

Pursuant to the authority vested in the Commissioner of Health by Public Health Law sections 206(1)(n), 1370 and 1370-a, Subparts 67-1 and 67-3 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended, to be effective October 1, 2019, to read as follows:

Subdivision (e) of section 67-1.1 is amended to read as follows:

(e) "Elevated blood lead level" means a blood lead concentration equal to or greater than [10] 5 micrograms per deciliter of whole blood.

Paragraphs (8) through (10) of subdivision (a) of section 67-1.2 are amended to read as follows:

(8) Primary health care providers shall provide or make reasonable efforts to ensure the provision of risk reduction education and nutritional counseling for each child with an elevated blood lead level equal to or greater than [10] 5 micrograms per deciliter of whole blood.

(9) Primary health care providers shall confirm blood lead levels equal to or greater than [10] 5 micrograms per deciliter of whole blood obtained on a capillary specimen from a child using a venous blood sample.

(10) For each child who has a confirmed blood lead level equal to or greater than [15] 5 micrograms per deciliter of whole blood, primary health care providers shall provide or make reasonable efforts to ensure the provision of a complete diagnostic evaluation; medical treatment, if necessary; and referral to the appropriate local or State health unit for environmental management. A complete diagnostic evaluation shall include at a minimum: a detailed lead

exposure assessment, a nutritional assessment including iron status, and a developmental screening.

Section 67-3.3 is repealed.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) § 206 (1)(n) authorizes the Commissioner of Health to establish rules and regulations for the protection of the public health against lead poisoning. PHL § 1370 authorizes the New York State Department of Health (Department) to establish a blood lead level that constitutes an elevated lead level. As part of the New York State Fiscal Year (NYS FY) 2020 Enacted Budget, the Legislature amended PHL § 1370 to change the definition of “elevated lead levels” to a blood lead level equal to or greater than 5 micrograms per deciliter ($\mu\text{g}/\text{dL}$). PHL § 1370-a authorizes the Department to establish programs to prevent lead poisoning, including requirements for follow-up of children who have elevated blood lead levels.

Legislative Objective:

PHL sections 206(1)(n), 1370 and 1370-a charge the Department with regulating testing, reporting, follow-up and prevention of lead poisoning. This proposal implements that charge by updating the blood lead level that constitutes an elevated lead level, as well as the blood lead levels that trigger medical and environmental interventions, to reflect current understanding of the risks of lead poisoning to children and to meet the statutory mandate of the recently enacted amendment to the definition of “elevated lead level” in PHL § 1370.

Needs and Benefits:

Lead is a toxic metal that is harmful to human health if ingested or inhaled. Children under six years old are more likely to get lead poisoning than any other age group. Most often, children get

lead poisoning from breathing in or swallowing dust from old lead paint that gets on floors, window sills, hands, and toys. Children are at the greatest risk from lead exposure as scientists have linked lead exposure to reduced growth indicators; delayed puberty; lowered IQ; hyperactivity; attention, behavior, and learning problems; as well as other adverse health effects.

For these reasons, and to meet the statutory mandate of the recently enacted amendment to the definition of “elevated lead level” in PHL § 1370, the Department is proposing to change the definition of an elevated blood lead level from greater than or equal to 10 $\mu\text{g/dL}$, to greater than or equal to 5 $\mu\text{g/dL}$. This lowers the level at which primary health care providers must provide education and counseling on risk reduction and nutrition, complete a diagnostic evaluation, provide follow-up blood testing, and perform medical treatment and/or other activities. The local or State health departments must also ensure primary health care providers are performing the required activities and may assist with the delivery of these services, including providing education, counseling, and follow-up interventions.

Additionally, the Department is proposing to lower the level at which local or State health departments conduct environmental management activities to address lead sources, from a blood lead level greater than or equal to 15 $\mu\text{g/dL}$, to greater than or equal to 5 $\mu\text{g/dL}$. Environmental management activities include education, exposure assessment, inspection, and enforcement.

Compliance Costs:**Costs to Private Regulated Parties:**

The number of children with blood lead levels of 5 µg/dL or greater is larger than the number of children who have a blood lead level of 10 µg/dL or greater. Therefore, there will be an increase in the number of children (from approximately 3,000 children to an expected 18,200 per year) who will require education, counseling, diagnostic evaluation, and medical treatment from a primary health care provider. This will likely increase costs to the health care industry, including private and public insurers, as primary health care providers will likely bill for time spent providing education, counseling, diagnostic evaluation, and medical treatment to a greater number of children.

