Michigan Office of Administrative Hearings and Rules

Administrative Rules Division (ARD)

MOAHR-Rules@michigan.gov

REGULATORY IMPACT STATEMENT and COST-BENEFT ANALYSIS (RIS)

Agency Information:

Department name:

Licensing and Regulatory Affairs

Bureau name:

Bureau of Professional Licensing

Name of person filling out RIS:

Andria Ditschman

Phone number of person filling out RIS:

517-290-3361

E-mail of person filling out RIS:

DitschmanA@michigan.gov

Rule Set Information:

ARD assigned rule set number:

2021-51 LR

Title of proposed rule set:

Pharmacy - Pharmacist Continuing Education

Comparison of Rule(s) to Federal/State/Association Standard

1. Compare the proposed rules to parallel federal rules or standards set by a state or national licensing agency or accreditation association, if any exist.

Each state establishes its own requirements with respect to a pharmacist's continuing education, so the proposed rules cannot be compared to federal rules or standards set by a national or state agency.

A. Are these rules required by state law or federal mandate?

The proposed rules are required by sections 16204, and 17731 of the Public Health Code (Code), MCL 333.16204, and MCL 333.17731. The rules are not federally mandated.

The following provisions allow for rule making: MCL 333.16145, MCL 333.16148, MCL 333.16184, MCL 333.16201, MCL 333.16205, MCL 333.17767, MCL 338.3501, MCL 445.2001, MCL 445.2011, and MCL 445.2030.

B. If these rules exceed a federal standard, please identify the federal standard or citation, describe why it is necessary that the proposed rules exceed the federal standard or law, and specify the costs and benefits arising out of the deviation.

The proposed rules do not exceed any federal standards.

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

Each state establishes its own requirements with respect to a pharmacist's continuing education. The proposed rules are consistent with the standards required by the public health code and are largely consistent with the continuing education requirements of other states in the Great Lakes region.

In the proposed rules, a licensee must accumulate thirty continuing education credit hours during each 2-year licensing cycle. All other states in the Great Lakes region require a pharmacist to accumulate continuing education during each licensing cycle, but the number of continuing education credits required differ from state to state. In Illinois, Indiana, Minnesota, Pennsylvania, and Wisconsin, a licensee must accumulate thirty continuing education credits in each 2-year licensing cycle. In Ohio, a licensee must accumulate forty continuing education credits in each 2-year licensing cycle. In New York, a licensee must accumulate forty-five continuing education credits in each 3-year licensing cycle.

Some states also have additional requirements that apply to the required continuing education credits. Of the total continuing education credit hours required, a licensee must accumulate the following: in Pennsylvania, 2 hours in patient safety, 2 hours in pain management, 2 hours in child abuse recognition and reporting, and 2 hours in injectable medications; in Ohio, 3 hours in jurisprudence or law and 2 hours in medications errors or patient safety; in Indiana, 6 hours in computer related strategies to reduce medication errors; and 3 hours in medication errors in New York.

A. If the rules exceed standards in those states, please explain why and specify the costs and benefits arising out of the deviation.

All states in the Great Lakes region require a pharmacist to accumulate continuing education during each licensing cycle. There are differences between states, however, the requirements are similar. Overall, the standards in the proposed rules do not exceed those of the other states in the Great Lakes region.

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

There are no other laws, rules or other legal requirements that duplicate, overlap, or conflict with the proposed rules. Each state establishes its own requirements with respect to a pharmacist's continuing education. There are no federal rules or standards set by a national or state agency that the proposed rules exceed.

A. Explain how the rules have 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 no other laws, rules, or other legal requirements that conflict with the proposed rules. There are no federal rules or standards set by a national or state agency that the proposed rules exceed.

4. If MCL 24.232(8) applies and the proposed rules are more stringent than the applicable federally mandated standard, provide a statement of specific facts that establish the clear and convincing need to adopt the more stringent rules.

MCL 24.232(8) does not apply.

5. If MCL 24.232(9) applies and the proposed rules are more stringent than the applicable federal standard, provide either the Michigan statute that specifically authorizes the more stringent rules OR a statement of the specific facts that establish the clear and convincing need to adopt the more stringent rules.

