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

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 Office of Regulatory Reinvention (ORR) at **orr@michigan.gov** no less than 28 days before the public hearing.

1. Agency Information

Agency name:	Health and Human Services
Division/Bureau/Office:	Bureau of Epidemiology and Population Health
Name, title, phone number, and e-mail of person completing this form:	Sarah Lyon-Callo, Director, lyoncallos@michigan.gov, 517-284-4910
Name of Departmental Regulatory Affairs Officer reviewing this form:	Mary E. Brennan

2. Rule Set Information

ORR assigned rule set number:	**2018-074 HS**
Title of proposed rule set:	REPORTING OF POISONINGS DUE TO THE USE OF PRESCRIPTION OR ILLICIT DRUGS

PART 2: KEY SECTIONS OF THE APA

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.

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: 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.

No parallel federal rules or standards set by state or national licensing agency or accreditation association exist.

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

These rules are not required by state law or federal mandate. However, in order to address the ongoing increase in the use of both legal and illicit drugs, the federal government is providing states with grants to decrease the number of overdoses and/or deaths due to poisoning by legal and illegal drugs.

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.

No parallel federal rules or standards set by state or national licensing agency or accreditation association exist.

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

Illinois- 210 ILCS 85/6.14g-Reports to the Department; Opioid Overdoses; Ohio-ORC 3711.30-maternity units, newborn care nurseries and maternity homes to report the number of newborns opioid dependent; Kentucky- 902 KY. Admin Regs. 2:020; Ken Rev Stat §218A.202-mandatory reporting of suspected drug overdoses.

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

Michigan's proposed rules address all poisonings related to prescription and illicit drugs, whereas other states focus only on opioid poisonings. The benefit is with the rapidly evolving use of drugs that may cause overdose, the proposed rules enable MDHHS to proactively identify new issues and more rapidly respond, rather than change a rule, in reaction to issues identified by other states.

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

Federal rules on privacy of substance abuse treatment data, specifically 42 CFR Part 2, have been addressed by these rules. Health facilities are prohibited from releasing records on substance abuse disorders under Part 2. These rules do not conflict with Part 2 as they specifically forbid dissemination of the data which is aligned with Part 2.

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 currently no requirements for providing data to assess the current opioid crisis. The state will work with local health departments in ensuring the coordination needed to address opioid and street drug overdoses statewide. 42 CFR Part 2 has clearly been identified to not include substance abuse records that a health facility may have in this statewide reporting.

Purpose and Objectives of the Rule(s):

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

Requiring health professionals and health facilities to report specific data will identify the drugs associated with overdoses and/or deaths and ensure a proportionate share of critical resources and funding is made available to all areas of the state based upon findings from the reporting data. Further, the identification of specific drug(s) causing deaths will improve the accuracy of death certificates issued by the state when many cite only "unspecified" or "drug abuse" on the death certificate.

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

These rules will allow for timely receipt of information on nonfatal and fatal overdoses, allowing for information to plan and assess response at state and local levels over time.

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

There is no requirement for health professionals and/or health facilities to provide data regarding overdoses and/or fatalities from drug overdose. With required reporting, the state and local health departments can utilize the data to plan and assess response activities by health care providers, first responders, and public health agencies.

C. What is the desired outcome?

Data provided will enable the state and local health departments to more appropriately allocate resources to all counties based on both fatal and nonfatal overdoses. These proposed rules will also enable public health agencies to pursue federal funding for response to both current and future opioid crises relating to drug poisonings.

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.

There is no current requirement for health professionals or health facilities to report data from overdoses and/or death from prescription and illicit "street" drugs. Without these proposed rules, state and local health departments will face difficulty obtaining data on nonfatal overdoses from health care facilities and providers. The rules aid health care providers in sharing data, as they make clear the use of the information is for public health purposes, a sharing which is allowable under federal privacy rules.

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

N/A. This is a new rule set.

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.

These proposed rules will enable collection of data for guiding and evaluating public health response to opioid or other future drug crises. These proposed rules are modeled after injury and chemical poisoning reporting rules, which are intended to be used when an unusual event is occurring. The data will provide public health analysis to aid partners, such as the Michigan Team to End Drug Addiction (MiTEDA), to conduct their work. The intended implementation of these proposed rules will make use of existing data streams through Michigan Health Information Network, limiting the burden of reporting by health care facilities. These proposed rules have similar limitations to other reporting rules. These proposed rules allow health care facilities to claim the HIPAA waiver for sharing data for public health purposes.

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

N/A. This is a new rule set.

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.

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

The proposed rules will improve our ability to obtain additional federal funding for opioid response, as state and local health departments will be able to access needed data in a timely fashion. Existing federal grants from the Centers for Disease Control and Prevention are being used for cost of the rule implementation.

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 general funds are requested at this time for support of the implementation of these proposed rules. Federal dollars are currently being used to support its implementation.

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.

The proposed rule allows state and local health departments to obtain data essential to their role in addressing public health crises. The rules will require health care facilities and providers to send data to public health departments in response to poisoning events upon request. Most facilities have existing data networks in place through electronic health records and linkages to the Michigan Health Information Network to enable routine sharing of overdose events to MDHHS once a use case is agreed upon. The burden of collecting and managing the data from existing electronic linkages falls on MDHHS and local public health departments. Critical care access hospitals do not have the same level of infrastructure, but this reporting poses a similar burden as for communicable disease reporting these hospitals are already accomplishing.
In case of a cluster of poisonings, state and local public health departments would request additional detail about specific poisonings by requesting more detailed information from medical records. This process is similar to how communicable disease outbreaks are currently investigated.