Also, lowering the blood lead level that triggers environmental management to 5 µg/dL will increase the number of properties that may need remediation to address lead exposures to children. Remediation actions may include replacing leaded components, covering lead paint with durable materials, removing lead paint, and stabilizing and maintaining defective lead paint. Since remediation can encompass a variety of different actions, the costs to an owner of a property that is determined, after an environmental investigation, to have condition(s) conducive to lead poisoning can range from approximately \$600 to \$10,000.

Costs to State Government and Local Government:

Current regulations require local and State health departments to implement measures to identify and provide case management for children with elevated blood lead levels. The number of children with blood lead levels of 5 µg/dL or greater is expected to be six times greater than the number of children with blood lead levels equal to or greater than 10 µg/dL, which will result in

a six-fold increase in the number of children in need of case coordination by local and State health departments. Case coordination typically includes ensuring primary health care providers are performing the required activities and assisting with the delivery of these services including providing education, counseling, and follow-up interventions at an estimated cost of \$713 per child. Because each county differs in population, the costs of the proposed amendment will vary by county.

In addition, lowering the blood lead level that triggers environmental management to 5 µg/dL will increase the number of environmental management activities that will need to be conducted by the local or State health departments. Environmental management activities include education, exposure assessment, inspection, and enforcement. The estimated number of children that may require environmental management activities is expected to increase statewide from approximately 1,100 to 18,200. It is estimated that local and State health departments spend \$2,123 per environmental investigation. However, as stated above, the costs to each local health department will depend on the number of children with elevated blood lead levels in each county.

Additionally, the State will fund a portion of the local health department costs through State Aid available pursuant to Article 6 of the Public Health Law. As part of the NYS FY 2020 Enacted Budget, approximately \$9,400,000 was invested to support local health department implementation of this proposal. In addition, approximately \$4,400,000 was invested to support costs to the State to implement this proposal.

Local Government Mandates:

Current regulations require the local and State health departments to implement measures to identify and provide case coordination to children with blood lead levels of 10 µg/dL or greater to ensure appropriate follow-up, and to provide environmental management activities for children with blood lead levels of 15 µg/dL or greater. The proposed amendments require that these services be provided to children with blood lead levels equal to 5 µg/dL or greater, which is a larger number of children.

Paperwork:

The proposed regulation will not impose any new paperwork. The current paperwork that is utilized when a child has an elevated blood lead level will continue to be used, however it is expected that there will be an increase in the volume of paperwork needed as the number of children with an elevated blood lead level will increase.

Duplication:

There will be no duplication of existing State or Federal regulations.

Alternatives:

No alternatives were considered with regard to changing the definition of an “elevated lead level” as this proposed regulation is a result of a statutory mandate. Additionally, no alternatives were considered for lowering the level at which primary health care providers must provide education and counseling on risk reduction and nutrition, complete a diagnostic evaluation,

provide follow-up blood testing, and perform medical treatment and/or other activities, as these activities occur when a child is determined to have an elevated lead level.

With regard to the blood lead level that triggers environmental management, leaving the blood lead level unchanged at 15 mcg/dL was considered. This option had the lowest associated cost but left a wide disparity in the number of children with blood lead levels considered elevated and those receiving environmental management. This option would result in approximately 16,200 children with an elevated blood lead level not receiving environmental management.

Another alternative that was considered was to provide environmental management at a blood lead level of 10 mcg/dL. This option would reach more children with an elevated blood lead level, but still results in approximately 13,500 children with an elevated blood lead level not receiving environmental management.

Consequently, lowering the blood lead level that requires environmental management activities to 5 mcg/dL was determined to be the most appropriate action. Matching the blood lead level that requires environmental management with the definition of an elevated blood lead level ensures that all children with an elevated blood lead level are receiving environmental management activities. Additionally, this change would harmonize State regulations with federal reference level as well as the activities and local requirements of a number of municipalities, standardizing responses across the State.

Federal Standards:

The Centers for Disease Control and Prevention currently has a recommended reference level of 5 µg/dL to identify if a child has an elevated blood lead level.

Compliance Schedule:

The proposed regulations will become effective October 1, 2019.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect on Small Business and Local Governments:

The proposed amendments will increase the number of children that have an elevated blood lead level (from approximately 3,000 children to an expected 18,200 per year). Therefore, primary health care providers will now be required to provide education, counseling, diagnostic evaluation, and medical treatment to a greater number of children. Many primary health care providers are small businesses.

