Michigan Office of Administrative Hearings and Rules
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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 Michigan Office of Administrative Hearings and Rules (MOAHR) at **o'berryd@michigan.gov** no less than 28 days before the public hearing.

1. Agency Information

Agency name:	Department of Health and Human Services
Division/Bureau/Office:	Policy and Planning
Name, title, phone number, and e-mail of person completing this form:	Jared Welehodsky, Analyst, 517-284-4761, welehodskyj@michigan.gov
Name of Departmental Regulatory Affairs Officer reviewing this form:	Mary Brennan

2. Rule Set Information

MOAHR assigned rule set number:	**2019-045 HS**
Title of proposed rule set:	Nonopioid Directive

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.

There are no parallel set of rules or standards by federal, state, licensing, or an accreditation association.

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

These rules are required by state law. See MCL 333.9145.

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 is no federal standard for these rules.

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

Ohio- SB51 (2019-20) has been created to establish non-opioid directives; coverage of non-opioid therapy, no statute change as of this date; Pennsylvania-2016-Act 126, known as the Safe Opioid Prescribing Education and Voluntary Non-Opioid Directive Act – required the Department of Health (DOH) to draft and publish the PNOD form, along with guidelines for health care professionals; Massachusetts-2016-The STEP Act requires any person who wishes to decline future treatment with opioids may fill out a directive and give it to their care provider, who will record it in the patient's

electronic health record ("EHR"), or medical record if the patient does not have an EHR, or responding emergency medical services ("EMS") personnel. The patient, or the patient's guardian or health care proxy, may revoke the Directive, orally or in writing, for any reason, at any time.

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

The proposed rules do not exceed standards in the only two other states to have directive legislation.

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

There is no other law, rule, or legal requirements that may duplicate, overlap, or conflict with the proposed rules.

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 is no similar activity in federal, state, or local law that needs to be coordinated to avoid duplication.

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:

This section is not applicable as there is no federal standard.

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:

This section is not applicable as there is no federal standard.

Purpose and Objectives of the Rule(s):

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

Over 9 million opioid prescriptions were filled in Michigan in 2017. Over 2,000 people died of opioid overdoses in 2017. Many of those people started misusing prescription opioids. This will increase the use of alternatives to opioids and reduce the number of opioid prescriptions written. This could help reduce the number of opioid overdose deaths in Michigan.

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

Only a small percentage of patients that could potentially receive opioids will complete the form.

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

Providers often prescribe opioids for pain without considering alternatives. This will require providers to provide alternatives to patients that fill out the directive.

C. What is the desired outcome?

It documents a patient's decision that opioids are a course of treatment that a patient is not interested in. This will lead to discussions between the prescriber and the patient on alternatives to

opioids for pain treatment. The legislature was concerned about the risk of relapse in patients with a substance use disorder and risk of overdose in other high-risk patients. Opioids are commonly prescribed without understanding the substance use disorder risk for patients.

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.

Over 2,000 people died of opioid overdoses in Michigan in 2017. Most people with an opioid use disorder start misusing prescription opioids. This will help prevent the misuse of opioids that could lead to a potential fatal overdose.

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

There are new rules required by MCL 333.9145.

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.

It documents a patient's decision that opioids are a course of treatment that a patient is not interested in. This will lead to discussions between the prescriber and the patient on alternatives to opioids for pain treatment. The legislature was concerned about the risk of relapse in patients with a substance use disorder and risk of overdose in other high-risk patients. Opioids are commonly prescribed without understanding the substance use disorder risk for patients. This is done by simply filling out a form that is placed in patient's medical record.

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

There are no rules in the affected rule that are obsolete or unnecessary that can be rescinded. 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.

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

There will be minimal fiscal impact. MDHHS will develop administrative rules and will need to maintain information on our website. This information will need be updated periodically. This will require a small portion of employees' time to maintain.

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).

Per the response in Answer 10, an appropriation or funding source is not necessary due to the minimal fiscal impact provided by these rules.

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.

The proposed rules are being created due to legislative mandate under MCL 333.9145. There is no anticipated burden on the agency or an individual(s) in completing a directive and having health facilities and professionals document the directive in an individual's history; whether electronic or paper file.

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

Only minimum administrative costs are necessary. Merely entering the form into a patient's record is a reasonable requirement to reduce the epidemic of opioid deaths.

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.

There is no anticipated increase or decrease in revenues for other state or local government 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.

There are no anticipated cost increases or reductions for other state or local governmental units as a result of this rule.

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

There is no impact of any program, service, duty, or responsibility imposed on any city, county, town, village, or school district by the rules.

