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HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF FAMILY HEALTH SERVICES

Child and Adolescent Health Program

Screening of Children for Blood Lead at or Above the Blood Lead Reference Value

Proposed Readoption with Amendments: N.J.A.C. 8:51A

Authorized By: Kaitlan Baston, MD, MSc, DFASAM, Commissioner, Department of Health (in consultation with the Public Health Council).

Authority: N.J.S.A. 26:2-137 et seq., particularly 26:2-137.7.

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

Proposal Number: PRN 2024-051.

Submit electronic comments to http://www.nj.gov/health/legal/ecomments.shtml, or written comments to the address below, by July 5, 2024, to:

Kimberly E. Jenkins, Administrative Practice Officer

Office of Legal and Regulatory Compliance

Office of the Commissioner

New Jersey Department of Health

PO Box 360

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The agency proposal follows:

Summary

N.J.S.A. 26:2-137 et seq. (P.L. 1985, c. 84) (the Act), which became effective on March 25, 1985, established the Department of Health's 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 Act directs the Department of Health (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. 26:2-137.4.e and 137.7. Accordingly, the Department promulgated N.J.A.C. 8:51A. The Department proposes to readopt and amend the rules at N.J.A.C. 8:51A, as described below. N.J.A.C. 8:51A was scheduled to expire on December 7, 2025, in accordance with N.J.S.A. 52:14B-5.1.c. As the Department filed this notice of readoption prior to that date, the expiration date is extended 180 days to June 5, 2026, pursuant to N.J.S.A. 52:14B-5.1.c(2).

The proposed amendments would continue to provide the regulatory framework to fulfill the Department's obligation to protect children from adverse health effects due to exposure to lead hazards in their homes and in the environment. The proposed amendments discussed below would also continue to protect children that have been identified with elevated blood lead levels from further exposure to lead hazards.

Following is a summary of the rulemaking history of N.J.A.C. 8:51A:

Chapter 51A, Screening of Children for Lead Poisoning, was adopted effective December 1, 1997. See: 29 N.J.R. 990(a); 5081(a). Chapter 51A, Screening of Children for Lead Poisoning, expired on May 30, 2003. Chapter 51A, Screening of Children for Lead Poisoning, was adopted as new rules effective December 19, 2005. See: 36 N.J.R. 5068(a); 37 N.J.R. 4963(a). In accordance with N.J.S.A. 52:14B-5.1b, Chapter 51A, Screening of Children for Lead Poisoning, was scheduled to expire on June 17, 2013. See: 43 N.J.R. 1203(a). Chapter 51A, Screening of Children for Lead Poisoning, was readopted effective June 14, 2011. See: 43 N.J.R. 118(a); 1591(c). Chapter 51A, Screening of Children for Lead Poisoning, was renamed Screening of Children for Elevated Blood Lead Levels, effective September 18, 2017. See: 48 N.J.R. 2571(a); 49 N.J.R. 3219(a). Chapter 51A, Screening of Children for Lead Poisoning, was readopted effective December 7, 2018. See 50 N.J.R. 1526(a); 51 N.J.R. 83(a).

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 3.5 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 CDC concurred in principle with this recommendation. Accordingly, the Department is proposing to lower the reference value at N.J.A.C. 8:51A to 3.5 µg/dL, consistent with current CDC guidance, and this is the primary impetus behind the proposed amendments.

Following is a summary of the proposed amendments:

Throughout the chapter, to be consistent with current CDC guidance, the Department proposes to replace the term “elevated blood lead” with the term “blood lead reference value” or “at or above the blood lead reference value” as the context may require, except where the term is used as an historical reference or in the name of an official publication. At N.J.A.C. 8:51A-1.3, in order to comport with the current recommendations of the CDC, the Department proposes to delete the definition of “elevated blood lead” and replace it with the term “blood lead reference value,” which is defined as a blood lead test result, from either a venous or capillary sample, at or above 3.5 µg/dL of whole blood. The Department proposes to amend the definition of “anticipatory guidance” by replacing the term “elevated blood lead levels” with the term “at or above the blood lead reference value.” The Department proposes to amend the definition of the term “confirmed elevated blood lead” by replacing it with the term “confirmed blood lead reference value” and defining it as a blood lead test result on a venous blood sample at or above 3.5 µg/dL of whole blood. The Department also proposes to amend the definition of “currently accepted medical guidelines” by replacing

reference to “elevated blood lead levels” with “at or above the blood lead reference value.” Similarly, the Department proposes to amend the definition of “environmental follow-up” by replacing reference to “elevated blood lead” with “at or above the blood lead reference value.”

The Department also proposes to amend N.J.A.C. 8:51A-2.1(a)1 and 3, 2.2(a)3, 3.1(a), 4.1(a) and (b), and 4.2(a), (b), (c), and (e), to change the reference value from five µg/dL to a blood lead test result at or above 3.5 µg/dL in order to comport with the current CDC recommendations.

There are no proposed changes to the following subchapters and/or sections of Chapter 51A.

Subchapter 1 sets forth the general provisions of the chapter.

Subchapter 2 sets forth the screening regulations.

Subchapter 3 sets forth the specimen collection and laboratory testing rules.

Subchapter 4 sets forth the requirements for follow-up screening of lead screening results.

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 to assist them to develop to their potential as productive members of society.

