HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF FAMILY HEALTH SERVICES

Child and Adolescent Health Program

Screening of Children for Lead Poisoning

Proposed Amendments: N.J.A.C. 8:51A-1, 2.1, 2.2, 3.1, and 4

Authorized By: Cathleen D. Bennett, Commissioner, Department of Health (in consultation with the Public Health Council).

Authority: N.J.S.A. 26:2-137.2 et seq., particularly 26:2-137.7.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2016-200.

Submit electronic comments to http://www.nj.gov/health/legal/ecomments.shtml, or written comments to the address below, by February 3, 2017, to:

Joy L. Lindo, Director
Office of Legal and Regulatory Compliance
Office of the Commissioner
New Jersey Department of Health
PO Box 360
Trenton, NJ 08625-0360

The agency proposal follows:

Summary
N.J.S.A. 26:2-137.1 et seq. (P.L. 1995, c. 328) (the Act), which became effective on March 5, 1996, established the Department of Health’s (Department) Lead Screening Program. The Act was intended to help reduce and eventually eliminate elevated blood lead levels in children through lead screening. The Act requires physicians, registered professional nurses, as appropriate, and licensed health care facilities that serve children, to perform lead screening on each child to whom they provide health care services. N.J.S.A. 26:2-137.4. The Law directs the Department to promulgate rules providing for specific implementation of the lead screening requirements, including the age of the child when initial screening shall be conducted, the time intervals between screening, when follow-up testing is required, and the methods to be used to conduct the lead screening. N.J.S.A. 26:2-137.4e and 137.7.

On January 4, 2012, the Advisory Committee on Childhood Lead Poisoning Prevention (Advisory Committee) to the Federal Centers for Disease Control and Prevention (CDC) released its report entitled, “Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention.” On May 13, 2012, the CDC published the “CDC Response to Advisory Committee on Childhood Lead Poisoning Prevention Recommendations in Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention.” In its response, the CDC either concurred or concurred in principle with all of the Advisory Committee’s recommendations. One key recommendation was that the CDC should use a childhood blood lead level reference value based on the 97.5th percentile of the population blood lead level in children ages one through five, currently five micrograms per deciliter (µg/dL), to identify children and environments associated with lead exposure hazards. The Advisory Committee
recommended that the reference value should be updated by the CDC every four years based on the most recent population-based blood lead surveys among children. The CDCconcurred in principle with this recommendation. Accordingly, the Department is proposing to lower the reference value at N.J.A.C. 8:51A to five µg/dL.

Throughout the chapter, the Department proposes to correct the name of the Department from the “Department of Health and Senior Services” to the “Department of Health,” pursuant to P.L. 2012, c. 17. Throughout the chapter, the Department proposes to replace the term “lead poisoning” with the term, “elevated blood lead level,” except where the term is used as a historical reference or in the name of an official publication. Throughout the chapter, the Department proposes to amend the phrases, “under six years of age,” to “less than 72 months of age” and “between six months” to “at least six months,” to more precisely establish the ages of children to which this chapter applies. At N.J.A.C. 8:51A-1.3, in order to comport with the recommendations of the Advisory Committee discussed above, the Department proposes to amend the definition of “elevated blood lead” to mean a blood lead test result equal to or greater than five µg/dL. The Department proposes to add a definition at N.J.A.C. 8:51A-1.3 for “micrograms per deciliter” in order to improve the readability of the chapter. Accordingly, throughout the chapter, the Department proposes to abbreviate the term “micrograms per deciliter” to “µg/dL.” The Department proposes to amend N.J.A.C. 8:51A-1.3 (“currently accepted medical guidelines”), 4.1(b), and 4.2(a), (b), (c), and (e) to change the reference value to a blood lead test result equal to or greater than five µg/dL in order to comport with the recommendations of the Advisory Committee.
As the Department has provided a 60-day comment period for this notice of proposal, this notice is excepted from the rulemaking calendar requirement, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

Lead is a heavy metal that has been widely used in industrial processes and consumer products. When absorbed into the human body, lead affects the brain, blood, kidneys, and nervous system. The effects of lead on the brain and nervous system are particularly serious and can cause learning disorders, developmental delays, hyperactivity, decreased hearing, and death. Research has shown that children under six years of age, especially children between six months and three years of age, are particularly sensitive to the adverse effects of lead exposure. Children who have suffered from the adverse effects of lead exposure may require special health and educational services in order to assist them to develop to their potential as productive members of society.

