

Title 26 DEPARTMENT OF THE ENVIRONMENT

Subtitle 02 OCCUPATIONAL, INDUSTRIAL, AND RESIDENTIAL HAZARDS

Chapter 01 Blood Lead Reporting

Authority: Environment Article, §6-303, Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Blood lead analysis" has the meaning stated in COMAR 10.11.04.02B.

(2) "Blood lead level test" means to:

(a) Draw a blood specimen, by either venous or capillary methodology, and:

(i) Send the blood specimen to a medical laboratory for blood lead analysis; or

(ii) Conduct a blood lead analysis at a health care provider's office subject to licensing, certification, and approval by the Laboratories Administration of the Maryland Department of Health; or

(b) Order a blood specimen to be drawn by a third-party health care provider, by either venous or capillary methodology, and send it to a medical laboratory for blood lead analysis.

(3) "Department" means the Maryland Department of the Environment.

(4) "Health care provider" has the meaning stated in COMAR 10.11.04.02B.

(5) "Laboratory" means a medical laboratory as defined in COMAR 10.10.01.03B.

(6) "Local health department" means the health department of the Maryland subdivision where the patient resides.

(7) "Parent or guardian" means an individual acting in a primary custodial capacity.

(8) "Reference level" means:

(a) 5 micrograms per deciliter; or

(b) Beginning 1 year after the date that the Centers for Disease Control and Prevention revises the blood lead reference level until 1 year after a subsequent revision, the revised blood lead reference level as determined by the Centers for Disease Control and Prevention.

.02 Information to be Reported.

A. Who Shall Report. The laboratory, health care provider's office, or other facility that draws a blood specimen from a child 18 years old or younger for a blood lead level test shall obtain the information required by §D(1)—(5) and (8) of this regulation at the time of drawing the blood specimen.

B. Time and Method for Reporting by a Facility that Initially Draws a Blood Specimen.

(1) A laboratory that performs blood lead analysis shall provide a referral form of paper or electronic requisition that specifies the required information for use by a laboratory, a health care provider's office, or another facility that draws a blood specimen.

(2) The facility that draws a blood specimen shall:

(a) Record the information required under §D(1)—(5) and (8) of this regulation on the laboratory's referral form or similar form; and

(b) Forward the required information concurrently with the blood specimen to the laboratory that performs blood lead analysis.

C. Time and Method for Reporting by a Laboratory. A laboratory required to report a blood lead level test under this regulation shall report the blood lead level test in the format approved by the Department and include all of the information required under §D of this regulation.

D. The blood lead level test to be reported shall include the following information:

(1) The child's demographic information, including:

(a) First name, last name, and middle initial;

(b) Date of birth, country of birth, sex, race, and ethnicity;

(c) Medical assistance number if the child is enrolled in Medicaid or the Maryland Children's Health Program;

(d) Complete home address at the time the blood specimen was drawn, including house or apartment number, street, city or town, county or Baltimore City, zip code, and state;

(e) Telephone number; and

(f) Parent or guardian's name;

(2) If the child being tested is female, whether the child was pregnant at the time of the blood lead level test;

(3) Type of blood specimen, venous or capillary, and the blood draw date;

(4) The health care provider's office name, address, telephone number, and national provider identifier (NPI);

(5) If the draw site is different from the health care provider's office, the laboratory's or other facility's name, address, telephone number, and NPI;

(6) All of the following information about the laboratory performing the blood lead analysis:

(a) Laboratory name, address, telephone number, and clinical laboratory improvement amendment number (CLIA);

(b) Laboratory method used to analyze the blood specimen;

(c) The limit of detection for the method used to analyze the blood specimen; and

(d) If reporting a "no result" test result, the limit of detection for the laboratory;

(7) Blood lead level in micrograms per deciliter expressed with a numeric results comparator of:

(a) Equal, if the blood lead level is an exact measurement; or

(b) Less than or greater than, if a blood lead level reading is below or above a certain level that a device used to analyze a blood specimen can accurately record; and

(8) Additional information as may be required by the Department.

.03 Missing Information.

