Michigan Office of Administrative Hearings and Rules
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REGULATORY IMPACT STATEMENT and COST-BENEFIT ANALYSIS (RIS)

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 orr@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 Ditschman Senior Analyst 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:	2019-057 LR
Title of proposed rule set:	Board of Pharmacy – Controlled Substances

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.

Under the Controlled Substances Act (21 USC 801 et seq.), the federal government regulates the production, possession, and distribution of controlled substances. The Act places drugs, chemicals, and plants into one of five schedules based on certain factors, including but not limited to, the medical use of the substance and the potential abuse of the substance. In addition, the Act requires individuals who manufacture, distribute, or dispense a controlled substance to be registered with the Drug Enforcement Administration in the U.S. Department of Justice. The Act doesn't require registrants to take training on opioids and controlled substances. Registrants, however, are required to keep a record of each controlled substance that was manufactured, received, sold, delivered, or disposed of, and maintain detailed inventories.

Each state establishes its own requirements with respect to the manufacture, distribution, and dispensing of controlled substances. In Michigan, Article 7, Controlled Substances, of the Public Health Code provides for the scheduling of controlled substances as well as establishing requirements for the manufacture, distribution, and dispensing of controlled substances.

While there is no federal rule or standard, or national licensing agency or accreditation association that requires a controlled substance licensee to take a training regarding opioids and controlled substances, the federal act requires individuals who are registered under that act to keep certain records.

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

R 338.3135: The Public Health Code does not specifically require an individual who has a controlled substance license or is applying for a controlled substance license to obtain opioid and controlled substances training. Section 7301 of the Code, MCL 333.7301, however permits the Board of Pharmacy (administrator) to promulgate rules relating to the manufacture, distribution, and prescribing of Schedule 2 controlled substances and the dispensing of controlled substances in this state.

R 338.3162b: Section 7333a of the Code, MCL 333.7333a, requires the Department, by rule, to establish an electronic system for monitoring schedule 2 to 5 controlled substances dispensed in this state by veterinarians, pharmacists, and dispensing prescribers or dispensed to an address in this state by a licensed pharmacy. The Code states that the rules "must provide an appropriate electronic format for the reporting of data including, but not limited to, patient identifiers, and the name of the controlled substance dispensed, the date of dispensing, the quantity dispensed, the prescriber, and the dispenser." The proposed rules will clarify and expand the information that will have to be reported.

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 is responsible for implementing its own laws and rules pertaining to scheduling controlled substances, licensing individuals and entities that will handle controlled substances, and determining requirements and limitations on prescribers and dispensers of controlled substances.

R 338.3135: The proposed rule will require any individual licensed under article 15 who is delegated, ordered, or allowed by a practice agreement to prescribe, dispense, or administer a controlled substance to also take the training. The proposed rule will also exempt an individual licensed under section 7303 of the code, MCL 333.7303, to prescribe or dispense controlled substances only for research on animals from taking the training.

Kentucky, New York, Pennsylvania, and Wisconsin require an education course for practitioners and pharmacists in pain treatment. Kentucky, New York, and Pennsylvania require their education course to include treatment of addiction. Ohio encourages all practitioners who encounter patients with chronic pain in the usual course of their practice to take a course in chronic pain and addiction. Ohio also requires that each person who holds a license to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine or surgery to be offered a continued education in diagnosing and treating chronic pain. Pennsylvania requires all dispensers and prescribers to be trained in the practices of prescribing or dispensing opioids. Beginning in 2020, Illinois requires a course on safe opioid prescribing practices. Beginning in July 1, 2019, Indiana requires a course on opioid prescribing and opioid abuse. Minnesota does not require an education course in opioids.

None of the states in the Great Lakes Region require individuals delegated, ordered, or allowed by a practice agreement to prescribe, dispense, or administer controlled substances to take a specific training in opioid and controlled substances awareness. New York requires every medical resident who is

prescribing under a facility registration number from the United States Department of Justice to take a course in pain management, palliative care, and addiction.

