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Michigan REGULATORY IMPACT STATEMENT and COST-BENEFIT ANALYSIS (RIS)

PART 1: INTRODUCTION

Under the Administrative Procedures Act (APA), 1969 PA 306, the agency that has the statutory authority to promulgate the rules must complete and submit this form electronically to the Michigan Office of Administrative Hearings and Rules (MOAHR) at MOAHR-Rules@michigan.gov no less than 28 days before the public hearing.

1. Agency Information:

Agency name:	Michigan Department of Health and Human Services
Division/Bureau/Office:	Environmental Health/ Bureau of Epidemiology and Population Health
Name, title, phone number, and e-mail of person completing this form:	Tom Largo, State Administrative Manager, 517-284-4806, largot@michigan.gov
Name of Departmental Regulatory Affairs Officer reviewing this form:	

2. Rule Set Information:

MOAHR assigned rule set number:	Mich Admin Code R 325.9081-9087
Title of proposed rule set:	Blood Lead Analysis Reporting

PART 2: KEY SECTIONS OF THE APA

MCL 24.207a "Small business" defined.

Sec. 7a. "Small business" means a business concern incorporated or doing business in this state, including the affiliates of the business concern, which is independently owned and operated, and which employs fewer than 250 full-time employees or which has gross annual sales of less than $6,000,000.00.

MCL 24.232 (8) Except for an emergency rule promulgated under section 48, and subject to subsection (10), if the federal government has mandated that this state promulgate rules, an agency shall not adopt or promulgate a rule more stringent than the applicable federally mandated standard unless the director of the agency determines that there is a clear and convincing need to exceed the applicable federal standard.

(9) Except for an emergency rule promulgated under section 48, and subject to subsection (10), if the federal government has not mandated that this state promulgate rules, an agency shall not adopt or promulgate a rule more stringent than an applicable federal standard unless specifically authorized by a statute of this state or unless the director of the agency determines that there is a clear and convincing need to exceed the applicable federal standard.

(10) Subsections (8) and (9) do not apply to the amendment of the special education programs and services rules, R 340.1701 to R 340.1862 of the Michigan Administrative Code. However, subsections (8) and (9) do apply to the promulgation of new rules relating to special education with the rescission of R 340.1701 to R 340.1862 of the Michigan Administrative Code.

MCL 24.240 Reducing disproportionate economic impact of rule on small business; applicability of section and MCL 24.245(3).

Sec. 40. (1) When an agency proposes to adopt a rule that will apply to a small business and the rule will have a disproportionate impact on small businesses because of the size of those businesses, the agency shall

consider exempting small businesses and, if not exempted, the agency proposing to adopt the rule shall reduce the economic impact of the rule on small businesses by doing all of the following when it is lawful and feasible in meeting the objectives of the act authorizing the promulgation of the rule:

(a) Identify and estimate the number of small businesses affected by the proposed rule and its probable effect on small businesses.

(b) Establish differing compliance or reporting requirements or timetables for small businesses under the rule after projecting the required reporting, record-keeping, and other administrative costs.

(c) Consolidate, simplify, or eliminate the compliance and reporting requirements for small businesses under the rule and identify the skills necessary to comply with the reporting requirements.

(d) Establish performance standards to replace design or operational standards required in the proposed rule.

(2) The factors described in subsection (1)(a) to (d) shall be specifically addressed in the small business impact statement required under section 45.

(3) In reducing the disproportionate economic impact on small business of a rule as provided in subsection (1), an agency shall use the following classifications of small business:

(a) 0-9 full-time employees.

(b) 10-49 full-time employees.

(c) 50-249 full-time employees.

(4) For purposes of subsection (3), an agency may include a small business with a greater number of full-time employees in a classification that applies to a business with fewer full-time employees.

(5) This section and section 45(3) do not apply to a rule that is required by federal law and that an agency promulgates without imposing standards more stringent than those required by the federal law.

MCL 24.245 (3) Except for a rule promulgated under sections 33, 44, and 48, the agency shall prepare and include with the notice of transmittal a **regulatory impact statement** which shall contain specific information (information requested on the following pages).

