

**Michigan Office of Administrative Hearings and Rules**  
611 West Ottawa Street; 2nd Floor, Ottawa 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 Michigan Office of Administrative Hearings and Rules (MOAHR) at [o'berryd@michigan.gov](mailto:o'berryd@michigan.gov) no less than 28 days before the public hearing.

**1. Agency Information**

Agency name:	Department of Licensing and Regulatory Affairs		
Division/Bureau/Office:	Bureau of Professional Licensing		
Name, title, phone number, and e-mail of person completing this form:	Andria M. Ditschman 517-241-9255 DitschmanA@michigan.gov		
Name of Departmental Regulatory Affairs Officer reviewing this form:	Liz Arasim Department of Licensing and Regulatory Affairs		

**2. Rule Set Information**

MOAHR assigned rule set number:	2019-022 LR
Title of proposed rule set:	Board of Pharmacy – Pharmacist Continuing Education

**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.

Each state establishes its own requirements with respect to a pharmacist’s continuing education, so there are no federal rules or standards set by a national or state agency that the proposed rules can be compared to.

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

The proposed rules are required by sections 16204, 17731, and 17737 of the Public Health Code (Code), MCL 333.16204, MCL 333.17731, and MCL 333.17737. The rules are not federally mandated.

The proposed rules are authorized by state law. Sections 16145, 16148, 16184, 16201, 16205, and 17767 of the Code, MCL 333.16145, MCL 333.16148, MCL 333.16184, MCL 333.16201, MCL 333.16205, and MCL 333.17767, authorize the Board of Pharmacy to establish specific requirements for licensure renewal for pharmacists and special volunteer pharmacists, including the standards for continuing education and training of applicants for renewal.

**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 proposed rules do not exceed any federal standards.

**2.** Compare the proposed rule(s) 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 30 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 30 continuing education credits in each 2-year licensing cycle. In Ohio, a licensee must accumulate 40 continuing education credits in each 2-year licensing cycle. In New York, a licensee must accumulate 45 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, 2 hours in jurisprudence or law and 2 hours in medications errors and patient safety; and in Indiana, 6 hours in computer related strategies to reduce medication errors.

**A.** If the rule(s) exceed standards in those states, 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 some differences between states, however, the requirements are very 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 rule(s).

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 rule has been coordinated, to the extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter. This section should include a discussion of the efforts undertaken by the agency to avoid or minimize duplication.

There are 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 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:

MCL 24.232(8) does not apply.

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:

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 rule(s) are designed to alter.

The purpose of the proposed rules is set forth below:

**R 338.3041:** This rule establishes continuing education requirements for the renewal of a license. The proposed revisions: clarify that the continuing education requirements also apply to a special retired pharmacist; require completion of the 1-time training identifying victims of human trafficking and 1-time training in opioids and other controlled substances awareness for existing licensees in order to renew a license; clarify that continuing education is only required if a licensee has been licensed for a full 2-year license cycle; require 1 of the 30 required hours of continuing education be in pharmacy ethics and jurisprudence; clarify what types of courses qualify for the pain and symptom management requirement; clarify that a licensee shall not earn credit for taking the same continuing education course or program twice during 1 renewal period; require that the licensee retain documentation of meeting the continuing education requirements for 4 years; allow the Board to require a licensee to submit evidence to demonstrate compliance with the continuing education requirements; and require a licensee who seeks a waiver of continuing education to submit the request prior to the expiration date of the license.

**R 338.3043:** This rule provides the standards for approval by the Board for continuing education courses and programs. The proposed revisions: require a patient protection form as part of the application for any course or program that involves treatment of live patients; require submission of an application at least 70 days prior to the continuing education course or program being conducted and 70 days prior to the next regularly scheduled Board meeting in order to be considered by the Board for approval; require that a continuing education course or program be relevant to health care and the advancement of the licensee’s pharmacy education; clarify that a course or program in emergency skills must be related to the health of the patient in the pharmacy setting; clarify that approval is for 3 years; require changes to an approved continuing education program or course to be reevaluated by the Board 70 days prior to the next regularly scheduled Board meeting and prior to the date the course or program is conducted unless the change is an emergency change; and require a continuing education certificate to include specific information.