MCL 24.232(9) does not apply as this state establishes its own requirements with respect to the continuing education requirements for pharmacists. There are no federal rules or standards set by a national or state agency that the proposed rules exceed.

Purpose and Objectives of the Rule(s)

6. Identify the behavior and frequency of behavior that the proposed rules are designed to alter.

R 338.3041: The contents of this rule are moved to R 338.3042 in order to add definitions under this rule number.

R 338.3042: This new rule number consists of the previous regulations in R 338.3041. This proposed rule establishes continuing education requirements for the renewal of a license.

The behavior and change in frequency of the targeted behavior expected from the proposed rules includes: a licensee will be able to earn continuing education for renewal, during the 60-day grace period, up to the date the licensee applies for renewal; a licensee may earn 1 hour in ethics and pharmacy law by completing multiple courses; a licensee may earn the 10 hours of live courses by attending in-person or virtual continuing education, as long as there is an opportunity for direct interaction between faculty and participants; Accreditation Council for Pharmacy Education (ACPE) courses that are designated as live may be used towards the 10 hours of required live courses; and a licensee may receive continuing education credit and training credit during the same renewal cycle for human trafficking training, opioid and controlled substances awareness training, and implicit bias training.

R 338.3043: This rule provides the standards for approval by the Board for continuing education courses and programs. The behavior and change in frequency of the targeted behavior expected from the proposed rules includes: applications for continuing education courses and programs must be submitted only 70 days before the course or program is conducted; a continuing education course must be relevant to health care services, pharmacy operations, or advancement of pharmacy education; the information that must be submitted with an application has been reduced; clarification is added that additional course dates do not require additional approval if given during the approved term; and the only modifications to the course that require review during the approved term are modifications to the title, number of continuing education hours, and learning objectives.

R 338.3044: This rule specifies acceptable continuing education activities. The behavior and change in frequency of the targeted behavior expected from the proposed rules is that continuing education credit will be given for attendance at a full board meeting, disciplinary meeting, and rules committee work group meeting.

A. Estimate the change in the frequency of the targeted behavior expected from the proposed rules.

It is expected that: licensees will earn continuing education, during the 60-day grace period, up to the date the licensee applies for renewal instead of the end of the licensure cycle; licensees will earn 1 hour in ethics and pharmacy law by completing multiple courses; licensees may earn the 10 hours of live courses by attending in-person or virtual continuing education, as long as there is an opportunity for direct interaction between faculty and participants; licensees will submit ACPE courses that are designated as live towards their 10 hour of required live courses; licensees will receive continuing education credit and training credit during the same renewal cycle for human trafficking training, opioid and controlled substances awareness training, and implicit bias training; applications for continuing education courses and programs will be submitted 70 days before the course or program is conducted; more courses will be approved as a continuing education course may be relevant to health care services, pharmacy operations, or advancement of pharmacy education; applicants for continuing education approval will be required to submit less support documentation; programs and courses may be offered more frequently as additional dates during a term of approval do not need review; the only modifications that require review during the approved term are modifications to the title, number of continuing education hours, or learning objectives; and continuing education credit will be given for attendance at a full board meeting, disciplinary meeting, and rules committee work group meeting, which should increase attendance at those meetings.

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

The difference between the current behavior/practice and desired behavior/practice is: licensees will submit and earn continuing education for renewal, during the 60-day grace period, up to the date the licensee applies for renewal, instead of ending at the end of the licensure cycle; licensees will earn 1 hour in ethics and pharmacy law by completing more than one course; licensees may earn the 10 hours of live courses by attending in-person or virtual continuing education; licensees will submit ACPE courses that are designated as live towards their 10 hour of required live courses; licensees will receive continuing education credit and training credit during the same renewal cycle for human trafficking training, opioid and controlled substances awareness training, and implicit bias training; applications for continuing education courses and programs will be submitted 70 days before the course or program is conducted; more courses will be approved as pharmacy operations has been added to the list of substantive areas of study for approval of continuing education; applicants for continuing education approval will be required to submit less support documentation; programs and courses may be offered more frequently as additional dates during a term of approval do not need review; the only modifications that require review during the approved term are modifications to the title, number of continuing education hours, or learning objectives; and continuing education credit will be given for attendance at a full board meeting, disciplinary meeting, and rules committee work group meeting, which should increase attendance at those meetings.

