

ADMINISTRATIVE AGENCY RULE REPORT
75 O.S. Supp. 2000, § 303.1
SUBMITTED TO THE GOVERNOR AND TO THE LEGISLATURE

1. Date the Notice of Intended Rulemaking was published in the Oklahoma Register:
October 17, 2016, Vol. 34 Ok Reg 3, Docket No. 16-751

2. Name and address of the Agency:
Oklahoma State Department of Health
1000 N.E. Tenth Street
Oklahoma City, Oklahoma 73117-1299

3. Title and Number of the Rule:
Title 310. Oklahoma State Department of Health
CHAPTER 512. CHILDHOOD LEAD POISONING PREVENTION RULES

4. Citation to the Statutory Authority for the Rule:
Oklahoma State Board of Health, Title 63 O.S. § 1-104 and Title 63 O.S. § 1-114.1.

5. Brief Summary of the Content of the Adopted Rule:
This proposal designates the Infant and Children’s Health Advisory Council as the advisory body, replacing the legislatively struck lead poisoning advisory board; clarifies that the Oklahoma Childhood Lead Poisoning Prevention Program maintains a statewide surveillance system as opposed to a ‘registry’ of all children’s blood lead levels as opposed to only elevated blood lead levels; adds definitions and terms used in the updated rules to ensure that all terms are defined; removes definitions of terms that are no longer used; adds the term for the risk assessment questionnaire to refer to the document as the Lead Exposure Risk Assessment Questionnaire (LERAQ) and allows for an alternative risk assessment questionnaire; clarifies the appropriate ages and times for lead screening for children up to the age of 72 months; amends and renumbers sections where extensive rewrite occurs; defines the role of the health care provider in assessment and screening of children under the age of 72 months for lead exposure; clarifies process regarding a refusal by a parent or guardian for blood lead testing of their child; clarifies continuing follow-up requirements and health care provider responsibilities as they pertain to blood lead screening and aftercare; add language indicating the domain and responsibility among health care providers to follow screening requirements.

The proposal changes guidance that a capillary blood lead sample may be obtained for confirmation of an elevated blood lead level when a venous sample is not obtainable; venous sample testing is required for confirmation of blood lead concentration equal to or greater than 10 µg/dL; and adds information regarding the use of Point-of-Care instruments for on-site lead testing and clarifies that Point-of-Care instruments are not to be used to confirm elevated blood lead levels.

The proposal provides clarification regarding primary prevention, the use of chelation therapy, developmental screening and directs providers to the Oklahoma Childhood Lead Poisoning Prevention Program’s Clinical Management Guidelines which are available on the program’s

website.

The rule is amended to address the procedure and terms of blood lead screening reporting requirements to clearly state the method of reporting the results to the Oklahoma Childhood Lead Poisoning Prevention Program; clarifies procedures for reporting by providers who use the Point-of-Care devices for blood lead testing; promotes electronic reporting. Various amendments are provided for improved clarity in terminology and references.

6. Statement explaining the Need for the Adopted Rule:

Definition of reference values which identify the current level of blood lead that is used for case management and referrals was updated by the Centers for Disease Control and Prevention in May 2012. The changes align with those CDC revisions.

7. Date and Location of the Meeting at which such Rules Were Adopted:

Adopted December 13, 2016, in the offices of the Oklahoma State Department of Health.

8. Summary of the Comments and Explanation of Changes or Lack of any Change Made in the Adopted Rules as a Result of Testimony Received at Public Hearings:

None received

9. List of Persons or Organizations Who Appeared or Registered For or Against the Adopted Rule at Any Public Hearing Held by the Agency or Those Who Have Commented in Writing Before or After the Hearing:

None

10. Rule Impact Statement: Hereto annexed as Exhibit A.

11. Incorporation by Reference Statement:

"n/a"

12. Members of the Governing Board of the Agency Adopting the Rules and the Recorded Vote of Each Member:

Dr. Jenny Alexopoulos - Aye
Mrs. Martha Burger - Aye
Dr. Terry Gerard - Aye
Dr. Charles Grim - Aye
Dr. R. Murali Krishna - Aye
Mr. Timothy Starkey - Aye
Dr. Robert Stewart - Aye
Ms. Cris Hart-Wolfe - Aye
Dr. Ronald Woodson - Aye

13. Additional information: Information regarding this rule may be obtained by contacting Susan

Quigley, Administrative Programs Manager, Childhood Lead Poisoning Prevention Program, Oklahoma State Department of Health, 1000 N.E. 10th Street, Oklahoma City, OK 73117-1207; phone (405) 271-6711, e-mail susanq@health.ok.gov.

