DEPARTMENT OF ~~COMMUNITY~~ HEALTH **AND HUMAN SERVICES**

DIVISION OF ~~FAMILY AND COMMUNITY~~ **ENVIRONMENTAL** HEALTH

BLOOD LEAD ANALYSIS REPORTING

Filed with the secretary of state on

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a(6) of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the department of community health by **sections 5111, 5474, and 20531 of the public health code,** 1978 PA 368, MCL 333.5111(1) and (2)(f), 333.5474(1)(c), and 333.20531; ~~1978 PA 312, MCL 325.72(a)(i), MCL 325.78~~; and Executive Reorganization Order No. ~~1996-1~~ **2015-1**, MCL ~~330.3101~~ **400.227**)

R 325.9081, R 325.9082, R 325.9083, R 325.9084. R 325.9085, and R 325.9086 of the Michigan Administrative Code are amended, as follows:

R 325.9081 Definitions.

Rule 1. (1) As used in these rules:

(a) "**D**~~d~~epartment" means the department of ~~community~~ health **and human services**.

(b) **"Limit of detection" means the lowest quantity of a substance that can be detected with reasonable certainty for a given laboratory analytical procedure**.

(~~b~~**c**)"Physician/provider" means a licensed professional who provides health care services and who is authorized to request the analysis of blood specimens. For this purpose, provider may also mean the local health department.

(~~c~~**d**) "Portable blood lead analyzer" means a point-of-care blood lead testing instrument or similar device used to ~~test~~ **determine** blood lead levels.

(~~d~~**e**) "User" means a physician/provider, local health department, Head Start agency, community action agency, and **any** other ~~agencies~~ **agency** or individual**s** who utilize**s** portable blood lead analyzers.

(2) The term "local health department," as defined in section 1105 **of the public health code**, 1978 PA 368, MCL 333.1105, has the same meaning when used in these rules.

R 325.9082 Reportable information.

Rule 2. (1) Reportable information pertains to the analysis of blood samples submitted to clinical laboratories and the results from portable blood lead analyzers.

(2) Upon initiating a request for blood lead analysis, the physician/provider or user ordering the blood lead analysis shall collect the following information:

(a) All of the following information with respect to the individual tested:

(i) Name.

(ii) Sex**.**

(iii) The individual's ~~ethnicity including either of the following~~ **ethnic origin.**

~~(a) Hispanic or Latino/Latina.~~
~~(b) Not Hispanic of Latino/Latina~~.
(iv) The individual's race~~,~~**.** ~~noting the following:~~
~~(a) American Indian or Alaska Native.~~
~~(b) Asian.~~
~~(c) Black or African American.~~
~~(d) Native Hawaiian or Other Pacific Islander.~~
~~(e) White or Caucasian~~.
(v) Birthdate.
(vi) Address, including county~~,~~**.** ~~and, to the extent available, whether the residence or property is owned or rented.~~
(vii) Telephone number.
(viii) Social security number and Medicaid number, if applicable.
(ix) If the individual is a minor, the name of a parent or guardian.
(x) If the individual is an adult, the name of his or her employer.
(xi) A secondary contact for the individual tested or, if the individual is a minor, a secondary contact for the individual's parent or guardian, including, to the extent available, name and phone number of the secondary contact.
(b) The date of the sample collection.
(c) The type of sample**, either** ~~(~~capillary or venous~~)~~.
(d) The physician's/provider's or user's name, name of practice **or agency,** ~~(~~if applicable~~)~~, telephone number, fax number, email address, and mailing address.
(3) The information collected in subrule (2) of this rule shall be submitted with the sample for analysis to a clinical laboratory that performs blood lead analysis or a user of a portable blood lead analyzer.
(4) Upon receipt of the blood sample for lead analysis, the clinical laboratory or user of a portable blood lead analyzer shall collect the following additional information:
(a) The name, address, and phone number of the laboratory or testing entity.
(b) The date of analysis.
(c) The specimen number.
(d) The results of the blood lead analysis in micrograms of lead per deciliter of whole blood ~~rounded to the nearest whole number~~. **If the result is below the limit of detection, report as less than the laboratory's limit of detection for that analytical procedure**.