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

Despite the identified burden to some health facilities regarding electronic reporting limitations, these rules are needed and are reasonable. These rules will reduce duplicate requests of hospitals and medical examiners by state and local public health departments during response, as it requires coordination between these public health entities in collection of data. Many health facilities are already reporting the data in various forms. MDHHS will need to capture the data that these facilities are currently reporting elsewhere.

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 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.

The availability of data may aid local public health departments in their applications for federal funding and would provide more information for targeting federal funding received by MDHHS to local governmental units. There would not be any expected decrease in revenue to state or local governmental units as a result of these rules.

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.

Currently, the local public health departments bear the costs to devise and plan responses to the opioid crisis without benefit of readily available data. Overall, the cost of utilizing this data will be offset by the ability to for these local health departments to obtain federal grants to assist in the mandate of reporting and should enable local health departments to use local limited resources for its response.

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

These rules enable local public health departments to obtain data needed in case of a cluster of unusual poisonings. This does not necessarily increase any responsibility; but rather provides better information for addressing an existing responsibility under the public health code.

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.

There are currently emergency rules in effect. These proposed rules will not require any further action than the emergency rules currently in effect, e.g. record keeping and reporting.

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).

There are no state appropriations being made or state funding source provided for the emergency rules currently in effect and these proposed rules.

Rural Impact:

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

These rules would provide more data about nonfatal overdoses in rural areas, information that is needed to better understand and respond to the opioid crisis. Given the higher rate of fatal overdoses in rural areas and the state and federal investment in response, this rule will aid rural areas to address the opioid crisis.

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

Critical access hospitals that lack the same level of health information technology investment as other hospitals will expend more effort in responding to requests for data under these rules. This is not different from their increased burden of reporting for other public health conditions, including communicable diseases.

Environmental Impact:

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

There is no expected impact on the environment.

Small Business Impact Statement:

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

Small businesses, by definition, are not anticipated to be impacted by these rules.

17. 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.

Small businesses are not anticipated to be impacted by these rules.

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

There are no small businesses anticipated to be impacted by these rules.

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 are no small businesses anticipated to be impacted by these rules.

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.

There are no small businesses anticipated to be impacted by these rules.

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

There are no small businesses anticipated to be impacted by these rules.

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

There are no small businesses anticipated to be impacted by these rules.

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 small businesses anticipated to be impacted by these rules.

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 small businesses anticipated to be impacted by 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 small businesses anticipated to be impacted by these rules.

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

There are no small businesses anticipated to be impacted by these rules.

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 small businesses anticipated to be impacted by these rules.

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

There are no small businesses anticipated to be impacted by these rules.

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

There are no small businesses anticipated to be impacted by these rules.

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

There are no small businesses anticipated to be impacted by these 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.

Statewide compliance costs are unknown at this time but are anticipated to be the same as statewide compliance costs for other mandatory reporting rules, i.e. communicable diseases.

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

Health care facilities and health care professionals as defined in the proposed rules.

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.

The additional costs are unknown at this time but are not anticipated to be high as most of the facilities as defined in the proposed rules are currently providing the data.

27. 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.

Federal privacy rules require health care facilities and professionals to record reporting of data for public health purposes. This overall burden is similar to that for other diseases and conditions reporting to public health and would not require development of new systems for recordkeeping.

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

Health care professionals are covered by the rules, but the data will flow from facilities. Individuals who have an overdose reported to MDHHS may have better availability and coordination of services.

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

The reporting of data should not impact individual licensed health care professionals. The public is the intended beneficiary of the improved public health response to the opioid crisis.

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

No cost reductions expected due to reporting requirements in the proposed rules.

29. 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 direct benefits of these rules will allow the state and local health departments to identify trends in opioid and other street drugs overdoses and assign the appropriate resources to key areas in the state as a result of these overdoses. The indirect benefit of the rules will be improved state and local response to the opioid crisis to the public.

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

The proposed rules are anticipated to have minimal 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 business anticipated to be affected by these proposed 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).

MDHHS relied on expert opinions of experienced public health staff and information provided by federal sources, including the Centers for Disease Control and from other sources, e.g. newspapers, that provide extensive research and information regarding the current opioid crisis.

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).

MDHHS staff, federal agencies, newspapers, periodicals, and articles regarding research on the opioid crisis.

Alternatives to Regulation:

33. 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.

Alternatives to proposed rules include new legislation requiring reporting and obtaining a court order for each health care facility and health care professional to provide the data needed to address public health needs.

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

The Public Health Code, MCL 333.1101 - 333.25211.

34. 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.

Private market-based systems do not have public health authority. A private market-based system would have to be given authority to act as an agent of the state.

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.

The Department considered utilizing existing authority to request, not require data, under the public health code. The concept of requiring reporting had been raised by the Governor's office, legislators, and participants in a surveillance work group convened to address Prescription Drug Overdose. The tracking of additional data was also a recommendation of the Michigan Prescription Drug Abuse and Opioid Overdose Task Force (https://www.michigan.gov/documents/snyder/Presciption_Drug_and_Opioid_Task_Force_Report_504140_7.pdf).

Additional Information:

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

A FAQ is currently being devised for the emergency rules.

↓ **To be completed by the ORR** ↓

PART 4: REVIEW BY THE ORR

Date RISCBA received:	1-16-2019

Date RISCBA approved:	**2/5/19**

Date of disapproval:	
Explanation:	