

HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF FAMILY HEALTH SERVICES

CHILD AND ADOLESCENT HEALTH PROGRAM

Screening of Children for Elevated Blood Lead Levels

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

Authorized By: Shereef Elnahal, M.D., M.B.A., 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 2018-062.

Submit electronic comments to <http://www.nj.gov/health/legal/ecomments.shtml>, or written comments to the address below, by September 14, 2018, 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. See N.J.S.A. 26:2-137.4. The Act 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. See N.J.S.A. 26:2-137.4e and 137.7.

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

On December 1, 1997, the Department promulgated rules at N.J.A.C. 8:51A to implement the enabling statute. (29 N.J.R. 990(a); 5081(a)) Although the Department filed a notice of proposal to readopt the chapter without change prior to the December 1, 2002 expiration date, the Department failed to take timely action on the adoption, and N.J.A.C. 8:51A expired on May 30, 2003. (34 N.J.R. 4285(b))

On November 15, 2004, the Department proposed N.J.A.C. 8:51A as new rules, which were identical in substance to the rules previously in effect. (36 N.J.R. 5068(a)) The new chapter was adopted with substantive and technical changes not requiring additional public notice and comment on November 14, 2005. (37 N.J.R. 4963(a)) New

N.J.A.C. 8:51A became effective on December 19, 2005, and was scheduled to expire on December 19, 2010.

Prior to the expiration date, the Department filed with the Office of Administrative Law (OAL) a notice to readopt N.J.A.C. 8:51A without change. (43 N.J.R. 118(a)) On June 6, 2011, the Department readopted N.J.A.C. 8:51A without change. (43 N.J.R. 1591(c))

The existing chapter was scheduled to expire on June 14, 2018, pursuant to N.J.S.A. 52:14B-5.1. As the Department submitted this notice of proposal to the OAL prior to that date, the expiration date is extended 180 days to December 11, 2018, pursuant to N.J.S.A. 52:14B-5.1.c(2).

A summary of the rules proposed for readoption with amendments follows:

N.J.A.C. 8:51A-1.1 would continue to prescribe the scope and applicability of the chapter and to describe the entities subject to its provisions. The Department proposes to amend N.J.A.C. 8:51A-1.1 by adding language that would include facilities that perform blood lead testing using tests approved for waiver under the New Jersey Clinical Laboratory Improvement Act (CLIA), found at N.J.S.A. 45:9-42.27 et seq., within the scope applicability of the chapter. N.J.A.C. 8:51A-1.2 would continue to prescribe the chapter's purpose. N.J.A.C. 8:51A-1.3 would continue to establish the defined terms of the chapter. The Department proposes to add a new definition for "CLIA" to N.J.A.C. 8:51A-1.3, which would recognize the acronym as shorthand for the New Jersey Clinical Laboratory Improvement Act (CLIA), found at N.J.S.A. 45:9-42.27 et seq.

N.J.A.C. 8:51A-2.1 would continue to prescribe the requirements for screening, including requirements for a Periodic Environmental Assessment for children and the

provision of anticipatory guidance to the parents on preventing elevated blood lead levels. N.J.A.C. 8:51A-2.2 would continue to prescribe the lead screening schedule. N.J.A.C. 8:51A-2.3 would continue to prescribe exemptions from screening, such as in the case of a health care provider or facility that does not have the capability to inform the parents or guardians of the blood test result and to ensure follow-up treatment and it also prescribes provisions for referral to another provider to perform the screening and for parental refusal.

N.J.A.C. 8:51A-3.1 would continue to prescribe the requirements for specimen collection and N.J.A.C. 8:51A-3.2 would continue to prescribe standards for laboratory testing. The Department proposes to amend N.J.A.C. 8:51A-3.2(a) to establish that this section would also apply to a facility that performs blood lead testing using tests approved for waiver under CLIA. The Department proposes to add a new N.J.A.C. 8:51A-3.2(c), which would require facilities that perform blood lead testing using tests approved for waiver under CLIA to report the results to the Department in the same manner as laboratory supervisors in accordance with N.J.A.C. 8:44-2.11.

N.J.A.C. 8:51A-4.1 would continue to establish the requirements for reporting of screening test results and N.J.A.C. 8:51A-4.2 would continue to prescribe standards for medical follow-up of elevated results. The Department proposes to delete a reference to “Chapter XIII of the New Jersey State Sanitary Code” at N.J.A.C. 8:51A-4.2(d). It is archaic and redundant because the existing subsection already contains an appropriate reference to N.J.A.C. 8:51.