The Department anticipates that the change to reduce the reference value from five µg/dL to 3.5 µg/dL would have a positive social impact. While the proposed amendment 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 blood lead at or above the blood lead reference value pursuant to 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. As 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 rules proposed for readoption with amendments would not result in additional children being tested, so the costs of lead screening would not change as a result of this rulemaking. The Department estimates that the cost range of an individual blood lead screening is between $10.00 and $75.00. According to the publication, "the social costs of childhood Lead Exposure in the Post-Lead Regulation Era," September, 2009, the “… net societal benefits arising from these improvements in high school graduation rates and reductions in crime would amount to $50,000 per child” across the

entire cohort of children aged zero to six years. These savings apply only to the present cohort of children aged zero to six years. We would expect savings to increase as additional cohorts of children are born in New Jersey." Source: Muennig P. Lead Exposure in the Post-Lead Regulation Era, September 2009. https://jamanetwork.com/journals/jamapediatrics/fullarticle/382153.

The costs of lead screening are more than offset by the economic benefits resulting from reducing blood lead in children and preventing the serious medical and developmental consequences of blood lead at or above the blood lead reference value.

Federal Standard 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 existing 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 rulemaking to adopt a reference value of 3.5 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'," and the CDC's current guidance.

Jobs Impact

The implementation of the rules proposed for readoption with amendments would not increase or reduce 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 Statement

The rules proposed for readoption with amendments would not have an impact on the agriculture industry of the State because the existing rules do not, and the proposed amendments would not, apply to or affect the agriculture industry.

Regulatory Flexibility Statement

The rules proposed for readoption with amendments do not impose any new requirements on health care providers, many of which may be small businesses as defined pursuant to 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. The rules proposed for readoption with amendments implement the requirements imposed on all health care providers pursuant to N.J.S.A. 26:2-137.2 et seq., which does not provide for any business-size related requirements or exemptions, and no such requirements or exemptions are provided in the proposed amendments.

Housing Affordability Impact Analysis

The rules proposed for readoption with 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 screening from five µg/dL to 3.5 µg/dL.

Smart Growth Development Impact Analysis

The rules proposed for readoption with 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, pursuant to the State Development and Redevelopment Plan in New Jersey because the proposed rulemaking would operate only to reduce the reference value for blood lead level screening from five µg/dL to 3.5 µg/dL.

Racial and Ethnic Community Criminal Justice and Public Safety Impact

The Department has evaluated this rulemaking and determined that the rules proposed for readoption with amendments will not have an impact on pretrial detention, sentencing, probation, or parole policies concerning adults and juveniles in the State. Accordingly, no further analysis is required.

Full text of the rules proposed for readoption may be found in the New Jersey Administrative Code at N.J.A.C. 8:51A.

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

CHAPTER 51A

SCREENING OF CHILDREN FOR [ELEVATED] BLOOD LEAD [LEVELS] **AT OR ABOVE THE BLOOD LEAD REFERENCE VALUE**

SUBCHAPTER 1. GENERAL PROVISIONS

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 [levels] **at or above the blood lead reference value** and the means of preventing lead exposure to parents or guardians of children less than 72 months of age.

…

"Blood lead reference value" means a blood lead test result, from either a venous or capillary sample, at or above 3.5 micrograms per deciliter (µg/dL) of whole blood.

…

"Confirmed [elevated] blood lead **reference value**" means a blood lead test result on a venous blood sample [equal to or greater than five micrograms per deciliter] **at or above 3.5** [(]µg/dL[)] of whole blood.

"Currently accepted medical guidelines" means that version of guidelines for the medical treatment of children with [elevated] blood lead [levels] **at or above the blood lead reference value** 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.

…

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

“Environmental follow-up” means actions taken by a local health department to identify and remediate lead hazards in the environment of a child with [elevated] blood lead **at or above the blood lead reference value** in accordance with Chapter XIII of the New Jersey State Sanitary Code, N.J.A.C. 8:51, as amended and supplemented.

…

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 less than 72 months of age, shall:

1. Inquire if the child has been appropriately assessed and screened for [elevated] blood lead [levels] **at or above the blood lead reference value** in accordance with this chapter;

2. (No change.)

3. Provide the parent or guardian of each child with anticipatory guidance on preventing [elevated] blood lead [levels] **at or above the blood lead reference value**.

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 at least six months [and] **but** less than 72 months of age according to the following schedule:

1.-2. (No change.)

3. Each child older than 26 months of age but less than 72 months of age shall be screened if the child has never previously been screened for [elevated] blood lead [levels] **at or above the blood lead reference value**.

SUBCHAPTER 3. SPECIMEN COLLECTION AND LABORATORY TESTING

8:51A-3.1 Specimen collection

(a) Screening for [elevated] blood lead [levels] **at or above the blood lead reference value** 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 [levels] **at or above the blood lead**

reference value 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 five micrograms per deciliter] **at or above the blood lead reference value**, 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 [levels] **at or above the blood lead reference value** 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 5 µg/dL] **at or above the blood lead reference value** 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 5 µg/dL] **at or above the blood lead reference value**.

(c) For each child who has [a] blood lead [level of 5 µg/dL or greater] **at or above the blood lead reference value** 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 5 µg/dL or greater] **at or above the blood lead reference value** 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 at least six months [and] **but** 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.