The Department anticipates that the proposal to reduce the reference value from 10 µg/dL to five µg/dL would have a positive social impact. While the proposed amendments would not change the number of children being screened, the Department estimates that an additional 4,000 children would be identified per year as having elevated blood lead levels under the new standard. This would lead to risk reduction education and nutritional counseling being provided to the parents and guardians of at-risk children sooner, thus, leading to healthier outcomes. Since the best health practice concerning lead exposure is to prevent it, risk reduction education being provided to more people would have a positive social impact.
Economic Impact

The proposed amendments would not result in additional children being tested, so the costs of lead screening would not change as a result of the proposed amendments. The Department estimates that the cost range of an individual blood lead screening is $10.00 to $75.00. According to a report from the New Jersey Department of the Public Advocate concerning the economic impact of reducing lead exposures, the “… net societal benefits arising from these improvements in high school graduation rates and reductions in crime would amount to $31,000 per child”; moreover, “(T)he New Jersey State budget would realize benefits of $14,000 per student and $9 billion across the entire cohort of children aged up to six years. These savings apply only to the present cohort of children aged up to six years. We would expect savings to increase as additional cohorts of children are born in New Jersey.” Source: Muennig P, Bao P., The social costs of childhood lead exposure in New Jersey, New Jersey Department of the Public Advocate, December 2009. http://leadpoisoninfo.com/pressreleases/NJ_Lead_Report_Final-5.pdf.

The costs of lead screening are more than offset by the economic benefits resulting from reducing blood lead levels in children and from preventing the serious medical and developmental consequences of elevated blood lead levels.

Federal Standards Statement

The only Federal regulation governing lead screening of children is a requirement of the U.S. Department of Health and Human Services that applies only to children enrolled in Medicaid and requires such children to be screened at 12 and 24 months, or between 36 and 72 months in the case of a child who has not been previously
screened. The current rules are as protective as the Federal rules. Accordingly, N.J.A.C. 8:51A would continue to govern lead screening for non-Medicaid enrolled children in New Jersey. The proposed amendments are as protective as Federal recommendations regarding childhood lead screening. The Department’s proposal to adopt a reference level of five µg/dL as the threshold for clinicians to provide education and to recommend follow up screenings is consistent with the CDC position expressed in the publication “CDC Response to Advisory Committee on Childhood Lead Poisoning Prevention Recommendations in ‘Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention’,” by the Centers for Disease Control and Prevention.

**Jobs Impact**

The implementation of the proposed amendments would not increase the number of blood lead screening tests performed by New Jersey licensed clinical testing laboratories. Accordingly, the Department believes that the proposed amendments would not result in the creation or loss of any jobs.

**Agriculture Industry Impact**

The proposed amendments would not have an impact on the agriculture industry of the State.

**Regulatory Flexibility Analysis**

The proposed amendments do not impose any new requirements on health care providers, many of which may be small businesses as defined under the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. All costs associated with lead screening will be covered by the fees charged for screening, to be paid by the child’s parent or
guardian, by the insurance carrier covering the child, the Department, or the local health department. As the proposed amendments implement the requirements imposed on all health care providers by N.J.S.A. 26:2-137.2 et seq., which provides for no business-size related requirements or exemptions, none are provided in the proposed amendments.

**Housing Affordability Impact Analysis**

The proposed amendments would have an insignificant impact on the affordability of housing in New Jersey and there is an extreme unlikelihood that they would evoke a change in the average costs associated with housing because the proposed amendments would operate only to reduce the reference value for blood lead level screening from 10 µg/dL to five µg/dL.

**Smart Growth Development Impact Analysis**

The proposed amendments would have an insignificant impact on smart growth and there is an extreme unlikelihood that they would evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan in New Jersey because the proposed amendments would operate only to reduce the reference value for blood lead level screening from 10 µg/dL to five µg/dL.

**Full text** of the proposal follows (additions indicated in boldface thus; deletions indicated in brackets [thus]):

SUBCHAPTER 1. GENERAL PROVISIONS

8:51A-1.1 Scope and applicability
The rules in this chapter apply to physicians, registered professional nurses, as appropriate, and licensed health care facilities that provide services to children [under six years] less than 72 months of age, and to licensed clinical laboratories that perform blood lead testing.

8:51A-1.2 Purpose

The purpose of this chapter is to protect children [under six years] less than 72 months of age from the toxic effects of lead exposure by requiring lead screening pursuant to N.J.S.A. 26:2-137.2 et seq. (P.L. 1995, [c.328] c. 328).

8:51A-1.3 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Anticipatory guidance" means the provision of information regarding the major causes of elevated blood lead [poisoning] levels and the means of preventing lead exposure to parents or guardians of children [under six years] less than 72 months of age.

"Commissioner" means the Commissioner of the New Jersey Department of Health [and Senior Services].