R 338.3162b: The proposed rule will require additional information to be submitted to the database which will reduce the frequency of abuse and diversion and more readily assist prescribers and dispensers in assessing a patient's risk. A pharmacist, dispensing prescriber, or veterinarian who dispenses a controlled substance listed in schedules 2 to 5, or a pharmacy licensed by this state that dispenses in this state or dispenses to an address in this state will now be required by rule to report the following information to the Prescription Drug Monitoring Program: an animal's name if the medication is being dispensed for an animal; patient's or client's full name, address, phone number, gender, and date of birth; the species code as specified by the American Society for Automation in Pharmacy (ASAP); number of refills authorized; refill number of the prescription fill; prescription transmission form code, as specified by ASAP, that indicates how the pharmacy received the prescription; prescription payment type; electronic prescription reference number, if applicable; and patient's or client's location code when receiving pharmacy services, as specified by ASAP. In addition, beginning January 1, 2020, the first and last name, relationship, and identifier of the patient, patient's representative, or client who is obtaining the dispensed controlled substance on behalf of the patient or animal will be required.

All states in the Great Lakes Region have a prescription drug monitoring program. States differ on the type of identifying information collected. The specific information that is required by prescription drug monitoring systems in the Great Lakes Region could be obtained on only Indiana, Minnesota, Pennsylvania, and Ohio. All four states require an animal's name when the medication is dispensed for an animal, the patient's or animal owner's full name, address, phone number, gender, and date of birth, the species code, number of refills authorized, and refill number of the prescription fill. Only Minnesota requires the prescription transmission code, as specified by ASAP, that indicates how the pharmacy received the prescription. None of the states require the electronic prescription reference number or the identifying information on the patient's representative or client who is obtaining the dispensed controlled substance on behalf of the patient or animal. Only Minnesota requires the patient's or animal owner's location code when receiving pharmacy services, as specific by ASAP. However, this is required by Massachusetts, and Oklahoma and New Jersey may collect the information in specific situations.

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

R 338.3135: The proposed rule exceeds the standards of other states in the Great Lakes Region as it requires individuals licensed under article 15 who have been delegated, ordered, or allowed by a practice agreement to prescribe, dispense, or administer controlled substances as authorized by the act to take a specific training in opioid and controlled substances awareness. The Board of Pharmacy and the Department have determined that requiring an opioid and controlled substances training for individuals who have been delegated, ordered, or allowed by a practice agreement to prescribe, dispense, or administer controlled substances will protect the public and result in a minimal cost of approximately $1 to $100 to the licensee, depending on who provides the training.

R 338.3162b: Collection of the prescription transmission code, as specified by ASAP, that indicates how the pharmacy received the prescription, the electronic prescription reference number, the identifying information on the patient's representative or client who is obtaining the dispensed controlled substance on behalf of the patient or animal, and the patient's or animal owner's location code when receiving pharmacy services, as specified by ASAP, exceeds the standards of other states in the Great Lakes Region. The Board of Pharmacy and the Department

have determined that requiring the additional information will reduce the frequency of abuse and diversion and more readily assist prescribers and dispensers in assessing a patient's risk.

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

There are no other Michigan laws, rules or other legal requirements that duplicate, overlap, or conflict with the proposed rules. R 338.3162b(1)(a) requires a pharmacist, dispensing prescriber, and veterinarian who dispenses a schedule 2 to 5 controlled substance drug or a pharmacy that dispenses one of these drugs to an address in the state to report to the electronic monitoring system the "patient identifier" as defined in R 338.3102(1)(f). R 338.3102(1)(f) specifies the information that is considered to be a patient identifier, including a patient's full name; address, including zip code, date of birth, and photo identification issued by this state. Rule 338.3162b is being amended to require the information included in the definition of "patient identifier" for both a patient and a client (owner) of an animal. The type of information being added to R 338.3162b(1) clarifies the information that is included in the definition of "patient identifier."

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.

