Michigan Department of Licensing and Regulatory Affairs
Office of Regulatory Reinvention
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REGULATORY IMPACT STATEMENT and COST-BENEFIT ANALYSIS

PART 1: INTRODUCTION

In accordance with 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 departmental 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 review by the ORR, the agency shall make copies available to the public at the public hearing [MCL 24.245(4)].

Please place your cursor in each box, and answer the question completely.

ORR-assigned rule set number:

2015-070 HS

ORR rule set title:

Cancer Reporting

Department:

Michigan Department of Health and Human Services

Agency or Bureau/Division

Population Health and Community Services\Division for Vital Records and Health Statistics

Name and title of person completing this form; telephone number:

Glenn Copeland, Director, DVRHS: 517 335-8677

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** containing…" (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, and 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 designed to meet existing federal legislation and national cancer registry accreditation standards. The Michigan cancer registry needs to comply with the federal Cancer Registries Amendment Act (PL 102-515) and with the standards established by the North American Association of Central Cancer Registries (NAACCR Requirement 2.2.2). The rules modifications proposed would assure regaining compliance with these national standards, without exceeding those standards.

(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 proposed rules changes will re-establish that Michigan requirements match but do not exceed the requirements in place across state-level cancer registries nationwide.

(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.

None

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 change would re-establish the ability and obligation for health care providers to report information on cancer patients to the state cancer registry

(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) and not leaving them as currently written?

Loss of this source of information will impair the ability to monitor cancer incidence, severity and outcomes within Michigan

(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 rules change is needed to assure continuation of the completeness and quality of cancer case information within the state cancer registry.

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

None

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 on the agency promulgating the rule).

There is no fiscal impact on the agency.

(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).

There have been no appropriations made or a funding sources provided that are associated with these rules.

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

The rules re-establish the framework for reporting of cancer cases in Michigan and assure full compliance with federal law. Compliance with federal law is critical to federal funding for this activity.

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 on 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.

No direct impact on local government. Assuring the completeness and quality of the state cancer registry is, however, important to local health agencies as they rely on registry data to assess local concerns over cancer incidence in their communities.

(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 programs, services, duties or responsibilities imposed on the entities named.

(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).

Not applicable.

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 impact to rural areas.

Environmental Impact:

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

There is no impact to the environment.

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 rules.

The rules address the need for disease reporting by health care providers which is an essential component of existing disease surveillance in Michigan and across the country.

(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.

The reporting requirement are carefully designed to minimize the impact on health care providers with reporting standards developed nationally.

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

In a typical year from 400 to 1250 individual physicians will be asked to provide patient data.

(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 have been no differing compliance or reporting requirements or timetables for small businesses.

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

National reporting standards are developed with the full involvement and support of the American College of Surgeons.

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

There are no performance standards replacing design or operation standards.

(18) 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.

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

Case abstracts include basic information on the type, status, and management of each cancer case. The cost of reporting is an estimated $15 per case for staff time.

(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 costs of compliances for small businesses associated with these rules.

(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 costs for legal, accounting, or consulting.

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

The modification to the rule would be to re-establish this rule which has been in effect since the 1940's. There will be no new cost above existing practice.

(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 is no cost to the agency to administer or enforce these rules.

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

Reductions in cancer registry quality can harm the ability to assess cancer incidence, risk or potential cancer clusters.

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

The rules have no impact on small businesses.

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.

There is not additional economic impact from these proposed changes.

(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 as the rules changes are re-establishing rules that had been in place since the 1940's.

(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 cost reductions impacting those entities identified as a result of these rules.

(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.

The rules modification will reinsure cancer registry completeness and quality and fitness for use and will also assure the legal framework for the registry complies with federal law which is a basic requirement for receiving federal funding to support registry operations.

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

There is no impact on business growth or job creation (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.

Directly affects health care providers diagnosing and treating cancer patients

(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).

Responses are based on the fact that the rules modifications are intended to reenact rules that have been in effect since th 1940s.

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 known reasonable alternatives other than the proposed rules.

(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.

This provision is not applicable to the proposed rule changes.

(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.

If the state is to comply with federal requirements, which is essential to operations, there is no clear alternative to re-establishing the obligation of health care providers to report cancer cases to the state-wide registry.

Additional Information

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

Not applicable

PART 4: REVIEW BY THE ORR

Date Regulatory Impact Statement (RIS) received:

Date RIS approved:	
ORR assigned rule set number:	

Date of disapproval:	Explain:

More information needed:	Explain:

(ORR-RIS March 2014)