**R 338.3044:** This rule specifies acceptable continuing education activities. The proposed revisions: organize the continuing education activities in R 338.3044, as well as the continuing education in R 338.3045(2) in a table. The proposed revisions also add the following activities to the table as acceptable continuing education activities: completion of a course or program which is offered or approved by a pharmacy school accredited by the Accreditation Council for Pharmacy Education (ACPE) or the Canadian Council for Accreditation of Pharmacy Programs, an entity approved by the ACPE, an entity approved by the Michigan Pharmacists Association (MPA), or another state Board of Pharmacy; participation in a home study program offered through an ACPE approved provider, or other instructional approaches that include an evaluation component; participation as a preceptor for at least 1 pharmacy intern for 120 hours; publication of an article or chapter related to the practice of pharmacy in a pharmacy textbook or peer reviewed journal; successful completion of a board certification national pharmacy examination through Board of Pharmacy specialties; presentation of a continuing education

program approved by the Board under R 338.3043 that is not a part of the licensee’s regular job description; and attendance at a pharmacy-related program approved by the Board pursuant to R 338.3043. The proposed rule also includes the proof required by the Department to show attendance at each activity and the number of continuing education hours that may be earned.

**R 338.3045:** This rule provides the renewal requirements for a pharmacist who resides or practices in another state. The rule is proposed for rescission. The existing rule allows a pharmacist who resides or practices in another state to renew in this state solely by showing proof of licensure in another state if the other state has substantially equivalent continuing education requirements. The rule also allows renewal if the pharmacist shows that they have accumulated continuing education substantially equivalent to the requirements in this state. The first option aforementioned will be deleted from the rules. The second option will be added to the acceptable continuing education table in R 338.3044.

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

**R 338.3041:** This rule establishes continuing education requirements for the renewal of a license. The change in frequency of the targeted behavior expected from the proposed rules includes: all licensees that have not been licensed for two years prior to renewing will not be required to meet the continuing education requirements; all licensees renewing will be required to have 1 hour of continuing education in pharmacy ethics and jurisprudence; no licensee will be able to take the same continuing education course or program twice during 1 renewal period; and no licensee will be allowed to waive continuing education after the license cycle has ended or at the time they are being audited.

**R 338.3043:** This rule provides the standards for approval by the Board for continuing education courses and programs. The change in frequency of the targeted behavior expected from the proposed rules includes: all applications for continuing education courses and programs must be submitted to the Department earlier so there is adequate time for review of an application for completeness and review by the Board before the course or program is given to licensees; all requests for approval of courses or programs that relate to emergency situations must relate to the health of the patient; and all continuing education certificates will contain specific information.

**R 338.3044:** This rule specifies acceptable continuing education activities. The change in frequency of the targeted behavior expected from the proposed rules is that no credit will be given for presentation of a continuing education program if the presentation is part of the licensee’s job.

**R 338.3045:** This rule provides the renewal requirements for a pharmacist who resides or practices in another state. The change in frequency of the targeted behavior expected from the proposed rules is that a pharmacist who resides or practices in another state will not be able to renew in this state solely by showing proof of licensure in another state even if the other state has substantially equivalent continuing education requirements. However, a pharmacist who resides or practices in another state may renew in this state by showing they have accumulated continuing education substantially equivalent to the requirements in this state which earns 30 continuing education credits pursuant to R 338.3044.

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

**R 338.3041:** This rule establishes continuing education requirements for the renewal of a license. The difference between the current behavior/practice and desired behavior/practice by enacting the proposed revisions is to: allow the Department to confirm by attestation by the licensee that he or she has met both of the 1-time training requirements, which help to reduce the number of licensees who are practicing without having taken the trainings; not require the licensee to accumulate continuing education for a partial license cycle; require 1 hour of continuing education in pharmacy ethics and jurisprudence; stop a licensee from earning credit for taking the

same continuing education course or program twice during 1 renewal period; put the licensee on notice that they must retain continuing education documentation for 4 years and may be required to submit evidence to demonstrate compliance with the continuing education requirements; and stop licensees from asking to waive continuing education after the license cycle has ended or at the time they are being audited.

