

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 512. CHILDHOOD LEAD POISONING PREVENTION RULES**

RULEMAKING ACTION:

Notice of proposed PERMANENT rulemaking

PROPOSED RULES:

Subchapter 1. General Provisions

310:512-1-3 [Amended]

310:512-1-4 [Amended]

Subchapter 3. Risk Assessment, Screening and Management

310-512-3-1 [Amended]

310-512-3-2.1 [Amended]

310-512-3-4.1 [Amended]

310-512-3-5 [Amended]

SUMMARY:

The purpose of the rule change is to align and comply with the change in the blood lead reference level from 5 micrograms per deciliter to 3.5 micrograms per deciliter, which became effective October 28, 2021, to add a small section that would allow flexibility for providers to test minors up to age 16 if they are part of a special high-risk population of recent refugees or immigrants. It also updates the level at which an environmental investigation is offered to families to help them determine the source of lead exposure from 20 micrograms per deciliter down to 10 micrograms per deciliter, allowing more families to receive this service to keep further detrimental effects of lead exposure and lead poisoning from affecting their family and to make some minor grammatical changes.

AUTHORITY:

Commissioner of Health; Title 63 O.S. § 1-104.

COMMENT PERIOD:

November 15, 2022 through the close of the Department's normal business hours, 5 PM, on December 15, 2022. Interested persons may informally discuss the proposed rules with the contact person identified below; or may, through the close of the Department's normal business hours, 5 PM, on December 15, 2022 submit written comment to the contact person identified below, or may, at the hearing, ask to present written or oral views.

PUBLIC HEARING:

Pursuant to 75 O.S. § 303(A), the public hearing for the proposed rulemaking in this chapter shall be on December 15, 2022 at the Oklahoma State Department of Health Auditorium, 123 Robert S. Kerr Avenue, Oklahoma City, Oklahoma 73102 from 9:30 AM to 12:30 PM. The meeting may adjourn earlier if all attendees who signed up to comment have completed giving their comments. The alternate date and time in the event of an office closure due to inclement weather is December 19, 2022 in the Auditorium, from 9:30 AM to 12:30 PM. Those wishing to present oral comments should be present at that time to register to speak. The hearing will close at the conclusion of those registering to speak. Interested persons may attend for the purpose of submitting data, views or concerns, orally or in writing, about the rule proposal described and summarized in this Notice. Validated parking will be provided for the parking lot located at the east corner of Broadway and Robert S. Kerr Avenue, subject to availability.

REQUESTS FOR COMMENTS FROM BUSINESS ENTITIES:

Business entities affected by these proposed rules are requested to provide the agency with information, in dollar amounts if possible, on the increase in the level of direct costs such as fees, and indirect costs such as reporting, recordkeeping, equipment, construction, labor, professional services, revenue loss, or other costs expected to be incurred by a particular entity due to compliance with the proposed rule. Business entities may submit this information in writing through December 15, 2022, to the contact person identified below.

COMMENT PERIOD:

COPIES OF PROPOSED RULES:

The proposed rules may be obtained for review from the contact person identified below or via the agency website at www.ok.gov/health.

RULE IMPACT STATEMENT:

Pursuant to 75 O.S., § 303(D), a rule impact statement is available through the contact person identified below or via the agency website at www.ok.gov/health.

CONTACT PERSON:

Audrey C. Talley, Agency Rule Liaison, Oklahoma State Department of Health, 123 Robert S. Kerr Avenue, Oklahoma City, OK 73102, phone (405) 426-8563, e-mail AudreyT@health.ok.gov.

INITIAL RULE IMPACT STATEMENT

(This document may be revised based on comment received during the public comment period.)

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 512. CHILDHOOD LEAD POISONING PREVENTION RULES

1. **DESCRIPTION:**

The two most recent surveys of the results of blood lead levels of the U.S. population of children ages 1-5 years who are in the highest 2.5% of children when tested for lead in their blood based on the 97.5 percentile of the National Health and Nutrition Examination Survey (NHANES) is used to determine the blood lead reference level or blood lead reference value. This level has changed from 5 micrograms per deciliter to 3.5 micrograms per deciliter based on these surveys. One of the services that families can receive from the Childhood Lead Poisoning Prevention Program is an environmental investigation to help them identify the source of lead exposure in the home. The level at which this benefit is offered before the rule change is when a child has a blood lead level of 20 micrograms per deciliter. This rule change allows the action level for the environmental investigation to be reduced to 10 micrograms per deciliter. Further, with the influx of refugee populations such as from Afghanistan, there are recommendations to test these children in special populations for lead in blood at ages up to 16 years since many use non-traditional products or have had exposures to lead prior to emigrating to the United States.

