024).

IMPACT ON THE STATE'S GREENHOUSE GAS EMISSIONS REDUCTION TARGETS AND RESILIENCY TO CLIMATE CHANGE:

The DPH Division Director has reviewed the proposed regulation as required by 29 *Del. C.* §10118(b)(3) and has determined that if promulgated, the regulation would have a de minimis impact on the State's resiliency to climate change because neither implementation nor compliance with the regulation would reasonably involve the increase in greenhouse gas emissions.

FINDINGS OF FACT:

No changes were made to the regulation since publication as re-proposed. The Department finds that the re-proposed regulations, as set forth in the attached copy should be adopted in the best interest of the public of the State of Delaware.

THEREFORE, IT IS ORDERED, that re-proposed 4459A Regulations Governing the Childhood Lead Poisoning Prevention Act is adopted and shall become effective May 11, 2024 (ten days), after publication of the final regulation in the *Delaware Register of Regulations*.

4/5/2024 | 4:47 PM EDT
Date

Josette D. Manning, Esq.
DHSS Cabinet Secretary

4459A Regulations Governing the Childhood Lead Poisoning Prevention Act

1.0 General Provisions

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

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

2.0 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.

"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 a licensed practitioner individual that generally provides medical care to a child including, but not limited to, a physician, a physician assistant, or a nurse, including a school nurse.

"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).

"**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.

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

3.0 Requirement for Blood Lead Level Screenings and Tests

3.1 Pursuant to 16 **Del.C.** §2602(a), a primary health care provider for a child 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~~ 18 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~~ the Division pursuant to Section 7.0.

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4.0 [Reserved.]

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5.0 Religious 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. The ~~DPH~~ Division affidavit of blood lead level screening or testing exemption for religious beliefs shall be signed and dated by the child's parent or guardian, notarized, and kept in the child's medical chart.

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

6.0 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 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 with blood lead levels above the reference value established by the Centers for Disease Control and Prevention must have a venous confirmation blood test if the original analysis was conducted through capillary screening.

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

7.0 Blood Lead Level Screening and Testing Documentation and Reporting Requirements

7.1 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 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.

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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 3 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 1 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.

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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 2 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.

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

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 1 of the following to 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~~ Division 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~~ child care facility, public or private nursery school, preschool, or kindergarten.

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 2 blood lead level screenings or tests administered from the ages of 9 months through 27 months then only certified documentation of the 2 most recent blood lead analyses shall be reported.

10.6 The information sent to or received by a ~~program~~ child care facility, public or private nursery school, preschool, kindergarten 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.

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

11.0 Division's Investigation and Reporting Obligations

11.1 Within 60 days of receiving notification that a child has a blood lead level at or above the reference level, the Division shall determine: the child's residential address from birth through testing, the site of the child's lead exposure, and the property owner of the site at which the child became exposed to lead. Any documents that the Division creates or holds that contain confidential health information shall be conspicuously marked and will not become public documents.

11.2 Within 10 days of identifying the site of lead exposure, the Division shall notify the Delaware State Lead-Based Paint Program, created by 16 **Del.C.** §2607, of the location and contact information of the property owner. These communications will be public records subject to disclosure under the Freedom of Information Act, Delaware Code, Title 29, Chapter 100.

~~11.0~~ 12.0 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.

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

~~12.0~~ 13.0 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)
27 DE Reg. 109 (08/01/23)
27 DE Reg. 864 (05/01/24) (Final)