**R 338.3043:** This rule provides the standards for approval by the Board for continuing education courses and programs. The difference between the current behavior/practice and desired behavior/practice by enacting the proposed revisions is to: require a patient protection form as part of the application for any course or program that involves treatment of live patients; require applications for continuing education courses and programs to be submitted to the Department earlier so there is adequate time for review of an application for completeness and review by the Board before the course or program is given to licensees; stop requests for approval of courses or programs that relate to emergency situations that are not related to the health of the patient; provide longer approval of programs and courses so reapplication is not necessary each year; limit changes to program speakers without approval by the Board before the course or program is given to licensees; and require certain information be contained in a continuing education certificate that makes reviewing compliance with requirements faster for the Department and reduce the uncertainty for the licensee.

**R 338.3044:** This rule specifies acceptable continuing education activities. The difference between the current behavior/practice and desired behavior/practice by enacting the proposed revisions is to: simplify the continuing education requirements for licensees by placing the acceptable continuing education in 1 rule and 1 table for easier use of the information; provide more options for continuing education; prohibit submission of a presentation of a continuing education program if the presentation is part of the licensee's job; and stop submission of continuing education without proper documentation as the requirements are included in the rule.

**R 338.3045:** This rule provides the renewal requirements for a pharmacist who resides or practices in another state. The difference between the current behavior/practice and desired behavior/practice by enacting the proposed revisions is to prohibit a pharmacist who resides or practices in another state from renewing in this state solely by showing proof of licensure in another state even if the other state has substantially equivalent continuing education requirements. However, a pharmacist who resides or practices in another state may renew in this state by showing they have accumulated continuing education substantially equivalent to the requirements in this state by earning 30 continuing education credits pursuant to R 338.3044.

#### C. What is the desired outcome?

**R 338.3041:** This rule establishes continuing education requirements for the renewal of a license. The desired outcome is to: ensure that licensees have taken both of the 1-time training requirements; avoid evaluating a licensee's continuing education until they have been licensed for a full licensing cycle; ensure licensees are receiving training in ethics and the laws of this state; stop licensees from taking the same continuing education course or program twice during 1 renewal period; avoid having to discipline a licensee because he or she did not maintain adequate records of their continuing education; and prohibit waivers of continuing education after a licensure cycle, when a licensee is in the audit process, or when a licensee is being disciplined for lacking continuing education.

**R 338.3043:** This rule provides the standards for approval by the Board for continuing education courses and programs. The desired outcome is to: require a patient protection form as part of the application for any course or program that involves treatment of live patients; require applications for continuing education courses and programs to be submitted to the Department earlier so there

is adequate time for review of an application for completeness and review by the Board before the course or program is given to licensees; approve courses or programs that relate to emergency situations that are only related to the health of the patient; reduce the number of reapplications for courses and programs each year; limit changes to program speakers without approval by the Board before the course or program is given to licensees; make reviewing compliance with continuing education requirements faster for the Department and reduce uncertainty for the licensee.

**R 338.3044:** This rule specifies acceptable continuing education activities. The desired outcome is to: simplify the continuing education requirements for licensees; provide more options for continuing education; prohibit credit for a program that is part of the licensee’s job; make reviewing compliance with continuing education requirements faster for the Department and reduce uncertainty for the licensee; and make reviewing compliance with continuing education requirements faster for the Department and reduce uncertainty for the licensee.

**R 338.3045:** This rule provides the renewal requirements for a pharmacist who resides or practices in another state. The desired outcome is to prohibit a pharmacist who resides or practices in another state from renewing in this state solely by showing proof of licensure in another state even if the other state has substantially equivalent continuing education requirements.

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.

**R 338.3041:** This rule establishes continuing education requirements for the renewal of a license. The harm resulting from the behavior that the proposed rules are designed to alter is: licensees who are practicing without having taken the human trafficking and opioid awareness 1-time trainings; licensees lacking knowledge of ethics and the laws in Michigan; licensees taking the same continuing education course or program twice during 1 renewal period; licensees failing to maintain their proof of attending a continuing education course or program; and licensees attempting to waive continuing education after the license cycle has ended, when they are being audited, or when they are being disciplined.

**R 338.3043:** This rule provides the standards for approval by the Board for continuing education courses and programs. The harm resulting from the behavior that the proposed rules are designed to alter is: licensees taking continuing education courses or programs that have not been approved by the Board; licensees taking continuing education courses or programs involving emergency situations that are not related to the health of the patient; the Board having to review programs and courses each year; continuing education sponsors changing speakers at the last minute that are not necessary; and licensees not having access to continuing education certificates that meet the requirements in these rules.