RULE IMPACT STATEMENT

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

1. DESCRIPTION:

This rule change will add amendatory language for Childhood Lead Poisoning Prevention in order to reflect current practice and modify terminology and definitions to coincide with current language used in the Oklahoma Childhood Lead Poisoning Prevention Program (OCLPPP).

- In May 2012, the Centers for Disease Control changed the blood lead level at which point certain actions should be initiated from 10 µg/dL to 5 µg/dL . See [CDC Response to Advisory Committee on Childhood Lead Poisoning Prevention Recommendations in “Low Level Lead Exposure Harms Children: A Renewed Call of Primary Prevention”](https://www.cdc.gov/nceh/lead/acclpp/cdc_response_lead_exposure_recs.pdf) (https://www.cdc.gov/nceh/lead/acclpp/cdc_response_lead_exposure_recs.pdf).
- The OCLPPP informally adopted this change in June 2012 and began offering follow-up services to children at the new lower level. However, sections of the rules regarding blood lead levels were last updated in 1994 and contain the older reference level. The current rules also have ambiguous language and outdated procedures and terms such as "environmental assessments" versus "environmental investigations."
- The most significant changes will be to update the definitions of elevated blood lead levels and to further clarify the role of the laboratories and providers in reporting lead results. Lead results are reportable pursuant to Title 63 O.S. Sections 1-114.1 and § 1-503 and the Reportable Disease Rules, OAC 310-515.
- The changes re-structure the order of some items to put them into more logical categories. This is part of OCLPPP's overall effort to make the rules more accessible, understandable, and usable without altering their sense, meaning, or effect. Some sections have been reclassified and rearranged in a more logical order, removing language that is invalid, repealed or duplicative to improve the draftsmanship of the rule. New technologies (Point-of-Care devices, electronic reporting capabilities) are incorporated to make screening and reporting easier.

2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:

- Individuals affected by proposed rule change include children less than 6 years of age, health care providers across Oklahoma, insurance companies regarding covering the cost for blood lead screenings and the Oklahoma State Department of Health regarding follow-up and management for children with elevated blood lead levels.
- Health care providers will have an increased responsibility to ensure all children receive a blood lead screen at 12 and 24 months of age (as is currently required under CMS rules for Medicaid providers), provide parent/guardian education and medical intervention for children with high blood lead levels.
- For every \$1 spent on lead poisoning prevention, \$17 to \$221 dollars are returned as health benefits, in the form of increased IQ, higher lifetime earnings, increased taxable earnings and tax revenue, reduced spending on special education, and reduced criminal activity.

- The health care system could save more than \$3,000 per child identified with high lead levels, if the source of lead exposure can be identified and removed prior to the need for chelation treatment.
- Public comment was sought to identify any unanticipated cost impacts. No comments were received.

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

- Persons who will benefit from the proposed rule include all children in the state of Oklahoma under the age of 72 months, their parents, as well as pediatricians and clinics who perform blood lead testing.
- Children with levels of 5 or more micrograms per deciliter will receive follow-up testing and verification of capillary blood screens based on the lowered criteria for rescreens and follow-up.
- Children who have already received a verified test result will receive follow-up at or above 5 micrograms per deciliter. This follow-up includes educational information, assistance in determining the source of lead exposure, and monitoring of continued follow-up testing until the levels are below 5 micrograms per deciliter.
- Earlier identification and removal of lead exposure source will reduce the likelihood of lasting damage caused by lead exposure. Damage includes loss of IQ points, behavioral problems, and damage to the nervous system and kidneys.

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

- It is estimated that approximately 700 more cases of screening tests at the level of action have been followed up with repeat screenings since implementing the recommended level to 5 micrograms per deciliter.
- OCLPPP spends approximately \$1,200 per month at the cost of \$10 per test to pay for testing for children not covered by Medicaid or private health insurance.
- OCLPPP has estimated the effect of compliance and economic impact and has compared the amount spent for lead testing in 2011 (prior to our change in practice regarding the new level of reference). In 2011, OCLPPP spent \$14,500 on blood lead testing. After implementation of the new level of concern, OCLPPP spent \$10,300 in 2013. This reduction is based mainly on a greater number of children who have been identified as at risk and receiving blood lead testing being covered by Medicaid and more children and families now eligible for the other health insurance. This represents a decrease in testing costs of nearly 33%.

