State Budget Office
Office of Regulatory Reinvention
111 S. Capitol Avenue; 8th Floor, Romney Building
Lansing, MI 48933
Phone: (517) 335-8658 FAX: (517) 335-9512

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:	LARA – Bureau of Marijuana Regulation
Division/Bureau/Office:	Michigan Medical Marijuana Program
Name, title, phone number, and e-mail of person completing this form:	BMR Legal Section: Jacob Nevin/ Department Analyst, Contact info.: 517-284-8583; LARA-BMR-Legal@michigan.gov
Name of Departmental Regulatory Affairs Officer reviewing this form:	Liz Arasim Department of Licensing and Regulatory Affairs

2. Rule Set Information

ORR assigned rule set number:	2018-095 LR
Title of proposed rule set:	Michigan Medical Marihuana

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.

There are no comparable federal rules set by a state or national licensing agency. There are 33 states with medical marijuana laws in place, which cover a variety of topics or concerns specific to their licensing and regulatory structure.

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

The proposed rules are required by authority conferred on the Department of Licensing and Regulatory Affairs by section 5 of the Michigan Medical Marihuana Act (MMMA), 2008 IL 1, MCL 333.26425. The rules are not required by federal mandate.

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.

The rules do not exceed a federal standard or law.

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

The Department is tasked with promulgating rules that govern the manner in which the Department shall consider the addition of medical conditions or treatments to the list of debilitating medical conditions set forth in section 3(a) of the act. The Department is also tasked with promulgating rules that govern the manner in which it shall consider applications for and renewals of registry identification cards for qualifying patients and primary caregivers.

When compared to other Great Lakes and surrounding states, Michigan's regulatory framework is similar to other states' programs. Michigan has one of the largest patient populations registered with its medical marijuana program in the country, which will presumptively create the consumer base for the facilities licensing division. The other states have a tenth of the patient population that Michigan has.

The Illinois qualifying patient application fee for one year is $100, two years is $200, and three years is $250. The Illinois caregiver application fee for one year is $25, two years is $50, and three years is $75.

The Ohio annual fee for a patient registration is $50. The annual fee for a caregiver registration is $25.

The Minnesota annual fee for patient enrollment is $200. If the patient attests to receiving Social Security disability, Supplemental Security Insurance payments, or being enrolled in medical assistance or MinnesotaCare, then the fee is $50.

The Pennsylvania fee for a medical marijuana ID card is $50.

While there are neighboring states with higher application fees, the patient population market is far less than that of Michigan.

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

The rule does not exceed those standards.

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

There are no federal regulations for medical marijuana. The Michigan Regulation and Taxation of Marihuana Act, which became effective December 6, 2018, does not conflict with these rules, but runs alongside these 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.

Marijuana continues to be classified as a Schedule 1 controlled substance under federal law, so it is not practicable to coordinate the proposed rules with federal law. No other state or local laws are in place regarding the subject matter in these rules and no state or local agencies have the authority to enact or implement laws, ordinances, or regulations regarding the application process or petition process. Therefore, there are no state or local laws applicable to the subject matter in these rules or potential for duplication.

Purpose and Objectives of the Rule(s):

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

The proposed rules allow for online applications in addition to physical, paper applications. The application fee being reduced by 1/3, the elimination of other fees, and the ease of an electronic form should make the application process more accessible and efficient for patients applying for or renewing their registrations. Further, the online application will significantly reduce the potential for applicants being denied for submitting an incomplete application. There are currently over 30 reasons an applicant can be denied for submitting an incomplete application. Applicants who utilize the online application will only be denied if the physician fails to certify the applicant or the applicant's proof of Michigan residency cannot be verified by the Department.

The proposed rules make clearer the requirements for a complete petition to add a condition to the list of debilitating medical conditions. This should assist in the submittals of complete petitions for review.

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

It is difficult to estimate the change in frequency at this time as there are competing factors.

The goal is to reduce the number of denials, reduce processing times, and provide better customer service by allowing applicants to update their active registrations online at no cost. The MMMP receives approximately 10,000 – 15,000 paper requests to update the active registration information now and these are usually behind schedule because applications are always the priority because of the statutory requirement they be approved or denied within 15 business days of receipt of the application.

Another objective of the rules is that the elimination of the amendment fees and the ability to submit them online will allow them to be processed in 10 business days or earlier. Further, the goal is that 90% of applications will be processed within 10 business days of receipt. In FY 2018, 72% of applications were processed within 10 business days.