The proposed amendments will also require local health departments to provide services at blood lead levels of 5 $\mu\text{g}/\text{dL}$ or greater, rather than 10 $\mu\text{g}/\text{dL}$ and 15 $\mu\text{g}/\text{dL}$ or greater, which will result in the local health department providing care coordination to a larger number of children, as well as conducting a greater number of environmental management activities.

Additionally, the proposed amendments will also affect small businesses that include landlords of residential rental properties, childcare facilities and any other small businesses where a child with an elevated blood lead level spends a significant amount of time. As a result of the anticipated increase in environmental investigations, more properties owned or leased by these small businesses will now be investigated by local health departments, and more small business owners will be required to remediate environmental lead hazards.

Compliance Requirements:

This proposal lowers the level at which primary health care providers must conduct education, counseling, diagnostic evaluation, and medical treatment, and at which local health departments must conduct care coordination, including ensuring primary health care providers are performing the required activities and assisting with the delivery of these services including providing education, counseling, and follow-up interventions. Similarly, it lowers the levels at which the local health departments must provide environmental management activities.

Reporting and Recordkeeping:

The proposed regulation will not impose any new reporting or paperwork. The current reporting and paperwork that is utilized when a child has an elevated blood lead level will continue to be used; however, it is expected that there will be an increase in the volume of reporting and paperwork needed as the number of children with an elevated blood lead level will increase.

Professional Services:

Some local health departments may hire additional professional staff to handle the increased number of children who require care coordination and environmental management activities, which may include nurses and lead risk assessors.

Compliance Costs:**Costs to Small Businesses:**

The number of children with blood lead levels of 5 µg/dL or greater is larger than the number of children who have a blood lead level of 10 µg/dL or greater. Therefore, there will be an increase in the number of children (from approximately 3,000 children to an expected 18,200 per year)

who will require education, counseling, diagnostic evaluation, and medical treatment. This will likely create increased costs to the health care industry.

Also, lowering the blood lead level that triggers environmental management to 5 µg/dL will increase the number of properties that may need remediation to address lead exposures to children. Remediations may include replacing leaded components, covering lead paint with durable materials, removing lead paint and stabilizing and maintaining defective lead paint. Since remediation can encompass a variety of different actions the costs to an owner of a property that is determined, after an environmental investigation, to have condition(s) conducive to lead poisoning can range from approximately \$600 to \$10,000.

Costs to Local Government:

Current regulations require local health departments to implement measures to identify and provide case management for children with elevated blood lead levels. The number of children with blood lead levels of 5 µg/dL or greater is expected to be six times greater than the number of children with blood lead levels equal to or greater than 10 µg/dL, which will result in a six-fold increase in the number of children in need of care coordination by local health departments. Case coordination typically includes ensuring primary health care providers are performing the required activities and assisting with the delivery of these services including providing education, counseling, and follow-up interventions at an estimated cost of \$713 per child. Because each county differs in population, the cost of the proposed amendment will vary by county.

In addition, lowering the blood lead level that triggers environmental management to 5 µg/dL will increase the number of environmental management activities that will need to be conducted by the local or state health departments. Environmental management activities include education, exposure assessment, inspection, and enforcement. The estimated number of children that may require environmental management activities would increase statewide from approximately 1,100 to 18,200. It is estimated that local health departments spend \$2,123 per environmental investigation. However, as stated above, the costs to each local health department will depend on the number of children with elevated blood lead levels in each county.

Additionally, the State will fund a portion of the local health department costs through State Aid pursuant to Article 6 of the Public Health Law. As part of the NYS FY 2020 Enacted Budget, approximately \$9,400,000 was invested to support local health department implementation of this proposal. In addition, approximately \$4,400,000 was invested to support costs to the State to implement this proposal.

Economic and Technological Feasibility:

Currently available technology is adequate to meet the proposal.

Minimizing Adverse Impact:

The State will be providing financial assistance, as stated above, to local governments to reduce the financial burden of this proposal.

Small Business and Local Government Participation:

Small business and local governments were consulted on this proposal. This proposal was included in the NYS FY 2020 Executive Budget. Additionally, the Department held a webinar to present the NYS FY 2020 Executive Budget proposals related to lead poisoning prevention to key stakeholders including members of the Advisory Council on Lead Poisoning Prevention as well as representatives of the New York State Association of County Health Officials, the Conference of Environmental Health Directors, Children's Environmental Health Centers of Excellence, Regional Lead Resource Centers, American Academy of Pediatrics, and the American College of Obstetricians and Gynecologists. The Department also convened the Advisory Council on Lead Poisoning Prevention, which was open to the public, to further discuss this proposal.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

The proposed amendments apply uniformly throughout the state, including rural areas.

