

State Budget Office
Office of Regulatory Reinvention
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**REGULATORY IMPACT STATEMENT (RIS)
and COST-BENEFIT ANALYSIS**

PART 1: INTRODUCTION

Under the Administrative Procedures Act (APA), 1969 PA 306, the department/agency responsible for promulgating the administrative rules must complete and submit this form electronically to the Office of Regulatory Reinvention (ORR) no less than 28 days before the public hearing (MCL 24.245(3)-(4)). Submissions should be made by the department Regulatory Affairs Officer (RAO) to orr@michigan.gov. The ORR will review the form and send its response to the RAO (see last page). Upon approval by the ORR, the agency shall make copies available to the public at the public hearing (MCL 24.245(4)).

1. ORR-assigned rule set number:

ORR No. 2017-022 HS, Birth Defects Reporting

2. ORR rule set title:

Mich Admin Code R 325.9071 through R 325.9076

3. Department:

Health and Human Services

4. Division/agency/bureau:

Division for Vital Records and Health Statistics

5. Name, title, and phone number of person completing this form:

Glenn Copeland, Director. 517-335-8677

6. Reviewed by department Regulatory Affairs Officer:

Mary E. Brennan

PART 2: APPLICABLE 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 24.240 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).

[**Note:** Additional questions have been added to these statutorily-required questions to satisfy the **cost-benefit analysis** requirements of Executive Order 2011-5].

MCL 24.245b Information to be posted on office of regulatory reinvention website.

Sec. 45b. (1) The office of regulatory reinvention shall post the following on its website within 2 business days after transmittal pursuant to section 45:

- (a) The regulatory impact statement required under section 45(3).
- (b) Instructions on any existing administrative remedies or appeals available to the public.
- (c) Instructions regarding the method of complying with the rules, if available.
- (d) Any rules filed with the secretary of state and the effective date of those rules.

(2) The office of regulatory reinvention shall facilitate linking the information posted under subsection (1) to the department or agency website.

PART 3: DEPARTMENT/AGENCY RESPONSE

Please place your cursor in each box, and provide the required information, using complete sentences. Please do not answer the 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. Are these rule(s) required by state law or federal mandate? If these rule(s) exceed a federal standard, please 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.

The rules are required under MCL 333.5721 and serve to regulate the Michigan birth defects registry required by MCL 333.5717. No licensing organization exists relative to birth defects registries. The National Birth Defects Prevention Network standards and guidelines are comparable to Michigan birth defects registry regulation.

2. Compare the proposed rule(s) to standards in similarly situated states, based on geographic location, topography, natural resources, commonalities, or economic similarities. If the rule(s) exceed standards in those states, please explain why and specify the costs and benefits arising out of the deviation.

The rules do not exceed standards in other states. Indiana’s IBDP Registry provides the same standards as the Michigan birth registry. Ohio, which lagged behind other state’s development of birth defects registries, has initiated a comprehensive system tracking birth defects in children from birth to 5 years old. Illinois has developed the Adverse Pregnancy Outcomes Reporting System designed to capture birth defect data to identify trends and provide services to families. The goals of each state are similar:

- To help parents of infants with special health care needs get necessary services.
- To find ways to prevent or reduce the impact of certain major birth defects.
- To identify factors that might be associated with birth defects.
- To address community concerns about environmental effects that might increase the risk of a certain birth defect.
- To provide education, screening, and prevention programs.

National standards established by the National Birth Defects Prevention Network for passive registries are approximately comparable to the rules proposed.

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

The proposed rules do not duplicate, overlap, or conflict with any laws, rules, or other legal requirements.

Purpose and Objectives of the Rule(s):

4. Identify the behavior and frequency of behavior that the proposed rule(s) are designed to alter. Estimate the change in the frequency of the targeted behavior expected from the proposed rule(s). Describe the difference between current behavior/practice and desired behavior/practice. What is the desired outcome?

The rules as they currently exist regulate the reporting of children with birth defects and other reportable conditions. The amendments to the rules as proposed would accomplish three basic changes to the regulations.

- 1) Update the name of the department to the current name.
- 2) Update the list of reportable conditions to include in utero Zika exposure.
- 3) Add an ability to exchange resident birth defects case information with state or national birth defects registries to assure complete case ascertainment for Michigan resident cases.

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

Without the rules change, the ability to monitor birth defects prevalence in Michigan will be curtailed. This is especially problematic for birth defects monitoring in Michigan's border county areas. With regard to Zika exposure, Michigan is coordinating with the centers for Disease Control in an effort to monitor Zika exposure in utero and the effect this has on newborns as the spectrum of effects on babies is still unknown. Clarifying the need to report Zika exposure will aid in assuring careful monitoring of these cases

6. 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.

The only accepted birth defects surveillance approach that would not require case reporting, based upon the standards of the National Birth Defects Prevention Network, would require active surveillance, where state birth defects registry staff review medical records and prepare case reports. This approach would require increasing the operating budget of the registry significantly.

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

No rules have been identified for rescission.

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, an increase in the cost of a contract, programming costs, changes in reimbursement rates, etc. over and above what is currently expended for that function. It would 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.

8. Please provide the fiscal impact on the agency (an estimate of the cost of rule imposition or potential savings for the agency promulgating the rule).

No additional costs are expected.

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

No appropriation or funding source is associated with the proposed rule.

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

There is no burden on an individual contemplated. In fact, there will be a benefit for those individuals who are in need of services due to reported birth defects and in particular, to those residents on Michigan's borders with other states who may not be entitled to services due using another state's facility for birthing.