PART 3: AGENCY RESPONSE

Please provide the required information using complete sentences. **Do not answer any question with "N/A" or "none."**

Comparison of Rule(s) to Federal/State/Association Standards:

1. Compare the proposed rule(s) to parallel federal rules or standards set by a state or national licensing agency or accreditation association, if any exist.

The proposal is to amend existing rules: Blood Lead Analysis Reporting. These rules describe the requirements for clinical laboratories to report blood lead test results to the department of health and human services. Michigan Administrative Code R 325.9081-9086 has been in effect since 1997. There are no federal rules or standards requiring laboratory reporting of blood lead test results.
Proposed amendments are to address the following: (1) Minor corrections are needed to update the Department and Division names and to make minor grammatical and formatting corrections. (2) One change is deleting the requirement that information about whether the address is for a residence that is owned or rented. This is because laboratories never have this information and cannot realistically be expected to obtain it. (2) Another change is to reflect current practice and upgraded technology for receipt of laboratory results with decimal points, rather than rounding to integers, and to specify how laboratories should report results less than their limit of detection. (3) Another change is the deletion of specific definitions of "ethnicity" and "race". This is so that if standards change in the future, laboratories can be requested to change the categories. Revised terminology here is consistent with terminology in the rules for Reporting of Communicable Diseases, Mich Admin Code R 325.171-325.199.

A. Are these rule(s) required by state law or federal mandate?

Yes. State law.:1978 PA 368, MCL 333.5111(1)-(2)(f); 333.5474(1)(c), and 333.20531.

B. If these rule(s) exceed a federal standard, identify the federal standard or citation, describe why it is necessary that the proposed rule(s) exceed the federal standard or law, and specify the costs and benefits arising out of the deviation.

There are no federal standards for this issue.

2. Compare the proposed rule(s) to standards in similarly situated states, based on geographic location, topography, natural resources, commonalities, or economic similarities.

All fifty states require clinical laboratories to report blood lead test results so that public health agencies can identify lead poisoned individuals and take actions to prevent and mitigate lead exposures resulting in lead poisoning. Michigan's reporting requirements are similar to those in most other states. Michigan's reporting requirements include the blood lead test result; name, address and demographic information about the person tested; and contact information for the health care provider who ordered the blood lead test. The rules also specify how the laboratory is to report the information electronically and requirements for maintaining confidentiality of the reported information. Regarding the first substantive proposed change (to the requirement for reporting of rental status of the home of the person tested): this requirement was added as an amendment in 2015. No other state contiguous to Michigan requires inclusion of this information in their lead laboratory reporting rules. In the four years since adoption of this amendment, it has become clear that laboratories will not ever have this information and therefore it is prudent to relieve them of this potentially burdensome requirement. Regarding the second substantive amendment: Previously, the department was unable to accept laboratory test results that included decimals in its electronic data management system, which necessitated the rounding requirement in the rules. The department now has a data management system that can accept and process unrounded results. No other contiguous state requires reporting of rounded results. Regarding the third proposed substantive amendment (to report race and ethnicity information in specific categories), no other contiguous state specifies categories for race and ethnicity, so this amendment brings these rules into alignment with other states' requirements.

A. If the rule(s) exceed standards in those states, explain why and specify the costs and benefits arising out of the deviation.

A limited number of states require that laboratories only report test results that are considered elevated. However, in the department's experience, it is easier and less costly for laboratories to report all results, not just elevated results. In addition, it is important to have all reports reported so that public health has a count of how many children are being tested and can calculate what percent of those tested are elevated.

3. Identify any laws, rules, and other legal requirements that may duplicate, overlap, or conflict with the proposed rule(s).

No duplicating, overlapping, or conflicting rules have been identified.

A. Explain how the rule has been coordinated, to the extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter. This section should include a discussion of the efforts undertaken by the agency to avoid or minimize duplication.

There are no other federal or Michigan-specific state or local laws applicable to reporting of blood lead test results. These requirements are closely coordinated with requirements for abatement of lead hazards in homes and certification of lead abatement workers, which are addressed in MCL 333.5451 et seq, because blood lead test results are used to target homes with lead poisoned children for lead abatement.