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

The cost to the Department to implement the amendments will be approximately \$4,409.89 to cover the costs of rule drafting, adoption, publication, distribution, and education. The proposed rules will be implemented and enforced by existing Department personnel and will have no anticipated effect on state revenues.

6. IMPACT ON POLITICAL SUBDIVISIONS:

The proposed rules will have no anticipated effect or impact on political subdivisions.

7. ADVERSE EFFECT ON SMALL BUSINESS:

The implementation of the proposed rule should have no adverse economic effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act.

8. EFFORTS TO MINIMIZE COSTS OF RULE:

The costs of the rule have been kept to a minimum. Less costly alternatives do not exist and a rule change is required to ensure that all providers in the State of Oklahoma are aware of the changes in elevated lead levels for Oklahoma children and have easier to understand guidelines for follow-up testing.

9. EFFECT ON PUBLIC HEALTH AND SAFETY:

- As discussed above, early identification and intervention for children with elevated lead levels is a positive contribution to child health and will improve the core public health services for children in Oklahoma.
- High lead levels or even 'low' levels for an extended period of time can cause irreparable damage to health and behavior.
- These rule changes will clarify the change from a level once considered a 'reference level' of 10 or more micrograms per deciliter to an 'action level' of 5 micrograms per deciliter or above.

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

- In 2015, 367 children with blood lead levels in the range of 5 to 9 micrograms per deciliter and their parents received educational materials on the health hazards of elevated blood lead levels and methods of reducing lead exposures in the child's environment as well as recommendations for follow-up testing. Without a change in the "action level" to 5 micrograms per deciliter, children may not be identified for treatment and follow-up.
- The largest percentage of children with elevated lead levels fall in the category of lead levels from 5-9 micrograms per deciliter; (approximately 81% of all children with blood lead levels of 5 micrograms per deciliter or higher).
- Without adopting this change, funding opportunities based on need as well as the ability to offer follow-up and education to a greater amount of children at risk for lasting effects from lead exposure are greatly diminished.
- Official adoption of the Centers for Disease Control and Prevention's recommended elevated level of 5 micrograms per deciliter will ensure that Oklahoma is following the national recommended action level and offering services to more children and reducing their risk of lasting damage through intervention, prevention, and educational efforts.

11. This rule impact statement was prepared on January 26, 2016 and updated on September 16, 2016. Modifications made subsequent to the publication of the Notice of Rulemaking Intent were made on: none.

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

SUBCHAPTER 1. GENERAL PROVISIONS

310:512-1-1. Purpose

~~Under 63 O.S. 1991, Sections 1-114.1 the following rules are established concerning the screening of all Oklahoma children, ages 6 months to 72 months of age, for lead poisoning, designated by the Oklahoma State Board of Health. The rules in this Chapter establish procedures and standards for childhood lead screening, assessment, poison prevention, and reporting as authorized under the provisions of Title 63 O.S. Section 1-114.1.~~

310:512-1-2. Criteria

- (a) ~~The Oklahoma State Board of Health shall establish procedures for blood lead screening which shall include risk assessment, laboratory assays, sample collection, reporting, follow-up, and parent education. The Infant and Children's Health Advisory Council shall advise the Oklahoma State Board of Health on the establishment of rules for the prevention of childhood lead poisoning which shall include risk assessment, blood lead screening, laboratory assays, sample collection, reporting, lead hazard control, and rules related to the role of the provider such as: follow-up, diagnosis and treatment, developmental screening, referral for environmental assessments and lead hazard control, and parent education.~~
- (b) All health care providers shall comply with the following procedures for blood lead screening ~~established by the Oklahoma State Board of Health.~~
- (c) After sufficient statewide data collection and documented incidence of low lead exposure, the Commissioner of Health may exempt a community or county from universal lead screening.

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

- (a) The Department shall ~~establish~~ maintain a lead poisoning prevention program. This program shall be responsible for establishing and coordinating activities to prevent lead poisoning and to minimize risk of exposure to lead.
- (b) The Department shall ~~promulgate and~~ enforce 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 shall ~~establish~~ maintain a statewide ~~registry~~ surveillance system of ~~children with elevated lead levels~~ all Oklahoma children's blood lead levels provided such information is monitored as confidential except for disclosure for medical treatment purposes ~~and~~ or disclosure of non-identifying epidemiological data.
- (e) The Department shall develop and implement 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 ~~advisory council on lead poisoning prevention~~ 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 shall 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 '88" **"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 a blood lead concentration measured on venous blood 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 ~~thereof~~, 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 shall without limiting the foregoing, include child care facilities for children under six years of age, schools and nursery schools.