2. **DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:**

Updating the blood lead reference level or value allows the program to focus resources on children with the highest levels of lead in their blood compared with levels in most children in their same age range, to identify and eliminate sources of lead exposure and to make more prompt actions to mitigate or reduce the harmful effects of lead. It also supports the Oklahoma State Department of Health's commitment to health equity since the risk for lead exposure is biased with significant disparities in health outcome across racial and ethnic groups and people with different socioeconomic status. The highest blood lead levels are more prevalent in children who live in housing built before 1978, children from low-income households, and children from ethnic and racial minority groups. Some ethnic and racial minority groups are more likely to live in conditions with the greatest likelihood of exposure due to poor housing and environmental exposures such as those to lead in air, soil, and water.

3. **DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:**

The change in reference level or value will increase the number of families receiving case management services roughly by 165% (2120 children versus 801 children using 2019 numbers) in terms of increased support through telephone calls, educational information, and interventions. The change in the level at which an environmental investigation occurs will see roughly 420% (161 families versus 31) more families receive this valuable service. A large percentage of the children/families affected by elevated lead levels are disproportionately children from lower socioeconomic status or from ethnic and racial minority groups. The cost of a lead hazard inspection to determine the source of lead is cost-prohibitive and there are only twenty-five (25) certified lead risk assessors available for private hire based in Oklahoma. Helping families identify and ameliorate the source of lead exposure is extremely important to prevent further health detriments. Expected health outcomes: Intervention more promptly for more families to

reduce the long-term effects. Despite the overall decline of blood lead levels over time, lead exposure continues to remain a significant public health concern for many children because of persistent lead hazards in the environment and hand to mouth activity. Sources of lead include lead-based paint, lead service lines, lead in household plumbing material, soil contaminated by past sources such as automobile gasoline and hazardous waste sites. Young children may also become exposed through folk remedies, cultural products, consumer products, or through a parent or caregiver's hobby or occupation that involves lead.

4. ECONOMIC IMPACT, COST OF COMPLIANCE, AND FEE CHANGES:

No additional economic impact or cost of compliance, no additional staff/personnel or changes to budgets need to be made for compliance.

5. COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:

The agency already has two case managers who can take on the additional role of case management for children at the updated blood lead reference level. The program has four certified lead risk assessors able to conduct environmental investigations, and partners with grantees and tribal programs with their own separate funding and refers families to them, when appropriate, for environmental investigations. Lead testing is covered by Medicaid and most private insurance, families who are unable to pay have the cost covered by the program through funding already set aside to pay for testing. The average cost of an environmental investigation is \$100 in laboratory fees for sampling and takes approximately 2 hours to perform.

6. IMPACT ON POLITICAL SUBDIVISIONS:

There will be no impact on political subdivisions.

7. ADVERSE EFFECT ON SMALL BUSINESS:

There will be no impact on small businesses.

8. EFFORTS TO MINIMIZE COSTS OF THE RULE:

There are no less costly means currently identified.

9. EFFECT ON PUBLIC HEALTH AND SAFETY:

Lead poisoning often has no symptoms but protecting children from exposure to lead is important for lifelong good health. No safe blood lead level has been identified. Even very low levels have been shown to reduce a child's capacity to learn, ability to pay attention, and their academic achievement. Many of the effects to lead exposure can be permanent, however, when caught early, parents, healthcare providers, and communities can take actions to prevent further exposure and reduce damage to a child's health.

10. DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:

Fewer children will be identified/targeted without these changes in place, leading to an increase in long term costs in terms of special education, reduced lifetime productivity, earning potential, higher need for support from services such as special education, health care and spending on social assistance. According to the Altarum Institute and Robert Wood Johnson Foundation's Study-Value of Lead Prevention 2019, the total lifetime economic burden or childhood lead exposure in Oklahoma was \$944.5 million for children in the 2019 birth cohort.

11. PREPARATION AND MODIFICATION DATES:

This rule impact statement was prepared on August 1, 2022.

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 512. CHILDHOOD LEAD POISONING PREVENTION RULES**

SUBCHAPTER 1. GENERAL PROVISIONS

310:512-1-3. Lead poisoning prevention program

- (a) The Department maintains a lead poisoning prevention program. This program is responsible for establishing and coordinating activities to prevent lead poisoning and to minimize risk of exposure to lead.
- (b) The Department enforces rules for screening children for lead poisoning, and for follow-up of children who have elevated blood lead levels.
- (c) The Department may enter into interagency agreements to coordinate lead poisoning prevention, exposure reduction, identification and treatment activities and lead reduction activities with other federal, state and local agencies and programs.
- (d) The Department maintains a statewide surveillance system of all Oklahoma ~~children's~~ resident's blood lead levels provided such information is monitored as confidential except for disclosure for medical treatment purposes or disclosure of non-identifying epidemiological data.
- (e) The Department develops and implements public education and community outreach programs on lead exposure, detection and risk reduction.