Impact on Other State or Local Governmental Units:

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

There is no anticipated increase or decrease in revenues.

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

There are no anticipated actions nor any program, service, duty or responsibilities that city, county, town, village or school districts will have to undergo with these rule changes.

13. 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 appropriation or funding source is associated with the proposed rule.

Rural Impact:

14. In general, what impact will the rules have on rural areas? Describe the types of public or private interests in rural areas that will be affected by the rule(s).

There is no anticipated on rural areas with these rule changes.

Environmental Impact:

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

There is no impact on the environment anticipated by the rule change.

Small Business Impact Statement:

[Please refer to the discussion of “small business” on page 2 of this form.]

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

State hospitals and laboratories are the private businesses involved in the reporting of birth defects. They cannot be exempt as their mandatory reporting provides the necessary data needed to achieve the goals of the birth defects registry.

17. If small businesses are not exempt, describe (a) the manner in which 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 (in accordance with MCL 24.240(1)(a-d)), or (b) the reasons such a reduction was not lawful or feasible.

There is no anticipated economic impact to small businesses to comply with these proposed rule changes.

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

All Michigan hospitals and cytogenetics laboratories are required to report birth defects under the current rules. There are approximately 180 hospitals in Michigan. The number of cytogenetics laboratories is unknown.

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.

All compliance and reporting requirements are to be uniform and consistent with the current reporting practices and standards.

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

All compliance and reporting requirements are not anticipated to change, including the current skill set used to report the birth registry data.

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

Michigan follows the national standards as provide by the National Birth Defects Prevention Network.

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

There is no anticipated impact on small businesses due to size or geographic location.

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

There are no anticipated administrative costs associated with the rule.

20. 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 no anticipated costs for equipment, supplies, labor or increased administrative costs associated with the rule.

21. 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 anticipated legal, consulting, or accounting services associated with the rule.

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

No economic hard nor adverse competition will occur as a result of this rule.

23. 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 are no exemptions or lesser standards anticipated by small businesses for this rule.

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

With state departments, the rule change sets consistent standards for reporting on newly discovered diseases that impact birth defects. Exempting or setting lesser standards for those hospital and laboratories harms the public and defeats the purpose of the birth defects registry.

25. Describe whether and how the agency has involved small businesses in the development of the proposed rule(s). If small businesses were involved in the development of the rule(s), please identify the business(es).

Hospitals and laboratories were not involved in the development of the rule as they are currently performing the tasks necessary but statute and rules.

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

26. Estimate the actual statewide compliance costs of the rule amendments on businesses or groups. Identify the businesses or groups who will be directly affected by, bear the cost of, or directly benefit from the proposed rule(s). 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)? Please identify the types and number of businesses and groups. Be sure to quantify how each entity will be affected.

No additional costs are expected. The only work to be done to implement this rule change is to contact birth defects registries in states where Michigan newborns are being diagnosed or treated to establish the terms and conditions for the exchange and use of case information in a confidential and secure way. Reporting facilities will also be advised that in utero Zika is now a reporting condition. Contact will be made by the Director of the Division for Vital Records and Health Statistics or his designee to the appropriate border states' birth registries.

27. Estimate the actual statewide compliance costs of the proposed rule(s) on individuals (regulated individuals or the public). Please include the costs of education, training, application fees, examination fees, license fees, new equipment, supplies, labor, accounting, or recordkeeping. How many and what category of individuals will be affected by the rules? What qualitative and quantitative impact does the proposed change in rule(s) have on these individuals?

No additional costs are expected.

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

There are no anticipated cost reductions to businesses, individuals, groups, or governmental units.

29. Estimate the primary and direct benefits and any secondary or indirect benefits of the proposed rule(s). Please provide both quantitative and qualitative information, as well as your assumptions.

Establishing an exchange of resident case information with neighboring state birth defects registries will improve our ability to assess birth defects prevalence statewide and, especially, in border county areas of the state.

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

There is no anticipated impact on business growth and job creation or elimination in Michigan.

31. 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.

There are no identified individuals or businesses who will be disproportionately affected by the rules.

32. 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). 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).

These conclusions were drawn from an assessment of the rule change proposed. The focus of the rules change is to enable the interstate exchange of information on residents with birth defects that are diagnosed or treated outside of Michigan, including the release of such data by

Michigan to population-based birth defects registries in other states. This involves the exchange of previously collected information between registries that can properly protect the confidentiality of the information being shared. This does not create a new responsibility being placed on those required to provide birth defects case reports.

Alternatives to Regulation:

33. Identify any reasonable alternatives to the proposed rule(s) that would achieve the same or similar goals. In enumerating your alternatives, please include any statutory amendments that may be necessary to achieve such alternatives.

There are no alternatives available.

34. Discuss the feasibility of establishing a regulatory program similar to that proposed in the rule(s) that would operate through private market-based mechanisms. Please include a discussion of private market-based systems utilized by other states.

The rules contemplated are for use in the state department with vital statistics and birth registries in state departments nationwide. Private market-based mechanisms are not intended for this rule set.

35. 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.

There are no alternatives available.

Additional Information

36. As required by MCL 24.245b(1)(c), please describe any instructions regarding the method of complying with the rule(s), if applicable.

Communication with birth defects registries in states where Michigan newborns are being diagnosed to establish the terms and conditions for the exchange and use of case information in a confidential and secure way.

PART 4: REVIEW BY THE ORR

Date Regulatory Impact Statement (RIS) received:

7-31-2017

Date RIS approved:	08/07/2017
ORR assigned rule set number:	2017-022 HS

Date of disapproval:	Explain:
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More information needed:	Explain:
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