"Confirmed elevated blood lead” means a blood lead test result on a venous blood sample equal to or greater than [10] five micrograms per deciliter (µg/dL) of whole blood.
“Currently accepted medical guidelines” means that version of guidelines for the medical treatment of children with elevated blood lead poisoning levels most recent to the time of evaluation, treatment, and follow-up, published by a public health agency other than the Department, or recognized medical professional organization or agency, including the United States Centers for Disease Control and Prevention, the New Jersey Physicians Lead Advisory Committee, and the American Academy of Pediatrics.

“Department” means the New Jersey Department of Health [and Senior Services].

“Elevated blood lead” means a blood lead test result, from either a venous or capillary sample, equal to or greater than [10] five micrograms per deciliter (µg/dL) of whole blood.

“Micrograms per deciliter” or “µg/dL” means a unit of measure to express the ratio of millionths of a gram of lead in one-tenth of a liter of whole blood.

SUBCHAPTER 2. SCREENING
8:51A-2.1 Periodic Environmental Assessment and anticipatory guidance
(a) Every physician, registered professional nurse, as appropriate, or health care facility that provides health care services to a child who is at least six months of age, but [under six years] less than 72 months of age, shall:

1. – 2. (No change.)
3. Provide the parent or guardian of each child with anticipatory guidance on [lead poisoning prevention] preventing elevated blood lead levels.

8:51A-2.2 Lead screening schedule
(a) Every physician, registered professional nurse, as appropriate, or health care facility, unless exempt pursuant to N.J.A.C. 8:51A-2.3, shall perform lead screening on each patient who is [between] at least six months and [six years] less than 72 months of age according to the following schedule:

1. (No change).

2. For children found to be at high risk for lead exposure, as determined by the risk assessment performed pursuant to N.J.A.C. 8:51A-2.1:
   i. (No change.)
   
   ii. Each child [between] at least six months and [six years] less than 72 months of age shall be screened when the risk assessment indicates exposure to a new high dose source of lead since the last time that he or she was screened.
Examples of a new high dose source include, but are not limited to, a recent renovation of the child's residence (if built before 1960 or if lead-based paint is known to be present), deterioration of the paint in the child's residence, moving into a house built prior to 1960 that has peeling, chipping, or deteriorated paint, or an adult living in the household undertaking a new job or hobby that involves exposure to lead.

3. Each child older than 26 months of age but less than [six years] 72 months of age shall be screened if the child has never previously been screened for [lead poisoning] elevated blood lead levels.
SUBCHAPTER 3. SPECIMEN COLLECTION AND LABORATORY TESTING

8:51A-3.1 Specimen collection

(a) Screening for elevated blood lead [poisoning] levels shall be by blood lead test.

(b) - (c) (No change.)

SUBCHAPTER 4. FOLLOW-UP OF LEAD SCREENING RESULTS

8:51A-4.1 Reporting of lead screening results

(a) Each physician, registered professional nurse, as appropriate, or health care facility that screens a child for elevated blood lead [poisoning] levels shall provide the parent or legal guardian with the results of the blood lead test and an explanation of the significance of the results.

(b) For each child who has a blood lead test, on a venous blood sample, greater than or equal to [10] five micrograms per deciliter, the physician, registered professional nurse, as appropriate, or health care facility shall notify in writing, the child's parent or guardian of the test results and provide the parent or guardian with an explanation in plain language of the significance of the results.

8:51A-4.2 Medical follow-up of lead screening results

(a) Each physician, registered professional nurse, as appropriate, or health care facility that screens a child for elevated blood lead [poisoning] levels shall provide or make reasonable efforts to ensure the provision of risk reduction education and
nutritional counseling for each child with a blood lead level equal to or greater than [10 micrograms per deciliter (10 µg/dL)] of whole blood.

(b) The physician, registered professional nurse, as appropriate, or health care facility shall obtain, or make reasonable efforts to obtain, a venous confirmatory blood lead test whenever a capillary blood lead screening sample produces a result greater than or equal to [10 micrograms per deciliter (10 µg/dL)].

(c) For each child who has a blood lead level of [10 micrograms per deciliter (10 µg/dL)] or greater on a test performed with a venous blood sample, the physician, registered professional nurse, as appropriate, or health care facility shall provide, or make reasonable efforts to ensure, the provision of diagnostic evaluation, medical treatment, and follow-up blood lead testing in accordance with currently accepted medical guidelines.

(d) (No change.)

(e) When a physician, registered professional nurse, as appropriate, or health care facility performs lead screening on a child and receives a result of [10 micrograms per deciliter (10 µg/dL)] or greater on a test performed with a venous blood sample, the physician, registered professional nurse, as appropriate, or health care facility shall perform lead screening of all siblings or other members of the same household who are between six months and six years [less than 72 months] of age, if these children have not been screened previously, or are at high risk for lead exposure, as determined by a PEA performed in accordance with N.J.A.C. 8:51A-2.1.