R 325.9083 Reporting responsibilities.
Rule 3. (1) All clinical laboratories and users of portable blood lead analyzers doing business in this state that analyze blood samples for lead shall report all blood lead results~~,~~ ~~rounded to the nearest whole number,~~ for adults and children to the department electronically consistent with ~~R 325.9084~~ **subrule (4)**. If a result and required reportable information under ~~R 325.9082~~ **subrule (2)** cannot be reported electronically within the time frame specified by this rule, then the results shall be submitted to the Michigan Department of ~~Community~~ Health **and Human Services**, Childhood Lead Poisoning Prevention Program (CLPPP), ~~109 W. Michigan Avenue~~, **P.O. Box 30037**, Lansing, MI 48909**,** or **by fax to** (517) 335-8509 ~~(facsimile)~~. Reports shall be made to the department within 5 working days after test completion. Nothing in these rules shall prevent a person

or entity required to report under these rules from reporting results to the department sooner than 5 working days.

(2) Nothing in this rule shall be construed to relieve a clinical laboratory or a user of a portable blood lead analyzer from reporting results of a 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, except that reporting in compliance with this rule satisfies the blood lead reporting requirements of **section 5474 of the public health code,** 1978 PA 368, MCL ~~333.1101 to 333.25211~~ **333.5474(1)(c)**.

R 325.9084 Electronic communications.

Rule 4. (1) A clinical laboratory or user of a portable blood lead analyzer shall submit the data required in ~~R 325.9082~~ **subrule (2)** and ~~R 325.9083~~ **subrule (3)** electronically to the department.

(2) ~~For electronic reporting, upon mutual agreement between the reporting clinical laboratory or user of a portable blood lead analyzer and the department, the~~ **R~~r~~**eporting shall utilize the data format specifications provided by the department.

R 325.9085 Quality assurance.

Rule 5. For purposes of assuring the quality of submitted data, each clinical laboratory or user of a portable blood lead analyzer shall allow the department to inspect copies of the medical records **or laboratory test results** that will be submitted by the clinical laboratory or user of a portable blood lead analyzer to verify the accuracy of the submitted data. Only the portion of the medical record that pertains to the blood lead testing shall be submitted. The department shall protect the medical records submitted using reasonably appropriate privacy and security safeguards regardless of whether the medical records are received by the department in electronic or hard copy form. ~~After verification of submitted data, the department shall promptly destroy the copies of the medical records.~~

R 325.9086 Confidentiality of reports.

Rule 6. (1) Except as provided in subrule (2) of this rule, the department shall maintain the confidentiality of all reports of blood lead tests submitted to the department and shall not release reports or information that may be used to directly link the information to a particular individual.

(2) The department may release reports or information, otherwise protected under subrule (1) of this rule, under any of the following conditions:

(a) If the department has received written consent from the individual, or from the individual's parent or legal guardian, requesting the release of information.

(b) If necessary for law enforcement investigation or prosecution of a property manager, housing commission, or owner of a rental unit under section 5475a, 2004 PA 434, MCL 333.5475a.

(c) If the director of the department determines that release is crucial to protect the public health against imminent threat or danger.

(d) As necessary for the department to carry out its duties under 1978 PA 368, MCL 333.1101 to 333.25211.

(e) If necessary for the purpose of research designed to develop or contribute to generalizable knowledge, with documented approval by the department's institutional review board.

(f) If necessary for the purpose of public health activities designed to prevent **or mitigate** lead poisoning within a community.

(3) Medical and epidemiological information that is released to a legislative body shall not contain information that identifies a specific individual.

(4) Aggregate epidemiological information concerning the public health that is released to the public for informational purposes only shall not contain information that identifies a specific individual.