4. If MCL 24.232(8) applies and the proposed rule(s) is more stringent than the applicable federally mandated standard, **a statement of specific facts that establish the clear and convincing need to adopt the more**

stringent rule(s) and an explanation of the exceptional circumstances that necessitate the more stringent standard is required below:

The proposed amendments are not more stringent because there are no mandated federal standards.

5. If MCL 24.232(9) applies and the proposed rule(s) is more stringent than the applicable federal standard, **either the statute that specifically authorizes the more stringent rule(s) or a statement of the specific facts that establish the clear and convincing need to adopt the more stringent rule(s) and an explanation of the exceptional circumstances that necessitate the more stringent standard** is required below:

They are not more stringent because there are no mandated federal standards.

Purpose and Objectives of the Rule(s):

6. Identify the behavior and frequency of behavior that the proposed rule(s) are designed to alter.

Proposed amendments to the requirements for laboratory reporting of blood lead test results are minor and will simplify reporting because they more closely align with the information that laboratories collect for each test result.

A. Estimate the change in the frequency of the targeted behavior expected from the proposed rule(s).

Proposed amendments to the requirements make blood lead test results reporting less burdensome on the laboratory.

B. Describe the difference between current behavior/practice and desired behavior/practice.

Under the current rules, laboratories are required to report some information about each tested individual that the laboratory rarely has and to round test results to an integer for reporting. The amendments eliminate some reporting requirements and the requirement to round test results simplify the reporting.

C. What is the desired outcome?

Making reporting requirements less burdensome on laboratories and at the same time ensuring that information provided for public health use is consistent with current practices in public health and electronic data management.

7. Identify the harm resulting from the behavior that the proposed rule(s) are designed to alter and the likelihood that the harm will occur in the absence of the rule.

Without the proposed amendments, information needed for public health activities to prevent lead poisoning will be less accurate and actionable.

A. What is the rationale for changing the rule(s) instead of leaving them as currently written?

Proposed changes make the rules more consistent with current practice in public health data collection and management and electronic data management capacity.

8. Describe how the proposed rule(s) protect the health, safety, and welfare of Michigan citizens while promoting a regulatory environment in Michigan that is the least burdensome alternative for those required to comply.

Reporting of selected health conditions to public health so that actions can be taken to prevent these illnesses/injuries in others has been included in public health laws for over 100 years, starting with communicable diseases, because these data are essential for identifying individuals and their environments where actions are needed to prevent additional illnesses/injuries. Michigan's Public Health Code – Act 368 of 1978 – recognized lead poisoning as a condition that should be on the list of reportable conditions [MCL 333.5111 (2) (f)]. These rules for laboratory reporting of blood lead test results - R325.9081-9086 - were adopted in 1997, and they are accepted practice among laboratories and public health. The current

proposed amendments have been designed to make reporting simple, efficient, and complete, in line with expectations for the availability of information from the laboratories.

9. Describe any rules in the affected rule set that are obsolete or unnecessary and can be rescinded.

No sections of the rules are obsolete or unnecessary other than the amendments proposed here.

Fiscal Impact on the Agency:

Fiscal impact is an increase or decrease in expenditures from the current level of expenditures, i.e. hiring additional staff, higher contract costs, programming costs, changes in reimbursement rates, etc. over and above what is currently expended for that function. It does not include more intangible costs or benefits, such as opportunity costs, the value of time saved or lost, etc., unless those issues result in a measurable impact on expenditures.

10. Describe the fiscal impact on the agency (an estimate of the cost of rule imposition or potential savings).

The proposed amendments will improve the efficiency in processing laboratory reports and will align the department's data with the laboratory results that are provided to the health care provider and family of the person who was tested. They are not likely to result in specific costs or savings to the department.

11. Describe whether or not an agency appropriation has been made or a funding source provided for any expenditures associated with the proposed rule(s).

There are no expenditures associated with the proposed amendments thus there is no need for an agency appropriation.

12. Describe how the proposed rule(s) is necessary and suitable to accomplish its purpose, in relationship to the burden(s) it places on individuals. Burdens may include fiscal or administrative burdens, or duplicative acts.