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

The market for medical marijuana has changed since these rules began. The application for patient certification will be easier, more accessible, and more affordable in an increasingly dynamic industry.

C. What is the desired outcome?

- The ultimate desired outcome is reducing the processing time of patient applications.
- Improve customer service.
- Increase efficiencies in the registration process.
- Reduce costs for applicants and registrants and reduce the growth rate of the Marijuana Registry Fund.
- Reduce the number of denials because an application is incomplete or was filled out incorrectly.
- Improve security and reduce the potential for fraud through use of the online application and physician certification process.
- Reduce the MMMP's staffing costs.

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 harm resulting from the behavior the proposed changes are designed to alter. The changes reduce the cost of application, make available an online application, and make the process to review petitions more efficient.

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

The Department has a commitment to continuous quality improvement and improving customer service. In addition, the online application incorporates the Auditor General's recommendation to offer an online application and certification process.

Since the most recent hearing of the panel to review petitions, there is a need to make the petition process clearer so that the Department and the panel may better consider the addition of medical conditions or treatments to the list of debilitating medical conditions.

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 protecting the health, safety, and welfare of Michigan are as they were before these revisions. The changes to these rules alleviate the current burdens. The paper application will now have an electronic alternative online. The application fee will be reduced. The petition process to add more conditions will be clearer and the panel that makes recommendations will do so more effectively with an odd number of members.

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

R 333.115 exists in MCL 333.26424 and 333.26426.

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 Department would bring in $20 fewer per application. However, there may be an increase in the patient population as the application process will be more accessible.

The change may potentially reduce the number of departmental technicians required to process applications as more applicants, registrants, and physicians use the online process. The positions will not be eliminated but will be transferred to other areas of the BMR as the medical facility licensing and adult use programs grow.

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).

The online application is paid for with funds encumbered from previous fiscal years which were appropriated for the MMMP's operating expenses, but not used.

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 MMMA requires the promulgation of rules not later than 120 days after the effective date of the act. The Department is promulgating rules that govern the manner in which the Department shall consider the addition of medical conditions or treatments to the list of debilitating medical conditions set forth in section 3(a) of this act. The Department is also promulgating rules that govern the manner in which it considers applications for and renewals of registry identification cards for qualifying patients and

primary caregivers. These rules establish application and renewal fees that generate revenues sufficient to offset all expenses of implementing and administering this act.

The changes in the rules alleviates burdens, both fiscal and administrative, of the application process. The changes in the petition process bring more clarity to what condition or treatment is added to the list of qualifying conditions.

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 burden of changing the requirements of the petition process, the specificity of the petition is necessary in the evaluating of a complete petition. The panel members reviewing these petitions need to know the limits of their recommendation so that they may recommend without misunderstanding.

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.

There are no anticipated increases or decreases in revenues or costs to other state or local government units as a result of the proposed 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.

There are no anticipated increases or decreases in revenues or costs to other state or local government units as a result of the proposed rules.

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

There is no program, service, duty, or responsibility imposed upon any city, county, town, village, or school district by the proposed 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 governmental units would need to take any action to be in compliance with the changes to the application process.

The Department would need to appoint another member to the panel so that there may be an odd number of members.

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 appropriations have been made to any governmental units because of these rules. No additional expenditures are anticipated or intended with the proposed rules.

Rural Impact:

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

The proposed rules are not expected to impact rural areas in as much as the rules apply to all patients and caregivers regardless of location.

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

The proposed rules are not expected to affect public or private interests in rural areas.

Environmental Impact:

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

The proposed rules do not have any impact on the environment.

Small Business Impact Statement:

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

The proposed rules impose requirements on certifying physicians rather than small businesses. Even if a certifying physician's practice qualifies as a small business, the Department could not exempt his or her business because it would create a disparity in regulation.

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.

The proposed rules impose requirements on certifying physicians rather than small businesses. Even if a certifying physician's practice qualifies as a small business, the Department could not exempt his or her business because it would create a disparity in regulation.

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

The proposed rules impose requirements on certifying physicians rather than small businesses. Even if a certifying physician's practice qualifies as a small business, the Department could not exempt his or her business because it would create a disparity in regulation.

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 rules apply to patients and caregivers in the Michigan Medical Marijuana Program and certifying physicians.

The proposed rules impose requirements on certifying physicians rather than small businesses. Even if a certifying physician's practice qualifies as a small business, the Department could not exempt his or her business because it would create a disparity in regulation.