Except as discussed previously, there are no other federal, state, or local laws that require an opioid and controlled substance training for prescribers and dispensers of controlled substances in order to obtain or maintain a controlled substance license in this state. In addition, except as discussed previously, there are no federal, state, or local laws that require a pharmacist, dispensing prescriber, and veterinarian who are dispensers of controlled substances to submit information to an electronic system for monitoring controlled substances. As mentioned in an earlier response, the federal Controlled Substances Act (21 USC 801 et seq.) requires individuals who manufacture, distribute, or dispense a controlled substance to be registered with the Drug Enforcement Administration in the U.S. Department of Justice. Registrants are required to keep a record of each controlled substance that was manufactured, received, sold, delivered, or disposed of, and maintain detailed inventories.

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:

There is no applicable federally mandated standard. Consequently, MCL 24.232(8) is not applicable.

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:

There is no applicable federal standard. The federal Controlled Substances Act does not address controlled substances training or require a prescription drug monitoring program. Consequently, MCL 24.232(9) is not applicable. Section 7301 of the Code, MCL 333.7301, however permits the Board of Pharmacy (administrator) to promulgate rules relating to the manufacture, distribution, and prescribing of Schedule 2 controlled substances and the dispensing of controlled substances in this state. Establishing an electronic system for monitoring schedule 2 to 5 drugs dispensed in this state by veterinarians, pharmacists, and dispensing prescribers is mandated by section 7333a of the Public Health Code, MCL 333.7333a.

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 338.3135: This proposed rule requires an opioid and controlled substances awareness training for all individuals licensed under article 15 who are delegated, ordered, or acting pursuant to a practice agreement who prescribe, administer, or dispense on behalf of a licensee. The proposed rule is designed to require individuals licensed under article 15, who are delegated, ordered, or acting pursuant to a practice agreement, who prescribe, administer, or dispense on behalf of a licensee, to be educated on all of the following: the use of opioids and other controlled substances, integration of treatments, alternative treatments for pain management, how to counsel on the effects and risks associated with using opioids and controlled substances, the stigma of addiction, utilizing the Michigan Automated Prescription System, laws related to prescribing and dispensing controlled substances, and security and proper disposal of prescriptions.

The proposed rule will exempt an individual who is licensed under section 7303, MCL 333.7303, to prescribe or dispense controlled substances only for research on animals, from having to attend the opioid and controlled substances awareness training.

R 338.3162b: This proposed rule requires a pharmacist, dispensing prescriber, and veterinarian who dispense a controlled substance listed in schedules 2 to 5, or a pharmacy licensed by this state that dispenses in this state or dispenses to an address in this state to report the following information to the Prescription Drug Monitoring Program: an animal's name if the medication is being dispensed for an animal; patient's or client's full name, address, phone number, gender, and date of birth; the species code as specified by ASAP; number of refills authorized; refill number of the prescription fill; prescription transmission form code, as specified by ASAP, that indicates how the pharmacy received the prescription; prescription payment type; electronic prescription reference number, if applicable; and patient's or client's location code when receiving pharmacy services, as specified by ASAP. In addition, beginning January 1, 2020, the first and last name, relationship, and identifier of the patient, patient's representative, or client who is obtaining the dispensed controlled substance on behalf of the patient or animal will be required.

The database can be used by the state, prescribers, and dispensers to assess a patient's risk, to track controlled substances used in this state, identify and prevent opioid overdoses, and reduce substance abuse and drug diversion at the prescriber, pharmacy, and patient levels. The proposed rule requires additional information to be collected by a pharmacist, dispensing prescriber, and veterinarian who dispense a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by this state that dispenses in this state or dispenses to an address in this state. The information being added to the list of information that must be reported will enhance the state Prescription Drug Monitoring Program, as collecting additional identifying information on a patient, their representative, or client (animal's owner) will increase diversion and substance abuse prevention, and allow users of the database to assess overdose risk.

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

R 338.3135: The proposed rule will notify the licensee when he or she must comply with the requirements and who must obtain the training, which will assist licensees to meet the requirements of the rule. The proposed rule will ensure that as of the dates required in the proposed rule, all individuals licensed under article 15 who are delegated, ordered, or acting pursuant to a practice agreement who prescribe, administer, or dispense on behalf of a licensee will be trained in the use of opioids and other controlled substances.

The proposed rule will no longer require an individual who is licensed under section 7303, MCL 333.7303, to prescribe or dispense controlled substances only for research on animals, to attend a training on opioid and controlled substances awareness.