**R 338.3044:** This rule specifies acceptable continuing education activities. The harm resulting from the behavior that the proposed rules are designed to alter includes: licensees not having notice of the type of continuing education that is acceptable; licensees having limited continuing education options; licensees using activities in their course of employment for continuing education credit; and licensees failing to submit the proper documentation.

**R 338.3045:** This rule provides the renewal requirements for a pharmacist who resides or practices in another state. The harm resulting from the behavior that the proposed rules are designed to alter is the Department renewing a pharmacist’s license who resides or practices in another state without the pharmacist attesting on their renewal application that they have met the continuing education requirements because they can obtain renewal solely by showing proof of licensure in another state.

There is a great likelihood that the harms aforementioned will occur in the absence of the proposed rules.

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

**R 338.3041:** This rule establishes continuing education requirements for the renewal of a license. The rationale for changing the rules instead of leaving them as currently written is to avoid the following: licensees practicing without having taken the human trafficking and opioid awareness 1-time trainings; licensees lacking knowledge of ethics and the laws in Michigan; licensees taking the same continuing education course or program twice during 1 renewal period; licensees failing to maintain their proof of attending a continuing education course or program; and licensees attempting to waive continuing education after the license cycle has ended, when they are being audited, or when they are being disciplined.

**R 338.3043:** This rule provides the standards for approval by the Board for continuing education courses and programs. The rationale for changing the rules instead of leaving them as currently written is to avoid the following: licensees taking continuing education courses or programs that have not been approved by the Board; licensees taking continuing education courses or programs involving emergency situations that are not related to the health of the patient; the Board having to review programs and courses each year; continuing education sponsors changing speakers at the last minute that are not necessary; and licensees not having access to continuing education certificates that meet the requirements in these rules.

**R 338.3044:** This rule specifies acceptable continuing education activities. The rationale for changing the rules instead of leaving them as currently written is to avoid the following: licensees not having notice of the type of continuing education that is acceptable; licensees having limited continuing education options; licensees using activities in their course of employment for continuing education credit; and licensees failing to submit the proper documentation.

**R 338.3045:** This rule provides the renewal requirements for a pharmacist who resides or practices in another state. The rationale for changing the rules instead of leaving them as currently written is to avoid the Department renewing a pharmacist’s license who resides or practices in another state without the pharmacist attesting on their renewal application that they have met the continuing education requirements because they can obtain renewal solely by showing proof of licensure in another state.

**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.

**R 338.3041:** This rule establishes continuing education requirements for the renewal of a license. The rules protect the health, safety, and welfare of the Michigan citizens while promoting a regulatory environment in Michigan that is the least burdensome alternative for those required to comply by: ensuring by attestation instead of submitting documentation that licensees have taken both of the 1-time training requirements; requiring continuing education, but not until licensees have been licensed for a full licensing cycle; ensuring licensees are receiving training in ethics and the laws of this state but keeping the requirement at only 1 hour every 2 years; ensuring that licensees do not repeat the same course or program during a licensing cycle but not limiting a licensee from taking two classes during the same cycle that are similar; requiring licensees to maintain adequate records of their continuing education but not require submission of those records unless they are requested by the Department; and allowing waivers of continuing education, but only if filed before the end of the licensure cycle.

**R 338.3043:** This rule provides the standards for approval by the Board for continuing education courses and programs. The rules protect the health, safety, and welfare of the Michigan citizens while promoting a regulatory environment in Michigan that is the least burdensome alternative for those required to comply by: requiring a patient protection form, but only if the course or program involves treatment of

live patients; requiring applications for continuing education courses and programs to be submitted to the Department earlier so there is adequate time for review of an application for completeness and review by the Board before the course or program is given to licensees, but allowing changes by review, and allowing an exception to the time requirements for emergency changes to the course or program; requiring resubmittal of approved courses and programs, but only once every three years; and requiring only necessary information on continuing education certificates.

**R 338.3044:** This rule specifies acceptable continuing education activities. The rules protect the health, safety, and welfare of the Michigan citizens while promoting a regulatory environment in Michigan that is the least burdensome alternative for those required to comply by requiring licensees to meet continuing education requirements, by providing options to meet those requirements, putting the requirements in a table that is easy to understand, providing the proof necessary for each type of continuing education, and listing the number of credits that may be earned.