A. A laboratory that receives a blood specimen from a laboratory, a health care provider's office, or another facility without all of the required information listed in Regulation .02D(1)—(5) and (8) of this chapter included on the referral form required under Regulation .02B of this chapter shall:

(1) Within 3 business days of receipt of the blood specimen, send to the facility that provided the blood specimen a written or electronic message citing the regulations and requirements of this chapter, requesting that all the required missing information be forwarded to the laboratory; and

(2) Upon receipt of the required information, collate and transmit the information to the Department within the time frames set forth in Regulation .04C of this chapter.

B. When the laboratory reports a blood lead level test result to the Department with one or more of the requirements listed in Regulation .02D(1)—(5) and (8) of this chapter omitted, the laboratory shall concurrently provide the name and address of the facility that:

(1) Drew the blood specimen; and

(2) Failed upon request to forward the required information to the laboratory.

C. The facility that drew the blood specimen shall respond to a written or electronic message from a laboratory that did not receive all of the required information listed in Regulation .02D(1)—(5) and (8) of this chapter by providing the information to the laboratory within:

(1) 1 business day of receiving the message regarding a blood lead level test result of greater than or equal to the reference level; and

(2) 5 business days of receiving the message for a blood lead level test result of less than the reference level.

D. A laboratory not permitted in accordance with COMAR Title 10 to perform a blood lead analysis that accepts a blood specimen from a health care provider for referral to another laboratory for blood lead analysis shall ensure that:

(1) The requisition record includes all of the information that is required under Regulation .02D(1)—(5) and (8) of this chapter; and

(2) The required information is transmitted to the laboratory performing the blood lead analysis along with the blood specimen.

E. Reporting a Blood Lead Level Test Result with Missing Information.

(1) A laboratory shall collate information required under Regulation .02D of this chapter that is collected to complete a previously incomplete requisition record for a blood lead level test before submitting the information to the Department in accordance with §A of this regulation.

(2) A laboratory shall report to the Department the missing information collated pursuant to §E(1) of this regulation:

(a) Concurrently with the blood lead level test result, if the reporting time frame for a blood lead level test result established in Regulation .04C of this chapter has not concluded; or

(b) In a manner indicating that there has been a change in the blood lead level test record, if reporting the missing information after the initial blood lead level test result was reported to the Department.

.04 A Laboratory that Performs the Tests.

A. Reporting to the Department. The director of a laboratory shall report to the Department the result of a blood lead level test performed on a child 18 years old or younger, who resides in Maryland.

B. Additional Reporting Requirements.

(1) In addition to the requirements of §A of this regulation, the director of a laboratory shall report to the Commissioner of the Baltimore City Health Department the result of a blood lead level test performed on a child 18 years old or younger, who resides in Baltimore City.

(2) In addition to the requirements under §§A and B(1) of this regulation, a laboratory shall report the result of a blood lead level test to:

(a) The health care provider that ordered the blood lead level test; and

(b) Another entity as required by State, federal, or local statutes or regulations, or in accordance with accepted standards of practice.

C. A laboratory shall report the result of a blood lead level test to the Department by facsimile or other manner required by the Department within the following time frames:

(1) By the close of business of the next business day following a final blood lead level test result of greater than or equal to the reference level; and

(2) Within 2 weeks of a final blood lead level test result of less than the reference level.

D. A laboratory that uses an electronic system for tracking blood lead level test results shall report a result to the Department electronically in a manner consistent with the technical specifications established by the Department.

.05 Reporting by the Department.

A. Upon receipt of a blood lead level test result, the Department shall report the information required under Regulation .02D of this chapter and the result of a blood lead level test indicating a blood lead level greater than or equal to the reference level to the:

- (1) Local health department in the jurisdiction in which the child resides; and
- (2) Maryland Department of Health.

B. Time and Manner of Reporting by the Department.

(1) The Department shall report a blood lead level test result of:

- (a) Greater than or equal to 10 micrograms per deciliter by the close of business of the next business day following the receipt of the final test result; and
- (b) 5 micrograms per deciliter through 9 micrograms per deciliter within 2 weeks of the receipt of the final test result.

(2) The Department may report the information required under Regulation .02D of this chapter and the result of a blood lead level test indicating a blood lead level of less than 5 micrograms per deciliter to the local health department or the Maryland Department of Health, or both.

.06 Measures for Noncompliance.

A person who violates Environment Article, §6-303, Annotated Code of Maryland, or this chapter is subject to an administrative penalty of up to \$250 per violation, not exceeding \$10,000.