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 changes are needed for governmental units to be in compliance with this rule.

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).

There are no additional expenditures for state or local government units required, therefore, no appropriation was provided.

Rural Impact:

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

The rules will help reduce the epidemic of opioid overdose deaths. Many rural communities have been hit hard by the epidemic of opioid misuse and death. This has caused an economic hardship to communities by reducing the labor pool and increasing public resources.

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

Rural medical practices will have to enter the form into a patient's medical records.

Environmental Impact:

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

The rules do 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).

The statute requires all medical providers to participate, regardless of the size of the facility or the practice. Therefore, no exemptions were considered as it would discriminate against certain populations that, if not for the size of a business in their area, would not be able to request a directive.

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.

The requirement to comply with the directive procedure is the minimum required by statute for all businesses. The impact is anticipated to be minimal given the statute's parameters.

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

This will impact all small medical practices statewide. Number is unknown but fiscal impact is minimal.

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.

The only administrative action is placing the form in a patient's records. All providers regardless of size do this for other patient information.

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.

The requirement is the minimum required by statute for all businesses.

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

Health facilities and health providers will use a form created by the department for a patient desiring a directive and the performance standard for the business is to place or record that directive in a patient's file.

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

There will not be any anticipated impact on business because of their size or geographic location as a result of the rules.

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).

There will be no reporting requirements. Small businesses will just need to enter a form in a patient's medical record.

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 will be a minimal labor cost for staff to enter the form in a patient's record.

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 will no anticipated legal, consulting, or accounting service needs for small businesses as a result of these rules.

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

There will be a minimal labor cost for staff to enter the form in a patient's record.

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 will be a minimal labor cost for staff to enter the form in a patient's record.

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

Exempting small business could harm the public by increasing the number of opioid prescriptions. This could then increase opioid misuse and potentially opioid overdose deaths. There is no equal protection for those who attend small practices to be given the option of using a directive.

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

MDHHS involved all medical providers, including small businesses, via their organizations in the discussions regarding the proposed rules. MDHHS worked with small health facilities during the development of the legislation that enabled the proposed rules.

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

All businesses, including small medical providers and facilities, were represented through their various health professional associations involved with the legislative process. Michigan State Medical Society, Michigan Osteopathic Association, and Michigan Academy of Family Physicians were some of the associations identified and who did oppose this legislation while it was being developed.

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

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

There will be a minimal labor cost for staff to enter the form in a patient's record.

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

Michigan State Medical Society, Michigan Osteopathic Association, Michigan Academy of Family Physicians, Michigan Health and Hospital Association, and all citizens of the State.

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.

There will be a small administration cost of entering a form into a patient's records. Medical professional associations like Michigan State Medical Society and Michigan Osteopathic Association would have a minor cost of entering the form in a patient's records by their staff.

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.

There will be a minimal labor cost for staff at medical practices to enter the form in a patient's record.

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

All medical provider practices in Michigan will be affected.

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

There will be a minimal labor cost for staff to enter the form in a patient's record.

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

This will help reduce the number of people with opioid use disorder. Opioid use disorder increases health care costs and cuts the potential productivity of working age adults with an opioid use disorder.

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.

This rule will reduce the number of people with an opioid use disorder in Michigan, which will lead to less overdoses. This will reduce publicly funded opioid use disorder treatment costs which have significantly increased in Michigan. This will lead to an increase in the workforce and allow many to lead more productive and self-supporting lives.

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

This rule will reduce the number of people developing an opioid use disorder in Michigan. By not developing an opioid use disorder it will allow more workers to be more productive workers and to help Michigan businesses grow.

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.

The health care field will have some impact by the proposed regulation. However, the impact will be minimal concerning the documenting of records.

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).

MDHHS used vital records and Medicaid data for the cost-benefit analysis of the proposed rules.

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).

Our estimates were made using data collected by MDHHS.

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.

No reasonable alternatives were identified. The requirements are required by the statute.

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

There are no alternatives to these rules as required by statute.

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.

The two other states that have nonopioid directives in their laws work through the state's department of health. No private-market based mechanism is anticipated to be utilized for this process.

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.

There were no alternatives other than these rules because that is what was required by the statute.

Additional Information:

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

MDHHS will provide the form with instructions for the health facilities and staff to provide to their patients. The only requirement is that the health facility place the directive in the file of a patient and to honor that directive.

↓ **To be completed by the MOAHR** ↓

PART 4: REVIEW BY THE MOAHR

Date RISCBA received:	5-29-2019

Date RISCBA approved:	6/6/19

Date of disapproval:	
Explanation:	