R 338.3162b: The proposed rule requires additional information to be collected by dispensers of controlled substances. The proposed rule will require additional information to be submitted to the database which will reduce the frequency of abuse and diversion and more readily assist prescribers and dispensers in assessing a patient's risk.

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

R 338.3135: The proposed rule clarifies who is regulated by the rule. The proposed rule will notify the licensee when he or she must comply with the requirements and who must obtain the training. The proposed rule is designed to require individuals licensed under article 15, who are delegated, ordered, or acting pursuant to a practice agreement, who prescribe, administer, or dispense on behalf of a licensee, to attend a training on opioids and controlled substances. The proposed rule will require additional licensees who handle controlled substances to be educated on their use.

The proposed rule will no longer require an individual who is licensed under section 7303, MCL 333.7303, to prescribe or dispense controlled substances only for research on animals, to attend a training on opioid and controlled substances awareness.

R 338.3162b: The proposed rule requires additional information to be collected by a pharmacist, dispensing prescriber, and veterinarian who dispense a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by this state that dispenses in this state or dispenses to an address in this state. The proposed rule will require additional information to be submitted to the database which will reduce the frequency of abuse and diversion and more readily assist prescribers and dispensers in assessing a patient's risk. A dispenser of controlled substances will now have to report the following information to the Prescription Drug Monitoring Program: an animal's name if the medication is being dispensed for an animal; patient's or client's full name, address, phone number, gender, and date of birth; the species code as specified by ASAP; number of refills authorized; refill number of the prescription fill; prescription transmission form code, as specified by ASAP, that indicates how the pharmacy received the prescription; prescription payment type; electronic prescription reference number, if applicable; and patient's or client's location code when receiving pharmacy services, as specified by ASAP. In addition, beginning January 1, 2020, the first and last name, relationship, and identifier of the patient, patient's representative, or client who is obtaining the dispensed controlled substance on behalf of the patient or animal will be required.

C. What is the desired outcome?

R 338.3135: The proposed rule clarifies who is regulated by the rule and when the training is required. The desired outcome is that all individuals licensed under article 15, who are delegated, ordered, or acting pursuant to a practice agreement, who prescribe, administer, or dispense on behalf of a licensee will comply with the rule and become more informed about opioids and other controlled substances.

The desired outcome of the proposed rule is to allow an individual who is licensed under section 7303, MCL 333.7303, to prescribe or dispense controlled substances only for research on animals, without attending a training on opioid and controlled substances awareness.

R 338.3162b: The proposed rule requires additional information to be collected by a pharmacist, dispensing prescriber, and veterinarian who dispense a controlled substance listed in schedules 2

to 5 or a pharmacy licensed by this state that dispenses in this state or dispenses to an address in this state. The proposed rule will require additional information to be submitted to the database which will reduce the frequency of abuse and diversion and more readily assist prescribers and dispensers in assessing a patient's risk. The information being added to the list of information that must be reported will enhance the state Prescription Drug Monitoring Program, as collecting additional identifying information on a patient, their representative, or client (animal's owner) will reduce diversion, and help prescribers and dispensers to refrain from prescribing certain drugs to those persons who are more likely to overdose.

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 338.3135: The proposed rule clarifies who is regulated by the rule and when the training is required. The harm resulting from the behavior that the proposed rule is designed to alter is individuals licensed under article 15, who are delegated, ordered, or acting pursuant to a practice agreement, prescribing, administering, or dispensing controlled substances without adequate understanding of the drugs' effect on an individual. If the proposed rule is not adopted, the individuals aforementioned will not be required to attend a training on opioids and other controlled substances.

The harm resulting from the behavior that the proposed rule is designed to alter is individuals who are licensed under section 7303, MCL 333.7303, prescribing or dispensing controlled substances only for research on animals, having to attend a training on opioid and controlled substances awareness that is not necessary for the safety, health, and welfare of the public. If the proposed rule is not adopted individuals licensed to prescribe or dispense controlled substances only for research on animals will be required to attend the training.