Reporting of illnesses and injuries that pose health threats to the public has been accepted practice in all clinical laboratories for many years. With the advent of systems and capacity to report electronically, the burden of reporting has been greatly decreased, not only for reporting of lead results, but also for reporting of clinical tests indicating communicable diseases like tuberculosis and measles. The only burden these proposed amendments would make on laboratories is, for the short term, the cost of reprograming their systems to report the information as amended.

A. Despite the identified burden(s), identify how the requirements in the rule(s) are still needed and reasonable compared to the burdens.

Public health will need to be monitoring the problem of lead exposure in the population by collecting data on blood lead test results until lead has been removed from the environment. Although the proposed amendments will result in minor costs to laboratories to change their laboratory information systems, in the long term, these changes will simplify reporting by aligning information collected by the laboratories from doctors and their patients with information provided to the department.

Impact on Other State or Local Governmental Units:

13. Estimate any increase or decrease in revenues to other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Estimate the cost increases or reductions for such other state or local governmental units as a result of the rule. Include the cost of equipment, supplies, labor, and increased administrative costs in both the initial imposition of the rule and any ongoing monitoring.

These amendments will have no impact on revenues to other state or local governmental units.

A. Estimate the cost increases or reductions for other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Include the cost of equipment, supplies, labor, and increased administrative costs in both the initial imposition of the rule and any ongoing monitoring.

These amendments will result in no cost increases or reductions for other state or local governmental units.

14. Discuss any program, service, duty or responsibility imposed upon any city, county, town, village, or school district by the rule(s).

These amendments have no impact on cities, counties, towns, villages, or school districts.

A. Describe any actions that governmental units must take to be in compliance with the rule(s). This section should include items such as record keeping and reporting requirements or changing operational practices.

No actions would need to be taken by any governmental unit to be in compliance with these amendments to the rules.

15. Describe whether or not an appropriation to state or local governmental units has been made or a funding source provided for any additional expenditures associated with the proposed rule(s).

No additional funding is needed as a result of these proposed amendments.

Rural Impact:

16. In general, what impact will the rule(s) have on rural areas?

There will be no impact of these amendments on rural areas.

A. Describe the types of public or private interests in rural areas that will be affected by the rule(s).

There are no public or private interests that will be affected by the rules.

Environmental Impact:

17. Do the proposed rule(s) have any impact on the environment? If yes, please explain.

These proposed amendments will not have an impact on the environment.

Small Business Impact Statement:

18. Describe whether and how the agency considered exempting small businesses from the proposed rule(s).

Some laboratories are small businesses. However, public health must be provided with blood lead tests of *all* individuals tested in order to have the data to take public health actions, thus exempting small laboratories from reporting requirements is not consistent with public health practice.

19. If small businesses are not exempt, describe (a) how the agency reduced the economic impact of the proposed rule(s) on small businesses, including a detailed recitation of the efforts of the agency to comply with the mandate to reduce the disproportionate impact of the rule(s) upon small businesses as described below, per MCL 24.240(1)(a)-(d), or (b) the reasons such a reduction was not lawful or feasible.

These proposed amendments make no additional burden on reporting by laboratories that are considered small businesses, and in fact, will make reporting simpler and more efficient for them.

A. Identify and estimate the number of small businesses affected by the proposed rule(s) and the probable effect on small business.

An estimated 158 laboratories are considered small businesses. The effect of these proposed amendments should make reporting more efficient for them.

B. Describe how the agency established differing compliance or reporting requirements or timetables for small businesses under the rule after projecting the required reporting, record-keeping, and other administrative costs.

There is no need to establish differing compliance or reporting requirements for the 158 laboratories that are considered small businesses, because the amendments make only minor changes to existing requirements, and in fact make reporting requirements simpler than before.

C. Describe how the agency consolidated or simplified the compliance and reporting requirements for small businesses and identify the skills necessary to comply with the reporting requirements.

All laboratories, including small ones, already have staff with skills to report existing required data, and these amendments will not affect current laboratory functions.

D. Describe how the agency established performance standards to replace design or operation standards required by the proposed rule(s).

This question is not relevant to the proposed amendments.

