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
310:512-1-2. Criteria [AMENDED]
310:512-1-3. Lead poisoning prevention program [AMENDED]
310:512-1-4. Definitions [AMENDED]
Subchapter 3. Risk Assessment, Screening and Management
310:512-3-1. Risk assessment and screening criteria [AMENDED]
310:512-3-5. Reporting requirements [AMENDED]
SUMMARY:
Chapter 310:512-1-2. The current rule sets forth the criteria in regards to the establishment of rules and procedures. This proposal removes two instances of the word "shall."
310:512-1-3. The current rule sets forth the role of the lead poisoning prevention program. This proposal removes five instances of the word "shall."
310:512-1-4. The current rule sets forth the definitions as used in the General Provisions of the Childhood Lead Poisoning Prevention rules. This proposal removes three instances of the word "shall."
310:512-3-1. The current rule sets forth criteria for screening and risk assessment questionnaires. This proposal removes one instance of the word "shall."
310:512-3.5. The current rule sets forth reporting requirements for laboratories and health care providers in regards to blood lead testing. This proposal removes three instances of the word "shall."
The effect of these changes is in keeping with the Governor's Executive Order 2020-03 to undertake a critical and comprehensive review of the agency's administrative rules, identify unnecessary regulatory restrictions, and simplify language.
AUTHORITY:
Commissioner of Health, Title 63 O.S. § 1-104; and Title 63 O.S. § 1-114.1
COMMENT PERIOD:
November 16, 2020, through December 16, 2020, interested persons may informally discuss the proposed rules with the contact person identified below; or may, through December 16, 2020, 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 16, 2020, via WebEx accessible from the site www.publichearings.health.ok.gov, from 9AM to noon. The alternate date and time in the event of extreme inclement weather is December 18, 2020, via WebEx accessible from the site www.publichearings.health.ok.gov, from 9AM to noon. Those wishing to present oral comments should be registered to speak by 9:15 a.m. Directions for comment registration will be provided on the website. The hearing will close at the conclusion of comments from those registered to speak. Interested persons may attend for the purpose of orally submitting data, views, or concerns about the rule proposal described and summarized in this Notice.
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 16, 2020, to the contact person identified below.

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, 1000 N. E. 10th Street, Oklahoma City, OK 73117-1207, phone (405) 271-9444 ext.56535, 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:

310:512-1-2. The current rule sets forth the criteria in regards to the establishment of rules and procedures. This proposal removes two instances of the word "shall."

310:512-1-3. The current rule sets forth the role of the lead poisoning prevention program. This proposal removes five instances of the word "shall."

310:512-1-4. The current rule sets forth the definitions as used in the General Provisions of the Childhood Lead Poisoning Prevention rules. This proposal removes three instances of the word "shall."

310:512-3-1. The current rule sets forth criteria for screening and risk assessment questionnaires. This proposal removes one instance of the word "shall".

310:512-3.5. The current rule sets forth reporting requirements for laboratories and health care providers in regards to blood lead testing. This proposal removes three instances of the word "shall."

The effect of these changes are in keeping with the Governor's directive and executive order 2020-03 to undertake a critical and comprehensive review of the agency's administrative rules, identify unnecessary regulatory restrictions, and simplify language.

2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:

The proposed changes are being made to reduce regulatory restrictions in compliance with the Governor's directive and executive order 2020-03, it is not expected that these changes will affect health outcomes or cost impact.

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

The proposed changes are being made in an effort to align with the Governor's directive and executive order 2020-03 to identify unnecessary regulatory restrictions and simplify language.

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

There are no costs associated with implementation.

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

There are no costs associated with implementation.

6. IMPACT ON POLITICAL SUBDIVISIONS:

There will be no impact on political subdivisions and it will not require their cooperation in implementing or enforcing the proposed amendment.

7. ADVERSE EFFECT ON SMALL BUSINESS:

There is no known adverse economic effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act.

8. EFFORTS TO MINIMIZE COSTS OF RULE:

There are no less costly means currently identified.

9. EFFECT ON PUBLIC HEALTH AND SAFETY:

Public health and safety will not be impacted by these changes.

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

Public health and safety will not be impacted if the proposed policy change is not adopted this season.

11. PREPARATION AND MODIFICATION DATES:

This rule impact statement was prepared on September 30, 2020.

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

SUBCHAPTER 1. GENERAL PROVISIONS

310:512-1-2. Criteria
(a) The Infant and Children's Health Advisory Council ~~shall advise~~ advises 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.
(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 maintain~~ maintains a lead poisoning prevention program. This program ~~shall be~~ is responsible for establishing and coordinating activities to prevent lead poisoning and to minimize risk of exposure to lead.
(b) The Department ~~shall enforce~~ 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 ~~shall maintain~~ maintains a statewide surveillance system of all Oklahoma children'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 ~~shall develop~~ develops and ~~implement~~ 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 ~~shall~~ 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 ~~shall~~ without limiting the foregoing, ~~include~~ 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 ~~which,~~ that may include, 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 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 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 that 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.

"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 ~~is~~ based on recommendations from the CDC and ~~shall be~~ approved by the Department ~~prior to~~ before 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:lpp.health.ok.gov.

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

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 ~~shall be~~ 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) ~~Time limits for reporting test results~~ Test results that are reported to the Childhood Lead Poisoning Prevention Program ~~shall be as follows~~ 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 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 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 µg/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 ~~shall be~~ are confidential and may be utilized only for the purpose of assuring service delivery, program administration, data analysis, and evaluation.