R 338.3162b: The proposed rule requires additional information to be collected by a pharmacist, dispensing prescriber, and veterinarian who dispense a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by this state that dispenses in this state or dispenses to an address in this state and submitted to the state's electronic system for monitoring Schedule 2 -5 controlled substances. The harm resulting from the behavior that the proposed rule is designed to alter is dispensers diverting controlled substances or dispensing controlled substances to an individual who may abuse the drug. If the proposed rule is not adopted, less information will be collected in the Prescription Drug Monitoring Program and it is more likely that diversion and abuse will continue to occur.

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

R 338.3135: The proposed rule clarifies when the training is required and who is regulated by the rule. The rationale for changing the rule instead of leaving it as currently written is to require individuals licensed under article 15, who are delegated, ordered, or acting pursuant to a practice agreement, who prescribe, administer, or dispense controlled substances on behalf of a licensee to become more informed about opioids and other controlled substances so they do not prescribe, dispense, or administer controlled substances without an adequate understanding of the effect on an individual.

The rationale for changing the rule instead of leaving it as currently written is to exempt individuals who are licensed under section 7303, MCL 333.7303, to prescribe or dispense controlled substances only for research on animals, from attending a training on opioid and controlled substances awareness that is not necessary for the safety, health, and welfare of the public.

R 338.3162b: The proposed rule requires additional information to be collected by a pharmacist, dispensing prescriber, and veterinarian who dispense a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by this state that dispenses in this state or dispenses to an address in

this state. The proposed rule will require additional information to be submitted to the database which will reduce the frequency of abuse and diversion and more readily assist prescribers and dispensers in assessing a patient's risk.

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 338.3135: This proposed rule will increase the level of education regarding controlled substances for all individuals licensed under article 15 who are delegated, ordered, or acting pursuant to a practice agreement who prescribe, administer, or dispense on behalf of a licensee. The proposed rule is designed to require individuals licensed under article 15, who are delegated, ordered, or acting pursuant to a practice agreement, who prescribe, administer, or dispense on behalf of a licensee, to become educated on all of the following: the use of opioids and other controlled substances, integration of treatments, alternative treatments for pain management, how to counsel on the effects and risks associated with using opioids and controlled substances, the stigma of addiction, utilizing the Michigan Automated Prescription System, laws related to prescribing and dispensing controlled substances, and security and proper disposal of prescriptions.

This is a one-time training and it allows the participant to attend more than 1 program in order to meet the training requirements.

The proposed rule will exempt individuals who are licensed under section 7303, MCL 333.7303, to prescribe or dispense controlled substances only for research on animals, from attending a training on opioid and controlled substances awareness as it is not necessary for the safety, health, and welfare of the public.

R 338.3162b: The proposed rule requires additional information to be collected by dispensers of controlled substances to reduce the frequency of abuse, diversion, and more readily assist prescribers and dispensers in assessing a patient's risk. The information should be easily retrievable along with the information that is currently required.

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

There are no rules being 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 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.

R 338.3135: This proposed rule will increase the level of education regarding controlled substances for individuals licensed under article 15 who are delegated, ordered, or acting pursuant to a practice agreement who prescribe, administer, or dispense on behalf of a licensee. This is a one-time training and it allows the participant to attend more than 1 program in order to meet the training requirements. A licensee will pay an approximate fee of $1 to $100 to take the training depending on which training they attend. Training may be offered by a nationally recognized or state recognized health related organization, a state or federal agency, a continuing education program or activity, or educational program for initial licensure or registration by a college or university that is accepted by a licensing board established under article 15 of the Public Health Code. The training may be by teleconference, webinar, online presentation, live presentation, or printed or electronic media. However, the need to reduce diversion and abuse of opioids is necessary in relationship to the burden of the cost and time to attend the training.

R 338.3162b: The proposed rule requires additional information to be collected by dispensers of controlled substances. The proposed rule will require additional information to be submitted to the database which may require more time from a licensee to collect the information. However, use of the information to reduce the frequency of abuse and diversion and more readily assist prescribers and dispensers in assessing a patient's risk is necessary in relationship to the burden on the licensee.