20. Identify any disproportionate impact the proposed rule(s) may have on small businesses because of their size or geographic location.

There is no disproportionate impact on small businesses because of their size or geographic location. The burden of reporting results is directly related to the number of blood lead tests analyzed.

21. Identify the nature of any report and the estimated cost of its preparation by small businesses required to comply with the proposed rule(s).

Laboratories are only required to submit results of blood lead tests. They are not required to submit any other kind of report. These amendments make a few changes to the information contained in each clinical lab result report.

22. Analyze the costs of compliance for all small businesses affected by the proposed rule(s), including costs of equipment, supplies, labor, and increased administrative costs.

There are very minor labor costs to small businesses associated with implementation of these amendments involving minor changes to the forms they use to report (mostly spreadsheets.).

23. Identify the nature and estimated cost of any legal, consulting, or accounting services that small businesses would incur in complying with the proposed rule(s).

There are no costs related to legal, consulting or accounting services to small businesses associated with implementation of these amendments.

24. Estimate the ability of small businesses to absorb the costs without suffering economic harm and without adversely affecting competition in the marketplace.

Small business laboratories should be able to absorb the staff costs associated with modifications to their reporting forms easily and without suffering economic harm.

25. Estimate the cost, if any, to the agency of administering or enforcing a rule that exempts or sets lesser standards for compliance by small businesses.

There would be no cost to the department as there would be no exemption of the businesses and to set lesser standards would compromise the data results needed in order to protect the public.

26. Identify the impact on the public interest of exempting or setting lesser standards of compliance for small businesses.

These proposed amendments simplify laboratory reporting from small businesses, thus there is no need for exempting or setting lesser standards of compliance for small businesses. The department will continue to obtain the information about blood lead tests, which is essential for taking public health

actions, and the information must be provided consistently by all laboratories; exceptions for laboratories that are small businesses will be detrimental to protecting the public from hazards of lead exposure.

27. Describe whether and how the agency has involved small businesses in the development of the proposed rule(s).

Laboratories considered small businesses were not directly involved in the development of these amendments but were involved indirectly in that some had periodically requested the changes to help simplify their reporting systems in the past few years.

A. If small businesses were involved in the development of the rule(s), please identify the business(es).

In the answer above, small businesses were indirectly involved in the development and some had requested changes to simplify the reporting.

Cost-Benefit Analysis of Rules (independent of statutory impact):

28. Estimate the actual statewide compliance costs of the rule amendments on businesses or groups.

The laboratories with electronic Laboratory Information Management Systems (LIMS) will have some one-time programming costs associated with modifying the electronic reports they provide to the department, estimated to be five hours of programming at $100 per hour times an estimated 16 laboratories with LIMS = $8,000 in labor costs statewide. Laboratories that report on spreadsheets will have negligible labor costs associated with modifying their spreadsheet templates.

A. Identify the businesses or groups who will be directly affected by, bear the cost of, or directly benefit from the proposed rule(s).

Laboratories with LIMS will have some one-time costs as noted above. All laboratories will benefit long term from the amendments because they simplify reporting requirements.

B. What additional costs will be imposed on businesses and other groups as a result of these proposed rules (i.e. new equipment, supplies, labor, accounting, or recordkeeping)? Identify the types and number of businesses and groups. Be sure to quantify how each entity will be affected.

No additional costs other than one-time changes to reporting systems noted above, which will apply to all laboratories.

29. Estimate the actual statewide compliance costs of the proposed rule(s) on individuals (regulated individuals or the public). Include the costs of education, training, application fees, examination fees, license fees, new equipment, supplies, labor, accounting, or recordkeeping.

These amendments do not impose any costs on individuals. They do not require education or training, and they do not impose any fees.

A. How many and what category of individuals will be affected by the rules?

These amendments do not affect any categories of individuals.

B. What qualitative and quantitative impact does the proposed change in rule(s) have on these individuals?

These amendments do not impact any categories of individuals.

30. Quantify any cost reductions to businesses, individuals, groups of individuals, or governmental units as a result of the proposed rule(s).

These amendments will not result in any cost reductions.

