designated by the State Development and Redevelopment Plan as these State Planning Areas do not exist in the Pinelands Area.

Racial and Ethnic Community Criminal and Public Safety Impact

The Commission 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 proposal follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 6. MANAGEMENT PROGRAMS AND MINIMUM STANDARDS

PART VIII—WATER QUALITY

7:50-6.84 Minimum standards for point and non-point source discharges

(a) The following point and non-point sources may be permitted in the Pinelands:

1.-4. (No change.)

5. Individual on-site septic waste water treatment systems that are intended to reduce the level of nitrate/nitrogen in the waste water, provided that the following standards are met:

i.-iii. (No change.)

iv. The design of the system and its discharge point, and the size of the entire contiguous parcel on which the system or systems is located, will ensure that ground water exiting from the entire contiguous parcel or entering a surface body of water will not exceed two parts per million nitrate/nitrogen calculated pursuant to the Pinelands dilution model dated December, 1993, as amended, (Appendix A) subject to the provisions of (a)5v below and based on the following assumptions and requirements. For purposes of this section, the entire contiguous parcel may include any contiguous lands to be dedicated as open space as part of the proposed development but may not include previously dedicated road rights-of-way or any contiguous lands that have been deed restricted pursuant to N.J.A.C. 7:50-5.30 or 5.47:

(1) (No change.)

(2) For Amphidrome, Bioclere, and FAST systems:

(A)-(E) (No change.)

(F) The manufacturer or its agent shall provide to each owner an operation and maintenance manual and shall provide a five-year warranty consistent with the requirements of N.J.A.C. 7:50-10.22[(a)6viii]**(a)5viii**;

(G)-(J) (No change.)

(3) Other on-site septic waste water treatment systems shall only be credited with reducing total nitrogen concentration to the extent authorized by an experimental monitoring program approved by the Pinelands Commission. Such an experimental monitoring program shall only be approved if:

(A)-(E) (No change.)

(F) The system meets all the requirements in N.J.A.C. 7:50-10.22[(a)6i]**(a)5i** through x; and

(G) (No change.)

v.-ix. (No change.)

6. (No change.)

SUBCHAPTER 10. PILOT PROGRAMS

PART IV—ALTERNATE DESIGN TREATMENT SYSTEMS PILOT PROGRAM

7:50-10.22 General standards

(a) Alternate design pilot program treatment systems shall be authorized for residential use in all municipalities provided that the following standards are met:

1.-3. (No change.)

[4. The USEPA ETV or NSF/ANSI Standard 245 technologies approved by the Commission for participation in the pilot program pursuant to N.J.A.C. 7:50-10.23(b) are authorized to be installed until August 5, 2018.]

[5.] **4.** The Executive Director shall submit an annual report to the Commission describing installation, maintenance**,** and performance data for each technology. The Executive Director also shall submit an interim report to the Commission if it is determined there is a significant installation, maintenance**,** or performance issue with one or more technologies that needs to be addressed before the issuance of the next annual report. Copies of each annual and interim report shall be provided to each manufacturer and agent of a technology that is discussed in that report. If it is determined in a report either that a manufacturer or its agent is not adhering to any of the requirements of this pilot program or that any one of the technologies, based on maintenance or installation issues or on an evaluation of all the monitoring results for that technology under this pilot program, is not meeting the minimum water quality standards in N.J.A.C. 7:50-6.83 or the two parts per million total nitrogen requirement in [(a)6x] **(a)5x** below on all lots smaller than 3.2 acres or on lots smaller than a particular size because the effluent exiting the system is higher than was anticipated in establishing the lot sizes in (a)3 above:

i.-ii. (No change.)

[6.] **5.** Conditions for use of alternate design pilot program treatment systems are as follows:

i.-iv. (No change.)

v. The manufacturer or its agent **and a New Jersey licensed professional engineer** shall certify to the Commission and the local board of health that installation of each system has been properly completed and **that the system and all of its components are operating properly. The manufacturer or its agent** shall include in the certification the cost of the installation and a description of any problem encountered during the installation;

vi.-xiii. (No change.)

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

7:50-10.23 Pinelands Commission approval and evaluation

(a)-(g) (No change.)

[(h) Nothing in this section shall be construed to authorize the installation of any USEPA ETV and NSF/ANSI Standard 245 treatment technology approved by the Commission for participation in the pilot program after August 5, 2018 as set forth in N.J.A.C. 7:50-10.22(a)4, unless a rule has been adopted by the Commission that expressly authorizes such installation pursuant to (f) or (g) above.]

HEALTH

(a)

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/press releases/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.)