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

R 338.3135: This proposed rule will increase the level of education regarding controlled substances for individuals licensed under article 15 who are delegated, ordered, or acting pursuant to a practice agreement who prescribe, administer, or dispense on behalf of a licensee. This is a one-time training and it allows the participant to attend more than 1 program in order to meet the training requirements. Training may be offered by a nationally recognized or state recognized health related organization, a state or federal agency, a continuing education program or activity, or educational program for initial licensure or registration by a college or university that is accepted by a licensing board established under article 15 of the Public Health Code. The training may be by teleconference, webinar, online presentation, live presentation, or printed or electronic media. A licensee will pay an approximate fee of $1 to $100 to take the training depending on which training they attend. However, the need to reduce diversion and abuse of opioids is necessary in relationship to the burden of the cost and time to attend the training.

R 338.3162b: The proposed rule requires additional information to be collected by a pharmacist, dispensing prescriber, and veterinarian who dispense a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by this state that dispenses in this state or dispenses to an address in this state. The proposed rule will require additional information to be submitted to the database which may require more time from a licensee to collect the information. However, use of the information to reduce the frequency of abuse and diversion and more readily assist prescribers and dispensers in assessing a patient's risk is necessary in relationship to the burden on the licensee.

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 licensees 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 licensees 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).

R 338.3135: The proposed rule imposes requirements on individual licensees and not small businesses. The rules and regulations are necessary in order to provide a framework of standards for educating individuals licensed under article 15 who are delegated, ordered, or acting pursuant to a practice agreement who prescribe, administer, or dispense on behalf of a licensee. 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 education of licensees that prescribe, administer, or dispense controlled substances.

R 338.3162b: The proposed rule imposes requirements on individual licensees who dispense scheduled drugs and pharmacies. A pharmacy may be considered a small business. The agency did not consider exempting small businesses from the proposed rule as the proposed rule is required by statute and is necessary for the safety of the public no matter the size of the business.

Despite the cost-related burden of licensing and regulation, the rules and regulations are necessary in order to provide a framework of standards for licensure and practice requirements.

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.

R 338.3135: The rule regarding requiring an opioid and controlled substances training cannot exempt small businesses because the rule does not directly regulate small businesses, but individual licensees. The proposed rule may necessitate that a licensee pays a fee for the opioid awareness training which could range from $1 to $100 depending on the training. However, the need to reduce diversion and abuse of opioids is necessary in relationship to the burden of the cost and time to attend the training.

R 338.3162b: The proposed rules impose requirements on individual licensees and pharmacies. A pharmacy may be considered a small business. The rule is required by statute and is necessary for the safety of the public no matter the size of the business. Therefore, reducing any disproportionate impact upon small businesses is not lawful nor feasible.

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

There are approximately 3,443 pharmacies in Michigan that may be considered small businesses depending on their size and annual sales. There may be an additional cost to a user of the Prescription Drug Monitoring Program to modify their system to allow for collection of the additional information.

The Department does not collect or have access to information that would allow it to identify and estimate the number of small businesses involving prescribers and dispensers of controlled substances that may be affected. No matter what type of business environment a licensee works in, he or she will have to take the necessary steps in order to comply with the proposed rules. The rules do not affect small businesses differently. The anticipated effects on licensees are minimal because the proposed rules 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 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 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 rule(s).

The proposed rules require a pharmacist, dispensing prescriber, and veterinarian who dispense a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by this state that dispenses in this state or dispenses to an address in this state to report the following additional specific information to the Prescription Drug Monitoring Program: an animal's name if the medication is being dispensed for an animal; patient's or client's full name, address, phone number, gender, and date of birth; the species code as specified by ASAP; number of refills authorized; refill number of the prescription fill; prescription transmission form code, as specified by ASAP, that indicates how the pharmacy received the prescription; prescription payment type; electronic prescription reference number, if applicable; and patient's or client's location code when receiving pharmacy services, as specified by ASAP. In addition, beginning January 1, 2020, the first and last name, relationship, and identifier of the patient, patient's representative, or client who is obtaining the dispensed controlled substance on behalf of the patient or animal will be required. As use of the program is mandatory there is no cost to sign up and access the program. In addition, there is a process to request a waiver from reporting if the dispenser does not have the ability to report as required in this rule. There may be an additional cost to a user of the Prescription Drug Monitoring Program to modify their system to allow for collection of the additional information. There is no separate cost for report preparation specific to small businesses as this is an additional reporting requirement for all licensees who dispense controlled substances.