C. What is the desired outcome?

The desired outcome is more licensees will meet the continuing education requirements by adding more continuing education options; the process for continuing education approval is easier so more options for continuing education will be available for licensees; continuing education programs and courses will be offered more frequently; and attendance and interest in meetings is increased by allowing licensees to obtain continuing education credit for attendance.

7. Identify the harm resulting from the behavior that the proposed rules are designed to alter and the likelihood that the harm will occur in the absence of the rule.

The harm resulting from the behavior that the proposed rules are designed to alter and the likelihood that the harm will occur in the absence of the rule is: licensees would have less time to accumulate continuing education; licensees may have difficulty finding one course that covers both ethics and pharmacy law; licensees may have difficulty finding 10 hours of continuing education that is given in-person; and less continuing education options will be available for licensees if the review requirements are cumbersome and the approval standards are restrictive.

A. What is the rationale for changing the rules instead of leaving them as currently written?

The rationale for changing the rules is: more licensees will meet the continuing education requirements by adding more continuing education options; if the process for continuing education is easier more options for continuing education will be available for licensees; continuing education programs and courses will be offered more frequently; and attendance and interest in meetings is increased by allowing licensees to obtain continuing education credit for attendance.

8. Describe how the proposed rules 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 proposed rules 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, as the proposed rules will require the following: licensees will be able to submit and earn continuing education for renewal, during the 60-day grace period, up to the date the licensee applies for renewal, instead of ending at the end of the licensure cycle; licensees will earn 1 hour in ethics and pharmacy law by completing more than one course; licensees may earn the 10 hours of live courses by attending in-person or virtual continuing education, as long as there is an opportunity for direct interaction between faculty and participants; licensees will submit ACPE courses that are designated as live towards their 10 hour of required live courses; licensees will receive continuing education credit and training credit during the same renewal cycle for human trafficking training, opioid and controlled substances awareness training, and implicit bias training; applications for continuing education courses and programs will be submitted 70 days before the course or program is conducted; more courses will be approved as a continuing education course may be relevant to health care services, pharmacy operations, or advancement of pharmacy education; applicants for continuing education approval will be required to submit less support documentation; programs and courses may be offered more frequently as additional dates during a term of approval do not need review; the only modifications that require review during the approved term are modifications to the title, number of continuing education hours, or learning objectives; and continuing education credit will be given for attendance at a full board meeting, disciplinary meeting, and rules committee work group meeting, which may increase attendance at those meetings.

The proposed rules will allow more licensees to meet continuing education requirements, make continuing education approval easier, and add more options for continuing education. The proposed rules will allow licensees to maintain their education in pharmacy subjects, which is in the best interest of the citizens of Michigan.

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

No rules are rescinded.

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 reimbursements rates, etc. over and above what is currently expended for that function. It does not include more intangible costs for benefits, such as opportunity costs, the value of time saved or lost, etc., unless those issues result in a measurable impact on expenditures.

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

The proposed rules are not expected to have a fiscal impact on the agency.

11. Describe whether or not an agency appropriation has been made or a funding source provided for any expenditures associated with the proposed rules.

No agency appropriation has been made nor has a funding source been provided for expenditures associated with the proposed rules.

12. Describe how the proposed rules are necessary and suitable to accomplish their purpose, in relationship to the burden(s) the rules place on individuals. Burdens may include fiscal or administrative burdens, or duplicative acts.

There are no additional burdens placed on individuals as a result of the proposed rules. The proposed changes reduce burdens on licensees and entities applying for continuing education approval.

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

There are no additional burdens placed on individuals as a result of the proposed rules. The proposed changes reduce burdens on licensees and entities applying for continuing education approval.

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 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 in revenues, or cost increases or reductions, to other state or local government units as a result of the proposed rules.

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

There are no anticipated or intended programs, services, duties, or responsibilities imposed on any city, county, town, village, or school district as a result of these proposed rules.

A. Describe any actions that governmental units must take to be in compliance with the rules. This section should include items such as record keeping and reporting requirements or changing operational practices.

There are no actions that governmental units must take to comply with these proposed rules.

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 rules.

