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

PROPOSED

PUBLIC NOTICE

4459A Regulations Governing the Childhood Lead Poisoning Prevention Act

Pursuant to 16 **Del.C.** §122(3)t, the Department of Health and Social Services, Division of Public Health, Health Systems Protection section, is re-proposing revisions to 4459A Regulations Governing the Childhood Lead Poisoning Prevention Act. The revisions include:

- Amending the age limits for elevated blood lead level screening or testing in subsection 3.2;
- Clarified the acronym "DPH" in subsections 3.6, 5.0, and 10.3.2;
- Amended the use of the word "Program" in subsections 10.3.3.2 and 10.6;
- Amended references to "elevated blood lead levels" in subsection 11.1;
- Addition of the Division's investigation and reporting obligations; and
- Technical and renumbering revisions.

These amendments were previously published in the December 2023 issue of the *Register* (27 **DE Reg.** 409 (12/01/23) (Prop.) and are hereby re-proposed with substantive changes resulting from the public comment received (between December 1, 2023, and January 8, 2024). A summary of the written comments received on the proposed regulation as published in the December *Register* is provided below:

Entities offering written comments included:

Amy Roe, Ph.D. and Sarah Bucic, MSN, RN
Karl Markiewicz
Dawn E. Alexander, M. Ed and Dr. Tricia Dallas, Delaware Public Preschool Coalition
Jon Neubauer, Delaware State Education Association
Ronda Bostick, State Council for Persons with Disabilities
Ann Fisher and Pam Wier, Governor's Advisory Council for Exceptional Citizens
Judith Gorra, MD, Delaware Division of Health and Social Services

Comment by Amy Roe, Ph.D. and Sarah Bucic, MSN, RN:
1.0 General Provisions includes enforcement and penalties, yet these are not described in the regulations. Enforcement and penalties should be specific and explained.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and has determined that the regulation will remain as proposed in the December 2023 *Register*.

Comment by Amy Roe, Ph.D. and Sarah Bucic, MSN, RN:
2.0 Definitions. Administer a blood lead level screening or test includes ordering a blood specimen. This continues to be a problem. Ordering a test is not administering one, and there is no required follow-up to make sure that the test was performed.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and has determined that the regulation will remain as proposed in the December 2023 *Register*.

Comment by Amy Roe, Ph.D. and Sarah Bucic, MSN, RN:
Program is defined as the Delaware State Lead-Based Paint Program, but it is also used elsewhere in the regulations to refer to different things, including blood lead reporting, Medicaid, and children's health. Using this term in multiple ways is confusing.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and is proposing the following amendments for clarity:

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.

10.6 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:

Comment by Amy Roe, Ph.D. and Sarah Bucic, MSN, RN:
Screening should be limited to only FDA approved methodologies. DHSS has been allowing non-FDA approved approaches, such as filter paper, that are denounced by the CDC.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and has determined that the regulation will remain as proposed in the December 2023 *Register*. The Division has requested of the CDC Lead Poisoning Prevention and Surveillance Branch their official stance on the use of filter paper in a meeting in November 2023. No immediate knowledge of an official stance was known to the participant(s) and information forwarded to the CDC laboratory. To date no response was received. Actions may be taken once CDC's position is provided.

Comment by Amy Roe, Ph.D. and Sarah Bucic, MSN, RN:
3.6, 5.0, and 10.3.2 include DPH as an acronym, but this isn't defined in the regulations.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and is proposing the following amendments to the regulation:

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.

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~~ the 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.

10.3.2 The ~~DPH~~ the 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

Comment by Karl Markiewicz:
I'd like to suggest that a similar table which outlines the follow-up blood testing timeframes be included in the regulations. Parents/guardians and health care providers need to ensure the CDC's recommended follow up BLL testing is conducted.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and has determined that the regulation will remain as proposed in the December 2023 *Register*. In inclusion of guidelines will remove decision-making flexibility health care providers may need. Further, the Department would not be able to recommend revised guidelines without first reproposing and revising the regulations.

Comment by Ronda Bostick, State Council for Persons with Disabilities:
SCPD supports investigative and reporting requirements but questions the 60-day timeline that DPH is establishing for investigations. Further, SCPD would like for DPH to clarify the policy regarding storage and destruction of blood samples or information that could identify sensitive genetic and health information, as well as steps DPH will take to safeguard samples.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and has determined that the regulation will remain as proposed in the December 2023 *Register*.