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 approximately 3,443 pharmacies in the state. The Department does not determine which licensed pharmacies qualify as small business. In addition, the Department does not determine the annual gross sales or number of full-time employees associated with each pharmacy license to allow for determining the number of small businesses. However, the impact on licensees who qualify as a small business is minimized in the proposed rules because they are written to provide the minimum amount of regulation necessary to protect the public. There may be an additional cost to a user of the Prescription Drug Monitoring Program to modify their system to allow for collection of the additional information. There is no separate cost for report preparation specific to small businesses as this is an additional reporting requirement for all licensees who dispense controlled substances.

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.

All pharmacies doing business 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.

The costs to a pharmacy are outweighed by the benefit of ensuring that the public is protected. Despite the cost-related burdens of the proposed rules, the rules and regulations are necessary in order to

provide a framework of standards for licensure and practice requirements to protect the public. 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.

Exempting or setting lesser standards of compliance for pharmacies is not in the best interest of the public and would increase the cost of protecting the public.

The proposed rules also impose requirements on individual licensees rather than on small businesses. 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 controlled substance licenses. Therefore, exempting or setting lesser standards of compliance for small businesses is not in the best interest of the public.

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

The costs to a pharmacy are outweighed by the benefit of ensuring that the public is protected. Despite the cost-related burdens of the proposed rules, the rules and regulations are necessary to protect the public. Exempting or setting lesser standards of compliance for small businesses is not in the best interest of the public.

The proposed rules also impose requirements on individual licensees rather than small businesses. Even if a licensee's employer qualifies as a small business, the Department could not exempt his or her employer because it would create disparity in the regulation of controlled substance licenses. 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 rule(s).

The Department worked with the Board of Pharmacy in the development of the proposed rules. The Board is composed of members of health professions, individuals with controlled substance licenses, both small and large business entities in Michigan, as well as public members. Concerns were also received and discussed with various associations, educational institutions, and individual citizens,.

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 in the development of the proposed rules. The Board is composed of members of health professions, individuals with controlled substance licenses, both small and large business entities in Michigan, as well as public members. Concerns were also received and discussed with various associations, educational institutions, and individual citizens.

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 in addition to the impact on pharmacies aforementioned.

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 in addition to the impact on pharmacies.

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 in addition to the impact on pharmacies.

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.

R 338.3135: Regulated individuals may incur a fee for the one-time training on opioids and other controlled substances. A licensee will pay an approximate fee of $1 to $100 to take the training depending on which training they attend.

R 338.3162b: The Department does not expect the proposed rule to result in any additional educational costs, training, application fees, examination fees, license fees, new equipment, supplies, labor, accounting, or record keeping on regulated individuals or the public.

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

R 338.3135: All individuals licensed under article 15 who are delegated, ordered, or acting pursuant to a practice agreement who prescribe, administer, or dispense on behalf of a licensee will be required to attend an opioid and controlled substances awareness training. The number of individuals who will act in the future pursuant to delegation, an order, or a practice agreement are unknown and, therefore, the number of individuals that will be affected can not be stated.

R 338.3162b: The additional information to be collected by dispensers of controlled substances will be required by pharmacists, dispensing prescribers, and veterinarians who dispense a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by this state that dispenses in this state or dispenses to an address in this state. There are less than 54,000 licensees that fit the description of pharmacists, dispensing prescribers, and veterinarians who dispense a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by this state that dispenses in this state or dispenses to an address in this state.

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

R 338.3135: This proposed rule will increase the level of education regarding controlled substances for licensees, delegatees, and those acting pursuant to a practice agreement. This is a one-time training and it allows the participant to attend more than 1 program in order to meet the training requirements. A licensee will pay an approximate fee of $1 to $100 to take the training. However, the need to reduce diversion and abuse of opioids is necessary in relationship to the burden of the cost and time to attend the training.