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 rules proposed for readoption would continue to have the positive social impact of helping children who have been experiencing the adverse effects of lead exposure.

The main reason for these amendments to the rules proposed for readoption, N.J.A.C. 8:51A, is the adoption of the CLIA by the New Jersey Legislature, which became effective January 9, 2017. The Department anticipates that the incorporation of the CLIA into N.J.A.C. 8:51A will have the positive social impact of continuing to ensure that blood lead testing results are reported accurately and uniformly, which in turn ensures that case management services are provided in a timely fashion to children who have an elevated blood lead level.

Economic Impact

The rules proposed for readoption would not result in additional children being tested, so the costs of lead screening would not change as a result of the proposed readoption with 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 Department anticipates that the rules proposed for readoption would therefore have a positive economic impact to the State.

The proposed amendments to the rules proposed for readoption would permit CLIA waived tests to be conducted in non-traditional settings, such as in a doctor's office. The Department anticipates that the proposed amendments would help ensure accurate blood lead test reporting, which would in turn help more children with elevated blood lead levels. 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 rules proposed for readoption with amendments are as protective as Federal recommendations regarding childhood lead screening. A Federal standards analysis is not required.

Jobs Impact

The rules proposed for readoption with amendments would not increase or decrease the number of blood lead screening tests performed by New Jersey licensed clinical testing laboratories or CLIA-waived facilities. Accordingly, the Department believes that the rules proposed for readoption with amendments would not result in the creation or loss of any jobs.

Agriculture Industry Impact

The rules proposed for readoption with amendments would not have an impact on the agriculture industry of the State.

Regulatory Flexibility Analysis

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 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.

N.J.A.C. 8:51A-3.2 requires clinical laboratories to report blood lead testing results of all children under six years old to the Department. While the Department cannot calculate the particular costs of these requirements due to the varying impact of the requirements on each individual clinical laboratory, the Department would consider the reporting expense de minimus, particularly in light of the public health benefits. The Department notes that clinical laboratories may benefit financially from the requirement to perform lead screening analysis. The Department has determined that the reporting requirements provide a great benefit to the children of this State and that imposing different criteria for small businesses would jeopardize their health and welfare.

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 rules proposed for readoption with amendments would apply to

childhood lead screening and reporting required by licensed health care providers in the State. The proposed amendments would operate only to ensure that facilities that elect to perform CLIA-waived tests continue to report blood lead testing results to the Department.

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, under the State Development and Redevelopment Plan in New Jersey because the rules proposed for readoption with amendments require the screening of children for lead poisoning. The proposed amendments would operate only to ensure that facilities that elect to perform CLIA-waived tests continue to report blood lead testing results to the Department.

Racial and Ethnic Community Criminal and Public Safety Impact

The Department has evaluated this rulemaking and determined that it 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]):

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 less than 72 months of age, and to licensed clinical laboratories that perform blood lead testing **and to facilities that perform blood lead testing using tests approved for waiver under CLIA.**

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.

...

“CLIA” means the New Jersey Clinical Laboratory Improvement Act, found at N.J.S.A. 45:9-42.26 et seq.

...

SUBCHAPTER 3. SPECIMEN COLLECTION AND LABORATORY TESTING

8:51A-3.2 Laboratory testing

(a) All blood lead samples collected for lead screening in accordance with this chapter shall be sent for testing to a clinical laboratory licensed by the Department in accordance with N.J.A.C. 8:44-2, [as amended and supplemented] **or to a facility that**

performs blood lead testing using tests approved for waiver under CLIA.

(b) Laboratories shall report the results of blood lead testing to the Department in accordance with N.J.A.C. 8:44-2.11[, as amended and supplemented].

(c) Facilities that perform blood lead testing using tests approved for waiver under CLIA shall report the results of blood lead testing to the Department in the same manner as laboratory supervisors in accordance with N.J.A.C. 8:44-2.11.

SUBCHAPTER 4. FOLLOW-UP OF LEAD SCREENING RESULTS

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

(a)-(c) (No change.)

(d) To the extent permitted by New Jersey law regarding patient confidentiality, the physician, registered professional nurse, as appropriate, or health care facility shall cooperate with local health departments by providing information needed to ensure case management and environmental follow-up as specified in [Chapter XIII of the New Jersey State Sanitary Code,] N.J.A.C. 8:51[, as amended and supplemented].

(e) (No change.)