**R 338.3045:** This rule provides the renewal requirements for a pharmacist who resides or practices in another state. The rules protect the health, safety, and welfare of the Michigan citizens while promoting a regulatory environment in Michigan that is the least burdensome alternative for those required to comply by prohibiting a pharmacist who resides or practices in another state from renewing in this state solely by showing proof of licensure in another state even if the other state has substantially equivalent continuing education requirements, while still allowing renewal in this state by showing he or she has accumulated continuing education substantially equivalent to the requirements in this state by earning 30 continuing education credits pursuant to R 338.3044.

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

**R 338.3045:** This rule provides the renewal requirements for a pharmacist who resides or practices in another state. The rule is proposed for rescission. The existing rule allows a pharmacist who resides or practices in another state to renew in this state solely by showing proof of licensure in another state if the other state has substantially equivalent continuing education requirements. The rule also allows renewal if the pharmacist shows that they have accumulated continuing education substantially equivalent to the requirements in this state. The first option aforementioned will be deleted from the rules. The second option will be added to the acceptable continuing education table in R 338.3044.

**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).**

The Department does not expect the implementation of the proposed rules to result in additional costs or savings for the Department.

**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).**

The licensing and regulation of the profession, including the promulgation and implementation of rules, is funded by the collection of licensing fees. As a result, there was no reason to make an agency appropriation or provide a funding source. Also, the Department does not expect the proposed rules to increase expenditures.

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 will require a licensee to pay for a licensing fee of \$74.20 and the costs associated with a training on identifying victims of human trafficking, a training on opioids and other controlled substances awareness, and any other continuing education course or program they choose to attend.

The proposed rules are necessary, suitable, and the least burdensome requirements on licensees to ensure that licensees are educated, can communicate effectively with clients, and are safe to practice.

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

The rules are necessary to provide a mechanism for licensing and regulation of the profession. The rules are not any more restrictive than is allowed by statute. Despite the cost-related burden of continuing education, the rules and regulations are necessary in order to provide ongoing education for pharmacists for the safety of the public.

**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 are no anticipated increases or decreases in revenues 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 costs 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 rule(s).

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 rule(s). 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 be in compliance 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 rule(s).

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 rule(s) have on rural areas?

The proposed rules are not expected to impact rural areas. The proposed rules apply to a pharmacist's continuing education regardless of their 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 impact rural areas. The proposed rules apply to a pharmacist's continuing education regardless of their location.

**Environmental Impact:**

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

No, the rules will 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 proposed rules impose requirements on individual licensees not small businesses. Despite the cost-related burden of continuing education on licensees the rules and regulations are necessary in order to provide ongoing education for pharmacists.

**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 proposed rules impose requirements on individual licensees not small businesses. Despite the cost-related burden of continuing education on licensees, the rules and regulations are necessary in order to provide ongoing education for pharmacists.

**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 individual licensees not small businesses.

**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 agency did not establish separate compliance or reporting requirements for small businesses. 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 compliance and reporting requirements with the proposed rules.

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

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

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

There is no expected disproportionate impact 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 rule(s).**

The proposed rules do not require pharmacists to prepare a report. There is no separate cost for report preparation to small businesses.

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 are no costs of compliance for small businesses including costs of equipment, supplies, labor, or increased 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 rule(s).

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.

The proposed rules impose requirements on individual licensees not small businesses. Despite the cost-related burden of continuing education on licensees the rules and regulations are necessary in order to provide ongoing education for pharmacists. All pharmacists licensed in Michigan are subject to the same requirements and costs as a result of the proposed rules so there are no expected costs that should adversely affect competition in the marketplace.

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 individual licensees not small businesses. Exempting or setting lesser standards of compliance for pharmacists is not in the best interest of the public and would increase the cost of protecting the public.

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 individual licensees not small businesses.

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

The Department worked with the Board of Pharmacy as well as associations that represent pharmacies in the development of the proposed rules. The Board is composed of members of health professions, individuals, both small and large business entities in Michigan, as well as public members.

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

The Department worked with the Board of Pharmacy as well as associations that represent pharmacies in the development of the proposed rules. The Board is composed of members of health professions, individuals, both small and large business entities in Michigan, as well as public members.

**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 rule(s).

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)? 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 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 rules will require a licensee to pay for a licensing fee of \$74.20 and the costs associated with a training on identifying victims of human trafficking, a training on opioids and other controlled substances awareness, and any other continuing education course or program they choose to attend.