310:512-1-4. Definitions

The following words or terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise:

"Advisory Council" means the Infant and Children's Health Advisory Council.

"Anticipatory guidance" means providing parents or guardians of children under the age of six with information regarding the major causes of lead poisoning and means of preventing lead exposure. Such guidance is to be pertinent to the environment of the child.

"Blood lead screening" refers to measuring lead concentration by capillary or venous blood collection to identify elevated blood lead levels.

"Case Management" refers to providing a collaborative process to assess, educate, coordinate, monitor, or evaluate options and services required to meet the child's environmental health and human service needs.

"CLIA" means the Clinical Laboratory Improvement Amendments. These amendments apply to the Federal Law that governs laboratories who examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of the health of human beings.

"Clinical Management Guidelines" means voluntary guidelines produced by the Department for clinical management and treatment decisions based on the initial or confirmed blood lead level.

"Confirmatory testing" refers to the collection of a venous blood sample to confirm an initial elevated capillary blood lead screening result. The collection of a capillary sample within 12 weeks to confirm an initial elevated capillary blood lead screening test result may be used if the initial capillary level is less than 10 µg/dL.

"Confirmed elevated blood lead level" refers to a concentration of lead in the blood taken from a venous sample which is above the reference level. It may also refer to a second capillary test as described in "confirmatory testing".

"Department" refers to the Oklahoma State Department of Health.

"Dwelling" refers to a building or structure, including the property occupied by and appurtenant to such dwelling, which is occupied in whole or in part as the home, residence or sleeping place of one or more human beings and without limiting the foregoing, includes child care facilities for children under six years of age, schools and nursery schools.

"Elevated blood lead level" means a concentration of lead in blood at or above the current reference level as defined by the Centers for Disease Control.

"Environmental investigation" means an on-site dwelling investigation to determine the existence, nature, severity, and location of lead or lead-based paint hazards, completed by a person licensed as a certified risk assessor by the Oklahoma Department of Environmental Quality.

"Follow-up" refers to actions by local health departments and health care providers that ~~may include~~ may include, depending on the blood lead level and exposure history of the child: risk reduction education, follow-up testing, confirmatory testing, medical evaluation, medical management, environmental investigation, and case management, in accordance with generally accepted medical standards and public health guidelines.

"Follow-up testing" refers to repeat blood lead testing by venous blood draw for any child with a previously confirmed elevated blood lead level.

"Health care provider" means any health professional or facility authorized to conduct blood lead screening. Health care provider includes, but is not limited to, physicians, physician assistants, advance practice registered nurses, city-county health departments, county health departments, medical clinics, medical offices, hospitals, and Head Start programs.

"High risk lead exposure" refers to any positive response on the LERAQ or other suitable risk assessment questionnaire.

"Laboratory" refers to any in-state CLIA approved laboratory or out-of-state CLIA approved laboratory providing blood lead testing for residents of Oklahoma. Laboratory may also refer to any entity using a point of care instrument for the purpose of blood lead testing of Oklahoma residents.

"LERAQ" refers to the Lead Exposure Risk Assessment Questionnaire which consists of a model set of questions developed by the Department to assess a child's risk of exposure to lead and includes information regarding areas of the state with ~~higher than average~~ higher-than-average risks for lead exposure.

"Low risk lead exposure" refers to negative responses to all questions on the LERAQ or other suitable risk assessment questionnaire.

"Person" means any natural person.

"Point-of-Care Instrument" refers to a blood lead testing device designed for the quantitative measurement of lead in fresh whole blood.

"Primary Health Care Provider" refers to any person or government entity that provides well child health care services, such as annual examinations and immunizations, to children under six years of age. Primary health care provider includes, but is not limited to, physicians, physician assistants, advance practice registered nurse, local health departments, medical clinics, medical offices, and hospital outpatient clinics.

"Program" refers to the Oklahoma Childhood Lead Poisoning Prevention Program (OCLPPP) of the Department.

"Reference Level" means a level of lead in the blood measured in micrograms per deciliter used to identify children with lead levels that are much higher than most children's lead levels. This level is based on the U.S. population of children ages 1-5 years who are in the highest 2.5% of children when tested for lead in their blood based on the 97.5 percentile of the National Health and Nutrition Examination Survey (NHANES) for the two most recent surveys. The reference level currently in use is ~~5~~ 3.5 micrograms per deciliter.