Comment by Ann Fisher and Pam Wier, Governor's Advisory Council for Exceptional Citizens:
Presently, this regulation addresses that documents will be confidential but it does not address sample retention, nor safeguard this information from potential subpoenas such as what was utilized in the New Jersey news article. Council would like to request additional information on DPH's policy with respect to storage and destruction of blood samples; information that could identify sensitive genetic and health information, and steps DPH takes to safeguard samples from uses not contemplated by the lead poisoning law.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and has determined that the regulation will remain as proposed in the December 2023 *Register*.

Comment by Ronda Bostick, State Council for Persons with Disabilities:
Once the site of lead exposure is definitively identified, DPH's next steps must be within 10 days, DPH has 60 days to get to the point of triggering the 10-day timeline (note: this is consistent with 16 Del. C. § 2610). If a child is still at risk of exposure in their current home, such a lengthy timeline can prolong and increase the lead exposure the child faces, which can have long-term health implications and increase the potential for disability.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and has determined that the regulation will remain as proposed in the December 2023 *Register*.

Comment by Ann Fisher and Pam Wier, Governor's Advisory Council for Exceptional Citizens:
Although once the site of lead exposure is definitively identified, DPH's next steps must be within 10 days, DPH has 60 days to get to the point of triggering the 10-day timeline (note: this is consistent with 16 Del. C. § 2610). If a child is still at risk of exposure in their current home, such a lengthy timeline can prolong and increase the lead exposure the child faces, which can have long-term health implications and increase the potential for disability.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and has determined that the regulation will remain as proposed in the December 2023 *Register*.

Comment by Amy Roe, Ph.D. and Sarah Bucic, MSN, RN:
11.0 Division's Investigation and Reporting Obligations: This section should include all the investigation and reporting obligations of the Department, not just those pertaining to the Lead Based Paint Program. For example, other obligations include:

1. Case management for every child with a blood test at or above the reference value.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and has determined that the regulation will remain as proposed in the December 2023 *Register*.

Comment by Amy Roe, Ph.D. and Sarah Bucic, MSN, RN:
Direct referrals to IDEA Part C for eligible children for early intervention services (age birth to three with a blood lead level at or above 5 µg/dL). Coordination between the Childhood Lead Poisoning Prevention Program and IDEA Part C has been problematic, resulting in many eligible children who have never been offered the services to which they are entitled. This relationship and reporting obligation should be codified in regulations.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and has determined that the regulation will remain as proposed in the December 2023 *Register*. The Division provides the name and contact information of all children at or above the CDC reference level to the Delaware Birth to Three program.

Comment by Dawn E. Alexander, M. Ed and Dr. Tricia Dallas, Delaware Public Preschool Coalition:
Include language that requires referral to the IDEA Part C lead agency for children birth to three with blood lead levels at or above 5 µg/dL, as per the 2022 IDEA Part C "Established Conditions" adopted by DHSS.
Include language to ensure that if children received services from DE's IDEA Part C/Birth to Three program due to a BLL of 5 µg/dL or higher, this information is systematically communicated by the IDEA Part C/Birth to Three IFSP teams or via a Division of Public Health database to the children's public preschool program nurses and school psychologists. This information must be made available upon transition from IDEA Part C services to IDEA Part B services within the public school system.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and has determined that the regulation will remain as proposed in the December 2023 *Register*. The Division provides the name and contact information of all children at or above the CDC reference level to the Delaware Birth to Three program.

Comment by Jon Neubauer, Delaware State Education Association:
Include language that requires referral to IDEA Part C for eligible children age birth to three with blood lead levels at or above 5 µg/dL.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and has determined that the regulation will remain as proposed in the December 2023 *Register*. The Division provides the name and contact information of all children at or above the CDC reference level to the Delaware Birth to Three program.

Comment by Amy Roe, Ph.D. and Sarah Bucic, MSN, RN:
Clarifying language around IDEA Part B eligibility, for lead-exposed children aged 3-21, should be added to the regulations in order to provide guidance for school psychologists and school nurses determining eligibility for special education services.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and has determined that the regulation will remain as proposed in the December 2023 *Register*.

Comment by Dawn E. Alexander, M. Ed and Dr. Tricia Dallas, Delaware Public Preschool Coalition:
Provide criteria/clear guidance based on current CDC recommendations to assist DE public school IEP teams in determining eligibility for special education eligibility, as per IDEA Part B law, under the classification of Other Health

Impairment (OHI) for lead-exposed children aged 3-21.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and has determined that the regulation will remain as proposed in the December 2023 *Register*.