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 rules apply to patients and caregivers in the Michigan Medical Marijuana Program and certifying physicians.

The proposed rules impose requirements on certifying physicians rather than small businesses. Even if a certifying physician's practice qualifies as a small business, the Department could not exempt his or her business because it would create a disparity in regulation.

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

The rules apply to patients and caregivers in the Michigan Medical Marijuana Program and certifying physicians.

The proposed rules impose requirements on certifying physicians rather than small businesses. Even if a certifying physician's practice qualifies as a small business, the Department could not exempt his or her business because it would create a disparity in regulation.

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 business.

The proposed rules impose requirements on certifying physicians rather than small businesses. Even if a certifying physician's practice qualifies as a small business, the Department could not exempt his or her business because it would create a disparity in regulation.

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).

The proposed rules impose requirements on certifying physicians rather than small businesses. Even if a certifying physician's practice qualifies as a small business, the Department could not exempt his or her business because it would create a disparity in regulation.

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 compliance for any certifying physician. All physician offices utilize computers. The only requirement for a physician is to create a secure, online account and certify his or her patients when notified by the department.

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 of compliance for any certifying physician. All physician offices utilize computers. The only requirement for a physician is to create a secure, online account and certify his or her patients when notified by the department.

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 costs of compliance for any certifying physician. All physician offices utilize computers. The only requirement for a physician is to create a secure, online account and certify his or her patients when notified by the department.

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 costs of compliance as we are not administering or enforcing any exemptions or lesser standards for small businesses. All physician offices utilize computers.

The proposed rules impose requirements on certifying physicians rather than small businesses. Even if a certifying physician's practice qualifies as a small business, the Department could not exempt his or her business or set lesser standards because it would create a disparity in regulation.

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

There are no exemptions or lesser standards of compliance for small businesses.

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

Small businesses were not involved as the proposed changes in the administrative rules have no impact.

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

None.

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

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

The compliance costs are the new, lowered application fees.

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

Patients and caregivers will be directly affected by the rules. The new rules reduce the cost of the application or renewal.

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.

None.

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.

The proposed rule changes do not impose any additional costs on individuals.

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

As of 10/01/18, there are 297,515 registered qualifying patients active and 43,056 primary caregivers active.

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

The cost of continued registration would be reduced for qualifying patients and caregivers in this Medical Marijuana Program.

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

The proposed rule changes reduce the patient application fee by $20, eliminates the $25 caregiver criminal background check processing fee, and eliminates the $10 processing fee for updating information for an active registration.

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 proposed rule changes reduce the patient application fee by $20, eliminates the $25 caregiver criminal background check processing fee, and eliminates the $10 processing fee for updating information for an active registration.

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

Business and job growth will not be affected.

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.

No individuals or business will be disproportionately affected by the rules as a result of their industrial sector, segment of the public, business size, or geographic location.

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).

A primary source for the fiscal impact of the proposed rules was the LARA-BMR reports such as Medical Marihuana Act Statistical Report with Program Information and Financial Data Registry Program.
https://www.michigan.gov/lara/0,4601,7-154-10573_11550-454290--,00.html

Total Medical Marijuana Programs:
http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx

Sources from other states are the following:
Illinois:
http://www.ilga.gov/commission/jcar/admincode/077/077009460B02100R.html

Ohio:
http://codes.ohio.gov/oac/3796:7-3-01

Minnesota:
https://www.revisor.mn.gov/statutes/cite/152.35

Pennsylvania:
https://www.health.pa.gov/topics/programs/Medical%20Marijuana/Pages/Patients.aspx

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).

The estimates were made by noting the difference in the cost of registration in respect to the population of registered qualifying patients and primary caregivers.

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.

There are no reasonable alternatives. In fact, the changes to these rules make for an alternative to what has already existed in rule.

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

Statutory amendments will not be necessary.

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.

These rules are required by the MMMA; private, market-based systems cannot serve as an alternative.

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.

Since the rules are specifically required by the MMMA, there are no alternatives to the proposed rules that the agency could consider.

Additional Information:

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

Instructions for complying with the rules are available on the forms provided by the Department.

↓ To be completed by the ORR ↓

PART 4: REVIEW BY THE ORR

Date RISCBA received:	2-11-2019

Date RISCBA approved:	**2/15/19**

Date of disapproval:	
Explanation:	