31. Estimate the primary and direct benefits and any secondary or indirect benefits of the proposed rule(s).

Provide both quantitative and qualitative information, as well as your assumptions.

The benefits are as follows: (1) The first substantive amendment eliminates a reporting requirement that is burdensome to laboratories because it requires them to attempt to get information about rental status of homes of tested individuals, which is difficult if not impossible to obtain even with follow-up telephone calls that would be necessary for the over 150,000 individuals tested each year. (2) The second amendment requires the laboratories to report blood lead test results exactly as they are obtained from the equipment that performs the analysis of the blood samples, rather than requiring the laboratories to then perform a mathematical calculation (rounding) on the result, thus ensuring that the test result is reported to the department exactly as it is reported to the provider who ordered the blood lead test and the patient. This ensures consistency, reduces the possibility of error when communicating results, and ensures accuracy when performing epidemiologic analysis of blood lead test data. (3) The third amendment – eliminating specific race and ethnicity categories in the reporting requirements is a benefit for public health because it gives the department more flexibility in defining which race and ethnicity categories should be reported. The department uses race and ethnicity information when conducting epidemiologic analysis of the blood lead data to identify high risk groups, but over time these definitions change based on overall population changes, and thus flexibility is needed.

32. Explain how the proposed rule(s) will impact business growth and job creation (or elimination) in Michigan.

These amendments will have no impact on business growth or job creation.

33. Identify any individuals or businesses who will be disproportionately affected by the rules as a result of their industrial sector, segment of the public, business size, or geographic location.

These amendments only affect clinical laboratories that are approved to do blood lead testing.

34. Identify the sources the agency relied upon in compiling the regulatory impact statement, including the methodology utilized in determining the existence and extent of the impact of a proposed rule(s) and a cost-benefit analysis of the proposed rule(s).

The department has been working with laboratories since 1998 to ensure complete and accurate reporting of blood lead test results, thus providing extensive knowledge of how laboratories operate. The department has the list of laboratories that are required to report blood lead test results and knows which laboratories likely meet the definition of small business based on the way they submit reports to the department.

A. How were estimates made, and what were your assumptions? Include internal and external sources, published reports, information provided by associations or organizations, etc., which demonstrate a need for the proposed rule(s).

Estimates of the labor costs for modifying laboratory LIMS to accommodate these proposed changes is based on experience in working with contractors to develop and maintain electronic data management systems.

Alternatives to Regulation:

35. Identify any reasonable alternatives to the proposed rule(s) that would achieve the same or similar goals. Include any statutory amendments that may be necessary to achieve such alternatives.

There are no reasonable alternatives to the proposed amendments that would achieve the same or similar goals.

A. In enumerating your alternatives, include any statutory amendments that may be necessary to achieve such alternatives.

No statutory amendments are necessary.

36. Discuss the feasibility of establishing a regulatory program similar to that in the proposed rule(s) that would

operate through private market-based mechanisms. Include a discussion of private market-based systems utilized by other states.

A private market-based mechanism is not feasible for maintaining this public health surveillance system, including the blood lead data reported by laboratories and the follow-up public health interventions conducted by the department and local health departments to reduce/mitigate the health impacts of exposure to lead. No other state uses private market-based systems for this public health activity.

37. Discuss all significant alternatives the agency considered during rule development and why they were not incorporated into the rule(s). This section should include ideas considered both during internal discussions and discussions with stakeholders, affected parties, or advisory groups.

The department considered whether to make these changes or to leave the rule as is. Based on discussions with departmental staff who work with the data, regulated laboratories, and Local Health Departments who conduct follow-up public health interventions, these amendments were deemed necessary and important. No other changes were considered.

Additional Information:

38. As required by MCL 24.245b(1)(c), describe any instructions on complying with the rule(s), if applicable.

The department provides detailed written instructions to laboratories on the various alternatives for electronic reporting of blood lead test results and maintains staffing for a help-desk where questions can be answered by phone or email.

↓ **To be completed by MOAHR** ↓

PART 4: REVIEW BY MOAHR

Date RIS received:	7-12-2019

Date RIS approved:	**7/16/19**

Date of RIS disapproval:	
Explanation:	