"Risk Assessment Questionnaire" means a set of questions designed to determine an individual's risk for lead exposure and lead poisoning, as approved by the Department and based on recommendations from the CDC.

"Satisfactory specimen" means a specimen collected using an appropriate procedure which is suitable in both blood quantity and quality to perform screening for Blood Lead measurement.

"Target population" refers to any infant or child, 6 months to 72 months of age.

"Unsatisfactory specimen" means a blood specimen which is not suitable in quality or quantity to perform blood lead measurements.

SUBCHAPTER 3. RISK ASSESSMENT, SCREENING AND MANAGEMENT

310:512-3-1. Risk assessment and screening criteria

- (a) All children in Oklahoma, 6 months to 72 months of age shall be assessed for blood lead exposure utilizing the risk assessment questionnaire as defined in paragraph (c) as part of each periodic health care visit occurring at age 6, 12, and 24 months and age 3 years, 4 years and 5 years.
- (b) All children in Oklahoma shall have a blood lead screening test as part of each periodic health care visit occurring at age 12 and 24 months of age or at any age after age 24 months up to age 72 months, if not previously tested for blood lead.
- (c) A risk assessment questionnaire based on recommendations from the CDC and approved by the Department before implementation should include questions related to the following:
 - (1) Does the child live in or frequently visit a home built before 1978?
 - (2) Does the child have a sibling or playmate with an elevated blood lead level?
 - (3) Is the child eligible for Medicaid, WIC, or Head Start?
 - (4) Does the child live with someone who has a job or hobby that may involve lead (example: jewelry making, building renovation or repair, working with automobile batteries, lead solder, or battery recycling)?
 - (5) Does the child eat or mouth trinkets or items that contain lead?
 - (6) Does the child live in an area identified as a ~~high-risk~~ high-risk target area by the Program?
- (d) A "Yes" or "Don't know" answer to the questions in paragraph (c) is considered a positive answer and requires the child to have a blood lead test.
- (e) The Department publishes available information regarding current high-risk high-risk target areas on its website located at: ~~http://p.health.ok.gov.~~ <https://oklahoma.gov/health/leadprevention>.
- (f) The Department publishes the LERAQ as an approved risk assessment questionnaire on its website.

310:512-3-2.1. Primary health care provider responsibilities for risk assessment and screening

- (a) Every primary health care provider who provides a periodic health care visit to a child at age 6, 12, and 24 months and age 3, age 4 and 5 years shall assess the child for risk of lead exposure using the LERAQ, or suitable risk assessment questionnaire approved by the Department.
- (b) For children at high risk for lead exposure according to the LERAQ, or suitable risk assessment questionnaire, the primary health care provider shall perform a blood lead test beginning at 6 months of age, or when initially assessed, if older.
- (c) Every primary health care provider who provides a periodic health care visit to a child shall order an initial capillary or venous blood lead screening test at age 12 and 24 months, or at any age after age 24 months up to age 72 months if never tested.
- (d) Every primary health care provider who provides a periodic health care visit to a child at age 6, 12, and 24 months and age 3, age 4, and 5 years shall:
 - (1) Give oral or written anticipatory guidance to a parent or guardian on prevention of childhood lead poisoning, including, at minimum, the information that children can be harmed by exposure to lead, especially deteriorating or disturbed lead-based paint and the dust from it, and are particularly at risk of lead poisoning from the time the child begins to crawl until 72 months of age; and
 - (2) Discuss the child's blood lead test results with the child's family and any necessary follow up.
- (e) Any health care provider who performs blood lead screening of a child who is six months of age to six years of age and who is not the child's ongoing primary health care provider shall forward the blood lead test result, if elevated at or above the reference level, to the child's primary health care provider.
- (f) If a parent or guardian refuses blood lead testing screening of their child, the health care provider shall have the parent or guardian indicate in writing this refusal in the child's medical record and provide a copy via mail or by fax to the Oklahoma Childhood Lead Poisoning Prevention Program.
- (g) Any health care provider working with a special population such as a recent refugee or immigrant from a country known to have a higher incidence or risk of lead exposure may consider blood lead screening up to age 16.