Comment by Jon Neubauer, Delaware State Education Association:
Provide clarifying language to help guide IEP teams in determining eligibility for special education, as per IDEA Part B eligibility under the classification of "Other Health Impairment (OHI)", for lead-exposed children aged 3-21.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and has determined that the regulation will remain as proposed in the December 2023 *Register*.

Comment by Amy Roe, Ph.D. and Sarah Bucic, MSN, RN:
Data sharing with school nurses, as required by HB 227 (2023) and appears in Title 16 §2603 (d) as follows: "The Division of Public Health shall ensure that all school nurses have access to data that confirms or denies whether each enrolled child has been screened for lead poisoning. A record of the proof of screening shall be kept in each student's school health record."

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and has determined that the regulation will remain as proposed in the December 2023 *Register*. The Division is currently drafting a data sharing agreement with the Department of Education to address data availability to school nurses.

Comment by Dawn E. Alexander, M. Ed and Dr. Tricia Dallas, Delaware Public Preschool Coalition:
Include language that requires DHSS to share children's BLLs with school nurses and to share any lead related information with school nurses to identify children who may qualify for services under IDEA Part B as OHI due to lead exposure.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and has determined that the regulation will remain as proposed in the December 2023 *Register*. The Division is currently drafting a data sharing agreement with the Department of Education to address data availability to school nurses.

Comment by Jon Neubauer, Delaware State Education Association:
Add language that requires data sharing with school nurses to advocate for children who qualify for services under IDEA section B for consideration with the IEP team. In addition to confirmation of lead screening data, school nurses should be provided with blood lead levels for their students.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and has determined that the regulation will remain as proposed in the December 2023 *Register*. The Division is currently drafting a data sharing agreement with the Department of Education to address data availability to school nurses.

Comment by Amy Roe, Ph.D. and Sarah Bucic, MSN, RN:
We recommend: 4459A § 11.1 be amended as follows: 11.1 Within 60 days of receiving notification that a child has an elevated blood lead level, a blood lead test at or above the reference value, the Division shall determine…. We also recommend that the use of elevated blood lead level in 4459 be changed to "reference value", and that "reference value" be consistently applied in the future.

Comment by Dawn E. Alexander, M. Ed and Dr. Tricia Dallas, Delaware Public Preschool Coalition:
Replace "elevated blood lead levels" with "a blood lead test with results at or above the blood lead reference value" to align the DE regulation with Center for Disease Control (CDC) recommendations.

Comment by Jon Neubauer, Delaware State Education Association:
Replace the existing language of "elevated blood lead levels" with "a blood lead test with results at or above the blood lead reference value". This would align the regulation with recommendations from the Center for Disease Control (CDC).

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and proposes to amend the regulation as follows:

11.1Within 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.

Comment by Judith Gorra, MD:
Section 3 of the provision entitled: Blood Lead Level Screenings and Tests, has two subsections allowing the provider to obtain "a blood lead level screening or test if not medically indicated" (Subsection 3.4) and/or "at their discretion" (Subsection 3.6).

I wanted to confirm if there are any age limits for these two subsections, as immigrant children who are new to our country and state, have potential exposures to lead in numerous ways and the Child Health Clinics have routinely tested all immigrant children for possible lead poisoning.

Agency Response: The Division appreciates the submission of comments regarding this regulation. The Division has reviewed these comments and proposes to amend the regulation as follows for clarification:

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:

The Department of Health and Social Services, and the Division of Public Health greatly appreciate the thoughtful input given.

Copies of the re-proposed regulations are available for review in the February 1, 2024, issue of the *Delaware Register of Regulations*, accessible online at: http://regulations.delaware.gov, or by calling the Division of Public Health at (302) 744-4700.

Public comments will be received until the close of business Monday, March 4, 2024. Comments will be accepted in written form via email to DHSS_DPH_regulations@delaware.gov, or by U.S. mail to the following address:

Vicki Schultes, Hearing Officer
Division of Public Health
417 Federal Street
Dover, DE 19901

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.

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

4.0 [Reserved.]

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

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.

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

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.

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

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~~ 12.0Severability

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~~ 13.0Penalty

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. 570 (02/01/24) (Prop.)