

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Section 2602 (16 **Del.C.**, §2602)

FINAL

ORDER

4459A Regulations for the Childhood Lead Poisoning Prevention Act

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services (“DHSS”) initiated proceedings to adopt the State of Delaware Regulations Governing the Childhood Lead Poisoning Prevention Act for Children Between the Ages of 22 and 26 Months. The DHSS proceedings to adopt the regulations were initiated pursuant to 29 Del.C., Ch. 101 and authority as prescribed by 16 **Del.C.**, Ch. 26.

On October 1, 2010 (Volume 14, Issue 4), 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 November 1, 2010, or be presented at a public hearing on October 22, 2010, after which time the DHSS would review information, factual evidence and public comment to the said proposed regulations.

No oral comments were made at the public hearing and no written comments were received during the public comment period. Therefore, no evaluation or summarization of comments is presented in the accompanying “Summary of Evidence.” Two letters of endorsement were received from the Governor’s Advisory Council for Exceptional Citizens and the State Council for Persons with Disabilities, respectively.

SUMMARY OF EVIDENCE

In accordance with Delaware Law, public notices regarding proposed Department of Health and Social Services (DHSS) Regulations Governing the Childhood Lead Poisoning Prevention Act for Children Between the Ages of 22 and 26 Months were published in the *Delaware State News*, the *News Journal* and the *Delaware Register of Regulations*. No oral comments were received at the October 22, 2010 public hearing and no written comments were received on the proposed regulations during the public comment period (October 1, 2010 through November 1, 2010).

Only minor grammatical corrections were made to further clarify the proposed regulations.

The public comment period was open from October 1- November 1, 2010.

Verifying documents are attached to the Hearing Officer’s record. The regulation has been approved by the Delaware Attorney General’s office and the Cabinet Secretary of DHSS.

FINDINGS OF FACT:

There were no public comments received and only minor non-substantive changes were made to the proposed regulations. 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 the Childhood Lead Poisoning Prevention Act for Children Between the Ages of 22 and 26 Months are adopted and shall become effective December 11, 2010, after publication of the final regulation in the *Delaware Register of Regulations*.

Rita M. Langraf, Secretary

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

1.0 General 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. These regulations establish standards for blood lead testing of children between 22 and 26 months of age who are at high risk of lead poisoning. These regulations also establish a record retention policy, enforcement modalities and penalties for violators.

2.0 Definitions.

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

“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 finger or heel for lead analysis.

“Division” means the Delaware Division of Public Health.

“Department” means the Delaware Department of Health and Social Services.

“Health care provider” means the individual that generally provides medical care to a child including, but not limited to, a physician, a physician’s 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”**.

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

3.0 Requirement.

The health care provider of 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.

4.0 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.
- 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.

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 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.

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. 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 have venous confirmation by a laboratory prior to intervention.

7.0 Documentation.

- 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.

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.

9.0 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.

10.0 Penalty.

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