"Elevated blood lead level" means a ~~confirmed~~ concentration of lead of ~~10 micrograms (µg) per deciliter (dL) or greater~~ in blood at or above the current reference level as defined by the Centers for Disease Control.

"Environmental management investigation" ~~refers to on-site dwelling environmental investigation and exposure assessment, sampling for lead, environmental testing and reporting, notice of conditions conducive to lead poisoning, environmental intervention~~ 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 which, depending on the blood lead level and exposure history of the child, shall include as appropriate: risk reduction education, follow-up testing, confirmatory testing, medical evaluation, medical management, environmental ~~management~~ 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 ~~the Oklahoma State Department of Health Laboratory or a laboratory approved by the Oklahoma State Department of Health to conduct blood lead measurement~~ 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 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) lead poisoning prevention program in 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 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. ~~Federal CLIA '88 regulations require that the laboratory requisitions contain sufficient patient data that must include patient's name, date of birth, date of collection, test(s) to be performed, and name and address of person requesting the test.~~

"Submitter" any health care provider (primary and non-primary), hospital, physician, laboratory, or other facility that submits blood specimens for blood lead measurements.

"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. SPECIMEN RISK ASSESSMENT, SCREENING AND MANAGEMENT

310:512-3-1. Screening Parameters—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) and should have access to service which will assess the exposure to lead in their environment 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. An initial capillary or venous sample should be done at 12 months and 24 months of age, anytime the child has not had a baseline before the age of 72 months, or with any change in the child's assessment.~~

~~(b) A parent or guardian who refuses blood lead testing screening of their child shall also indicate in writing this refusal in the child's record. 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 is based on recommendations from the CDC and shall be approved by the Department prior to implementation. The questionnaire 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 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 current high risk target areas on its website located at: <http://pp.health.ok.gov>.~~

~~(f) The Department publishes the LERAQ as an approved risk assessment questionnaire on its website.~~

310:512-3-2. Screening criteria [REVOKED]

~~(a) For children at low risk for lead exposure, according to risk assessment questions, the health care provider should perform an initial blood lead test at 12 months of age, or when initially assessed if older.~~

~~(1) If the result is <10 $\mu\text{g}/\text{dL}$, the child should be retested at 24 months of age.~~

~~(2) If the result is between 10 – 19 $\mu\text{g}/\text{dL}$, the child should be retested every 3–4 months until two consecutive measurements are <10 $\mu\text{g}/\text{dL}$ or three consecutive measurements are <15 $\mu\text{g}/\text{dL}$. At this point, the child should be retested in one year.~~

~~(3) If the result is ≥ 20 $\mu\text{g}/\text{dL}$, retest every 3–4 months and individual case management should be provided.~~

~~(b) For children at high risk for lead exposure, according to risk assessment questions, the health care provider should perform an initial blood lead test at 6 months of age, or when initially assessed if older.~~

~~(1) If the result is $<10 \mu\text{g/Dl}$, the child should be retested every 6 months until two consecutive measurements are $<10 \mu\text{g/Dl}$ or three consecutive measurements are $<15 \mu\text{g/Dl}$. At this point, retested yearly, if the child remains at high risk for lead exposure.~~

~~(2) If the result is between $10-19 \mu\text{g/Dl}$, the child shall should be retested every 3-4 months until two consecutive measurements are $<10 \mu\text{g/Dl}$ or three consecutive measurements are $<15 \mu\text{g/Dl}$. At this point, retested yearly, if the child remains at high risk for lead exposure.~~

~~(3) If the result is $\geq 20 \mu\text{g/Dl}$, the child should be retested every 3-4 months and individual case management shall be provided.~~

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.

310:512-3-3. Blood collection-lead screening tests

(a) **Capillary sample for blood lead testing.** Capillary blood specimens are acceptable for initial blood lead screening if appropriate collection procedures are followed; to minimize the risk of environmental lead contamination. A capillary blood lead sample may be obtained for

confirmation of an elevated blood lead level less than 10 µg/dL when a venous sample is not obtainable.