Compliance Requirements:

This proposal lowers the level at which primary health care providers, including those in rural areas, must conduct education, counseling, diagnostic evaluation, and medical treatment, and at which local health departments must conduct care coordination, including ensuring primary health care providers are performing the required activities and assisting with the delivery of these services including providing education, counseling, and follow-up interventions. Similarly, it lowers the levels at which the local health departments must provide environmental management activities.

Reporting and Recordkeeping:

The proposed regulation will not impose any new reporting or paperwork. The current reporting and paperwork that is utilized when a child has an elevated blood lead level will continue to be used; however, it is expected that there will be an increase in the volume of reporting and paperwork needed as the number of children with an elevated blood lead level will increase.

Professional Services:

Some rural local health departments may hire additional professional staff to handle the increased number of children who require follow-up and environmental management activities, which may include nurses and lead risk assessors.

Costs to Rural Private Regulated Parties:

The number of children with blood lead levels of 5 µg/dL or greater is larger than the number of children who have a blood lead level of 10 µg/dL or greater. Therefore, there will be an increase in the number of children (from approximately 3,000 children to an expected 18,200 per year) who will require education, counseling, diagnostic evaluation, and medical treatment. This will likely increase costs to the health care industry, including private and public insurers, as primary health care providers will likely bill for time spent providing services to a greater number of children who have an elevated blood lead level.

Also, lowering the blood lead level that triggers environmental management to 5 µg/dL will increase the number of properties that may need remediation to address lead exposures to children. Remediation may include replacing leaded components, covering lead paint with durable materials, removing lead paint and stabilizing and maintaining defective lead paint. Since remediation can encompass a variety of different actions the costs to an owner of a property that is determined, after an environmental investigation, to have condition(s) conducive to lead poisoning can range from approximately \$600 to \$10,000.

Costs to Rural Local Government:

Current regulations require local health departments to implement measures to identify and provide case management for children with elevated blood lead levels. The number of children with blood lead levels of 5 µg/dL or greater is expected to be six times greater than the number of children with blood lead levels equal to or greater than 10 µg/dL, which will result in a six-fold increase in the number of children in need of care coordination by local health departments.

Case coordination typically includes ensuring primary health care providers are performing the required activities and assisting with the delivery of these services including providing education, counseling, and follow-up interventions at an estimated cost of \$713 per child. Because each county differs in population, the costs of the proposed amendment will vary by county.

In addition, lowering the blood lead level that triggers environmental management to 5 µg/dL will increase the number of environmental management activities that will need to be conducted by the local or state health departments. Environmental management activities include education, exposure assessment, inspection, and enforcement. The estimated number of children that may require environmental management activities is expected to increase statewide from approximately 1,100 to 18,200. It is estimated that local and State health departments spend \$2,123 per environmental investigation. However, as stated above, the costs to each local health department will depend on the number of children with elevated blood lead levels in each county.

Additionally, the State will fund a portion of the local health department costs through State Aid, pursuant to Article 6 of the Public Health Law. As part of the NYS FY 2020 Enacted Budget, approximately \$9,400,000 was invested to support local health department implementation of this proposal. In addition, approximately \$4,400,000 was invested to support costs to the State to implement this proposal.

Economic and Technological Feasibility:

Currently available technology is adequate to meet the proposal.

Minimizing Adverse Impact:

The State will be providing financial assistance, as stated above, to local governments to reduce the financial burden of this proposal.

Rural Area Participation:

Small business and local governments were consulted on this proposal. This proposal was included in the NYS FY 2020 Executive Budget. Additionally, the Department held a webinar to present the NYS FY 2020 Executive Budget proposals related to lead poisoning prevention to key stakeholders including members of the Advisory Council on Lead Poisoning Prevention as well as representatives with New York State Association of County Health Officials, the Conference of Environmental Health Directors, Children's Environmental Health Centers of Excellence, and Regional Lead Resource Centers. The Department also convened the Advisory Council on Lead Poisoning Prevention, which was open to the public, to further discuss this proposal.

**STATEMENT IN LIEU OF
JOB IMPACT STATEMENT**

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities. The Department believes this regulation will have a positive impact on jobs.