310:512-3-4.1. Health care provider responsibilities for follow-up after screening

- (a) Health care providers shall provide or make reasonable efforts to ensure the provision of confirmation and follow-up testing for each child with an elevated blood lead level above the reference level.
- (b) If the initial blood lead test result is below the reference level on either a venous or capillary sample, the health care provider shall retest the child annually if answers on the LERAQ or suitable risk assessment questionnaire indicate continuing high risk for lead exposure.
- (c) For each child who has an elevated blood lead level at or above the reference level, the health care provider shall take those actions that are reasonably and medically necessary and appropriate based upon the child's blood lead level to reduce, to the extent possible, the child's blood lead level below the reference level. Such actions may include the following:
 - (1) Education of a parent or guardian on lead hazards and lead poisoning;
 - (2) Clinical evaluation for complication of lead poisoning;
 - (3) Follow-up blood lead analyses as indicated based on level of elevation and period of time;
 - (4) Developmental screening;
 - (5) Referral to the Department for an environmental investigation for a single venous blood lead test result equal to or greater than ~~20~~ 10 µg/dL; and
 - (6) Chelation therapy should be considered and, when possible, a medical toxicologist, provider experienced in chelation therapy, or pediatric environmental health specialist should be consulted for a child with a blood lead test greater than 45 µg/dL.
- (d) If the initial capillary blood lead test result is elevated, the health care provider shall obtain a venous confirmation test in accordance with the Clinical Management Guidelines as established by the Department.
- (e) If the initial venous blood lead test result or the confirmation test is elevated, the health care provider shall obtain venous follow-up testing in accordance with the Clinical Management Guidelines as set forth by the Department.

310:512-3-5. Reporting requirements

(a) Laboratory.

- (1) Laboratories shall report the results of all blood lead tests performed on persons who are residents of Oklahoma to the Childhood Lead Poisoning Prevention Program. These reports are confidential and may be utilized only for the purpose of assuring service delivery, program administration, data analysis, and evaluation.
- (2) Federal CLIA regulations at Title 42, of the Code of Federal Regulations, Section 493.1241 (relating to standards for test requests), require that laboratory requisitions contain sufficient patient data that must include patient's name, sex, date of birth, date of collection, test(s) to be performed, the source of the specimen, name and address of person requesting the test, as well as "Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable." Laboratories shall report the following information to the Childhood Lead Poisoning Prevention Program by electronic data transmission: name, date of birth, sex, address, county of residence, type of sample (venous or capillary), blood lead level, health care provider ordering the test, laboratory identifiers, date the sample was collected, the date of analysis, and additional information already available such as race, ethnicity, Medicaid status and/or Medicaid Number. The laboratory receiving the sample from the health care provider taking the sample shall assure that the laboratory requisition slip is fully completed and includes the information required pursuant to the Subsection. In the event electronic submission is not available, lab reports must be submitted by a method and format approved by the Oklahoma Childhood Lead Poisoning Prevention Program.
- (3) Test results that are reported to the Childhood Lead Poisoning Prevention Program have the following time limits:

(A) Results of all blood lead levels less than the reference level at a minimum of a monthly basis.

(B) Results of all blood lead levels equal to or greater than the reference level at a minimum of a weekly basis and if possible daily.

(4) All clinical laboratories shall notify the health care provider ordering the blood lead test when the results of any analysis in a child up to 72 months of age is equal to or greater than ~~20~~ 10 $\mu\text{g/dL}$ within 24 hours of the date of the analysis.

(5) Nothing in this Subsection shall be construed to relieve any laboratory from reporting results of any blood lead analysis to the physician, or other health care provider who ordered the test or to any other entity as required by State, Federal or local statutes or regulations or in accordance with accepted standard of practice.

(b) Health care providers.

(1) All health care providers shall ensure that all of the information as specified in 310:512-3-5(b) (relating to standards for test requests), is completed for all blood lead analyses ordered and that this information accompanies the sample to the testing laboratory.

(2) On written or verbal notification of an elevated capillary lead level, equal to or greater than the reference level, the child's health care provider will obtain confirmatory testing.

(3) All health care providers shall notify the Childhood Lead Poisoning Prevention Program of any blood lead level in a child up to 72 months of age equal to or greater than the reference level within 1 week and equal to or greater than ~~20~~ 10 $\mu\text{g/dL}$ within 24 hours of having been notified of this result by the testing laboratory. The following information shall be provided when reporting: name, date of birth, sex, address, county of residence, type of sample (venous or capillary), blood lead level, health care provider ordering the test, laboratory identifiers, date the sample was collected and the date of analysis.

(4) Any health care provider utilizing a point-of-care instrument to test blood lead samples is required to report all such results, regardless of the level, to the Childhood Lead Poisoning Prevention Program, and follow the guidelines for reporting as stated in 310:512-3-5(a) (relating to laboratory reporting).

(5) Upon written notification of unsatisfactory specimens, the child's health care provider will obtain a repeat specimen.

(6) These reports are confidential and may be utilized only for the purpose of assuring service delivery, program administration, data analysis, and evaluation.