(b) **Venous sample for blood lead testing.** Venous blood is the preferred specimen for blood lead analysis and should be used for lead measurement whenever practical. A venous sample is required for confirmation of blood lead concentration equal to or greater than 10 µg/dL and preferred for confirmation of an elevated blood lead level less than 10 µg/dL.

(c) **Point-of-Care instruments.** Point-of-Care instruments shall not be used to confirm elevated blood lead levels even if the sample is collected by venipuncture.

310:512-3-4. Providers screening and follow-up [REVOKED]

~~(a) Primary provider screening and follow-up.~~

~~(1) At each routine well-child visit or at least annually if a child has not had routine well-child visits, primary health care providers should assess each child who is at least six months of age but under six years of age for high dose lead exposure using a risk assessment tool based on currently accepted public health guidelines. Each child at high risk for lead exposure should be tested.~~

~~(2) Primary health care providers should provide the parent or guardian of each child under six years of age anticipatory guidance on lead poisoning prevention as part of routine care.~~

~~(3) Primary health care providers should screen each child for lead exposure starting at 6 months of age, as part of routine well-child care.~~

~~(4) Each primary health care provider who screens a child for an elevated blood lead level should explain the blood lead test results and any necessary follow-up.~~

~~(5) Primary health care providers should provide or make reasonable efforts to ensure the provision of follow-up testing for each child with an elevated blood lead level ≥ 10 µg/dL.~~

~~(6) Primary health care providers should confirm blood lead levels ≥ 10 µg/dL of blood obtained on a capillary fingerstick specimen from a child using a venous blood sample.~~

~~(7) For each child who has a confirmed blood lead level of ≥ 20 µg/dL (micrograms per deciliter), the primary health care providers should provide or make reasonable efforts to ensure the provision of medical evaluation, or referral for medical evaluation; medical treatment if necessary; and referral to the appropriate local or state health department for environmental management. Medical evaluation should include at a minimum: a detailed lead exposure assessment, a nutritional assessment, including iron status, and a developmental screening.~~

~~(b) Non-Primary provider screening and follow-up.~~

~~(1) A health care provider who provides services to a child who is at least six months of age but under six years of age and who is not the child's ongoing primary care provider, (such as a hospital inpatient facility, an emergency service if the child's condition permits, or another facility or practitioner which provides services to the child on a one time or walk-in basis), should inquire if the child has been appropriately screened for lead exposure.~~

~~(2) If the child, under 72 months of age, has not received such appropriate lead assessment and screening, the health care provider should screen the child for a blood lead level.~~

~~(3) If screening is performed, the blood lead test result should be sent to the child's primary care provider or, if not available, to the local health department for appropriate follow-up.~~

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 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 ~~children 6 months to 72 months of age~~ persons ~~that~~ who are residents of Oklahoma to the Childhood Lead Poisoning Prevention Program. These reports shall be 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 ~~mail, telephone, facsimile, or~~ 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, ~~and~~ 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) Time limits for reporting test results to the Childhood Lead Poisoning Prevention Program shall be as follows:

(A) Results of all blood lead levels ~~<10 µg/dL~~ less than the reference level at a minimum of a monthly basis.

(B) Results of all blood lead levels equal to or ~~>10 µg/dL~~ 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 ~~by telephone or fax,~~ when the results of any analysis in a child up to 72 months of age is ≥ equal to or greater than 20 µg/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 ~~that~~ 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 ~~should~~ 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 ~~by health care providers~~ and that this information accompanies the sample to the testing laboratory.

(2) On written or verbal notification of an elevated capillary lead level, ~~≥10 mg/dL~~ equal to or greater than the reference level, the child's health care provider will obtain ~~a confirmatory test by venous sample~~ confirmatory testing.

(3) All health care providers shall notify the Childhood Lead Poisoning ~~and~~ Prevention Program of any blood lead level in a child up to 72 months of age ~~equal to or >10 µg/dL~~ equal to or greater than the reference level within 1 week and equal to or greater than ~~≥~~ 20 µg/dL within 24 hours of having been notified of this result by the testing laboratory; ~~the~~ 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) ~~Upon notification of a blood lead level ≥20 µg/dL, an environmental investigation and public health followup will be carried out by the Oklahoma State Department of Health. 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) ~~On~~ Upon written notification of unsatisfactory specimens, the child's health care provider will obtain a repeat specimen.

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