The proposed rules are necessary, suitable, and the least burdensome requirements on licensees to ensure that licensees are educated, can communicate effectively with clients, and are safe to practice.

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

There are approximately 15,915 licensed pharmacists in Michigan.

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

The proposed rules will require a licensee to pay for a licensing fee of \$74.20 and the costs associated with a training on identifying victims of human trafficking, a training on opioids and other controlled substances awareness, and any other continuing education course or program they choose to attend.

The proposed rules are necessary, suitable, and the least burdensome requirements on licensees to ensure that licensees are educated, can communicate effectively with clients, and are safe to practice.

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

There are no expected reductions in costs to businesses, individuals, groups of individuals or governmental units as a result of the proposed rules.

**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.

The primary and direct benefits and secondary or indirect benefits of the proposed rules include: licensees are more knowledgeable regarding human trafficking, opioid and other controlled substances, pain and symptom management, ethics and jurisprudence, and all other subjects that are included in their required 30 credits of continuing education; licensee do not repeat the same classes in 1 renewal period; licensees maintain adequate records of their continuing education; continuing education waivers are not given when a licensee is in the audit process or when a licensee is being disciplined for not having the required continuing education; the Department is aware of courses and programs that involve live patients; continuing education providers must submit applications to the Department earlier so there is adequate time for review of an application for completeness and review by the Board before the course or program is given to licensees; applications for programs and courses will be submitted once every 3 years; licensees will receive continuing education certificates that meet the Department's requirements for granting credit; the continuing education requirements will be easier to understand; the rules will list

the proof necessary for each type of continuing education, and list the number of credits that may be earned which will make reviewing compliance with continuing education requirements faster for the Department and reduce uncertainty for the licensee; and pharmacists who resides or practice in another state must renew his or her license by meeting the requirements in R 338.3044 by showing they have earned 30 continuing education credits similar to pharmacists residing or practicing in Michigan.

32. Explain how the proposed rule(s) 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 a proposed rule(s) and a cost-benefit analysis of the proposed rule(s).

Illinois

<https://www.continuingeducation.com/pharmacy/state-ce-requirements/illinois>

<https://www.elitecme.com/pharmacy/illinois/requirements/>

<http://www.ilga.gov/commission/jcar/admincode/068/068013300A01000R.html>

Indiana

<https://www.continuingeducation.com/pharmacy/state-ce-requirements/indiana>

<https://www.in.gov/pla/pharmacy.htm>

Minnesota

<https://mn.gov/boards/pharmacy/resources/faqs/faqs/educationrequirementsforpharmacists.jsp>

New York

<https://www.continuingeducation.com/pharmacy/state-ce-requirements/new-york>

<http://www.op.nysed.gov/prof/pharm/pharmceqa.htm>

Ohio

<https://www.pharmacy.ohio.gov/Licensing/CE.aspx>

Pennsylvania

<https://www.continuingeducation.com/pharmacy/state-ce-requirements/pennsylvania>

Wisconsin

<https://www.continuingeducation.com/pharmacy/state-ce-requirements/wisconsin>

<https://www.elitecme.com/pharmacy/wisconsin/requirements/>

<https://dsps.wi.gov/Documents/PharmacistCEFAQ.pdf>

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).

There were no estimates or assumptions made. All information used in the preparation of the proposed rules are included above.

#### 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.

The rules are required by statute. Section 17731(1)(a), MCL 333.17731, allows the Board to accept satisfactory completion of a proficiency examination in lieu of 30 hours of continuing education. The Board has allowed 10 hours of continuing education for successful completion of a board certification national pharmacy examination through Board of Pharmacy Specialties.

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

There is no reasonable alternative to the proposed rules.

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.

Since the rules are required by statute, private market-based systems cannot serve as an alternative. States regulate pharmacists and their continuing education by statute, regulation, or both. Private market-based systems are not used for licensing and regulation. The licensing and regulation of pharmacists are state functions, so a regulatory program independent of state intervention cannot be established. There are professional associations that establish criteria for membership, but 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 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 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), describe any instructions on complying with the rule(s), 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.

-----  
 ↓ **To be completed by the MOAHR** ↓

**PART 4: REVIEW BY THE MOAHR**

Date RISCBA received:	8-5-2019/ 6-20-2019
Date RISCBA approved:	8/5/19
Date of disapproval:	
Explanation:	