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

Rural Impact

16. In general, what impact will the rules have on rural areas?

The proposed rules are not expected to impact rural areas. The proposed rules apply to licensees, regardless of their location.

A. Describe the types of public or private interests in rural areas that will be affected by the rules.

The proposed rules are not expected to impact rural areas. The proposed rules apply to licensees in the state, regardless of their location.

Environmental Impact

17. Do the proposed rules have any impact on the environment? If yes, please explain.

No, the proposed rules do not have any impact on the environment.

Small Business Impact Statement

18. Describe whether and how the agency considered exempting small businesses from the proposed rules.

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

19. If small businesses are not exempt, describe (a) the manner in which the agency reduced the economic impact of the proposed rules 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 rules 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 proposed rules cannot exempt small businesses because the rules do not directly regulate small businesses, but individual licensees.

While licensees may practice independently or as part of a small business, the law does not allow the rules to exempt these individuals from the requirements of the rules. However, the impact on licensees who practice as part of a small business is minimized in the proposed rules, as the rules are written broadly. As a result, a licensee, whether in small business or not, should not be significantly impacted by the changes.

A. Identify and estimate the number of small businesses affected by the proposed rules and the probable effect on small businesses.

As of May 6, 2022, the most recent professional licensing active counts indicated that there were approximately 17,124 pharmacists licensed in Michigan.

No matter what type of business environment the licensee works in, he or she will have to take the necessary steps to comply with the proposed rules. The rules do not affect small businesses differently. The anticipated effects on licensees are minimal because they clarify what is already required of licensees and not of the business in which they may work.

B. Describe how the agency established differing compliance or reporting requirements or timetables for small businesses under the rules after projecting the required reporting, record-keeping, and other administrative costs.

The agency did not establish separate compliance or reporting requirements for small businesses. The proposed rules will apply to all licensed pharmacists. The rules were drafted to be the least burdensome on all affected licensees.

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 agency did not consolidate or simplify the compliance and reporting requirements for small businesses nor identify the skills necessary to comply with the reporting requirements, as the proposed rules impose requirements on individual licensees rather than small businesses.

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

The agency did not establish performance standards to replace design or operation standards required by these rules.

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

The proposed rules affect individual licensees, rather than small businesses. Therefore, there is no disproportionate effect on small businesses because of their size or geographic location.

21. Identify the nature of any report and the estimated cost of its preparation by small businesses required to comply with the proposed rules.

The proposed rules affect individual licensure applications and renewals, which are already required of all licensees, regardless of if they practice in a small business. There is no separate cost to small businesses.

22. Analyze the costs of compliance for all small businesses affected by the proposed rules, including costs of equipment, supplies, labor, and increased administrative costs.

There are no expected increased costs for small businesses concerning the costs of equipment, supplies, labor, or administrative costs.

23. Identify the nature and estimated cost of any legal, consulting, or accounting services that small businesses would incur in complying with the proposed rules.

There are no expected increased costs for small businesses concerning legal, consulting, or accounting services.

24. 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 expected costs to small businesses that will cause economic harm to a small business or the marketplace as a result of the proposed rules.

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.

The proposed rules impose requirements on licensees. Even if a licensee's employer qualifies as a small business, the Department could not exempt his or her business because it would create disparity in the regulation of licensees.

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

The proposed rules impose requirements on licensees. Even if a licensee's employer qualifies as a small business, the Department could not exempt his or her business because it would create disparity in the regulation of licensees. Therefore, exempting or setting lesser standards of compliance for small businesses is not in the best interest of the public.

27. Describe whether and how the agency has involved small businesses in the development of the proposed rules.

The Department worked with multiple stakeholders at the Michigan Board of Pharmacy Rules Committee Work Group meetings, which included members from the Board of Pharmacy, educational institutions, businesses, and other members of the public in the development of the proposed rules. The Board is composed of members of the profession and members of the public who may work in businesses in Michigan.

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

Representatives from businesses were involved in the development of the rules. However, the Department is not aware if they meet the definition of a "small business."

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

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

The Department does not expect any statewide compliance costs of the proposed rules on businesses or groups.

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

The Department does not expect any businesses or groups to be directly affected by, bear the cost of, or directly benefit from 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)? Please identify the types and number of businesses and groups. Be sure to quantify how each entity will be affected.

The Department does not expect the proposed rules to result in any additional costs such as new equipment, supplies, labor, accounting, or recordkeeping on businesses or other groups.

29. Estimate the actual statewide compliance costs of the proposed rules 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 are no additional compliance costs placed on individuals as a result of the proposed rules.

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

As of May 6, 2022, the most recent professional licensing active counts indicated that there were approximately 17,124 pharmacists licensed in Michigan.

B. What qualitative and quantitative impact do the proposed changes in rules have on these individuals?

The proposed rules will allow more licensees to meet continuing education requirements, make continuing education approval easier, and add more options for continuing education, which will allow licensees to maintain their education in pharmacy subjects.

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

There will be a reduction in costs to individuals as follows: licensees will be able to use human trafficking training, opioid and controlled substances awareness training, and implicit bias training towards their continuing education requirements; licensees will be able to use virtual courses towards the 10 hours of live courses requirement; and licensees will be able to attend board meetings, disciplinary meeting, and rules committee work group meetings for continuing education credit, which are free to attend. The savings to licensees due to these rule modifications cannot be quantified as the cost of a continuing education course varies, however, it is expected that there will be a reduction in costs.

There will be a reduction in costs to entities that apply for continuing education approval as they will be asked to submit less supporting documentation with their application.

31. Estimate the primary and direct benefits and any secondary or indirect benefits of the proposed rules. Please provide both quantitative and qualitative information, as well as your assumptions.

The proposed rules will allow more licensees to meet continuing education requirements, make continuing education approval easier, and add more options for continuing education, which will allow licensees to maintain their education in pharmacy subjects. This benefits both the licensees and indirectly benefits the citizens of Michigan.

There will be a reduction in costs to licensees as: licensees will be able to use human trafficking training, opioid and controlled substances awareness training, and implicit bias training towards their continuing education requirements; licensees will be able to use virtual courses towards the 10 hours of live courses requirement; and licensees will be able to attend board meetings, disciplinary meeting, and rules committee work group meetings for continuing education credit, which are free to attend.

There will be a reduction in costs to entities that apply for continuing education approval as they will be asked to submit less supporting documentation with their application.

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

The rules are not expected to have an impact on business growth, job creation, or job elimination.

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.

There is not expected to be a disproportionate effect due to industrial sector, segment of the public, business size, or geographic location.

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 the proposed rules and a cost-benefit analysis of the proposed rules.

Survey of Pharmacy Law, National Association of Boards of Pharmacy

NABP | National Association of Boards of Pharmacy

A. How were estimates made, and what were your assumptions? Include internal and external sources, published reports, information provided by associations or organizations, etc., that demonstrate a need for the proposed rules.

No estimates or assumptions were made.

Alternative to Regulation

35. Identify any reasonable alternatives to the proposed rules that would achieve the same or similar goals.

Since the rules are required by statute, there is no other reasonable alternative to the proposed rules that would achieve the same or similar goal.

A. Please include any statutory amendments that may be necessary to achieve such alternatives.

There is no other reasonable alternative to the proposed rules that would achieve the same or similar goal.

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

Since the rules are authorized by statute, private market-based systems cannot serve as an alternative. Each state is responsible for implementing its own laws and rules pertaining to licensing pharmacists. Private market-based systems are not used for regulating licensees. The licensing and regulation of pharmacists are state functions, so a regulatory program independent of state intervention cannot be established. The profession has numerous professional associations that could be considered regulatory mechanisms that are independent of state intervention; however, these professional organizations would provide the public with significantly less protection because membership in many of these organizations is voluntary. This means an individual who meets the membership requirements, but does not join one of the professional organizations, would be able to practice and there would be no way to ensure their competency or hold them accountable.

37. Discuss all significant alternatives the agency considered during rule development and why they were not incorporated into the rules. This section should include ideas considered both during internal discussions and discussions with stakeholders, affected parties, or advisory groups.

Since the rules are required by statute, there are no alternatives to the proposed rules that the agency could consider. They are necessary for the administration and enforcement of the licensing process.

Additional Information

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

The rules will explicitly inform licensees of the continuing education requirements. Additional direction regarding continuing education will be included on the Department's application for renewal and on the Department's website.