R 338.3162b: The proposed rule requires additional information to be collected by dispensers of controlled substances. The proposed rule will require additional information to be submitted to the database which may require more time from a licensee to collect the information, however, use of the information to reduce the frequency of abuse and diversion and more readily assist prescribers and dispensers in assessing a patient's risk is necessary in relationship to the burden on the licensee.

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

There may be reductions in costs associated with reductions in diversion and abuse of opioids, however, those costs cannot be estimated at this time.

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.

R 338.3135: The primary benefit of the proposed rule is to increase the level of education regarding controlled substances for all individuals licensed under article 15 who are delegated, ordered, or acting pursuant to a practice agreement who prescribe, administer, or dispense on behalf of a licensee so they do not prescribe, dispense, or administer controlled substances without an adequate understanding of their effect on an individual. Another primary benefit will be the reduction in diversion and abuse of opioids.

Another benefit of the proposed rule to exempt individuals who prescribe or dispense controlled substances only for research on animals from attending a training on opioid and controlled substances awareness is to reduce the regulations on licensees where they are not necessary for the safety, health, and welfare of the public.

R 338.3162b: The proposed rule requires additional information to be collected by pharmacists, dispensing prescribers, and veterinarians who dispense a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by this state that dispenses in this state or dispenses to an address in this state. The primary benefit of the proposed rule is to more readily use the data collected to determine instances of diversion and abuse of controlled substances and assist prescribers and dispensers in assessing a patient's risk of overdose. Another primary benefit is reduced diversions, abuse of controlled substances, and patient overdose.

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).

Centers for Disease Control and Prevention
https://www.cdc.gov/drugoverdose/policy/index.html

CDC Guideline for Prescribing Opioids for Chronic Pain
https://www.cdc.gov/drugoverdose/prescribing/guideline.html

Food and Drug Administration
https://www.fda.gov/Drugs/default.htm

National Association of State Controlled Substances Authorities
http://www.nascsa.org/rxMonitoring.htm

U.D. Department of Health and Human Services
https://www.hhs.gov/opioids/prevention/index.html

Substance Abuse and Mental Health Services Administration

https://www.samhsa.gov/medication-assisted-treatment/training-resources/opioid-courses

U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division
https://www.deadiversion.usdoj.gov/faq/rx_monitor.htm

National Alliance for Model State Drug Laws
https://namsdl.org/

Illinois
https://www.idfpr.com/profs/ContSub.asp

Illinois Rules
http://www.ilga.gov/commission/jcar/admincode/077/07703100sections.html

Illinois Statute
http://ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1941&ChapAct=720%26nbsp%3BILCS%26nbsp%3B570%2F&ChapterID=53&ChapterName=CRIMINAL+OFFENSES&ActName=Illinois+Controlled+Substances+Act%2E

Indiana
https://secure.in.gov/pla/3026.htm

Indiana Rules
https://www.in.gov/pla/3878.htm

Indiana Statute
http://iga.in.gov/

Ohio Board of Pharmacy
http://www.pharmacy.ohio.gov/

Ohio Controlled Substances Statute
http://codes.ohio.gov/orc/3719

Ohio Controlled Substances Rules
http://www.pharmacy.ohio.gov/rules/index.htm

Pennsylvania
https://apps.health.pa.gov/ddc/DDCFaqs.asp

Pennsylvania Rules
www.health.state.pa.us/ddc or www.pacode.com

Pennsylvania Statutes
https://apps.health.pa.gov/ddc/

Wisconsin
https://dsps.wi.gov/Pages/Professions/ControlledSubstancesSUA/Default.aspx

Wisconsin Statutes and Rules
https://dsps.wi.gov/Pages/RulesStatutes/ControlledSubstances.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).

R 338.3135: No estimates or assumptions were made.

R 338.3162b: No estimates or assumptions were made.

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.

There are no other reasonable alternatives to the proposed rules that would achieve the same or similar goals.

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

There are no other reasonable alternatives to the proposed rules that would achieve the same or similar goals.

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.

Section 7301 of the Code, MCL 333.7301, permits the Board of Pharmacy (administrator) to promulgate rules relating to the manufacture, distribution, and prescribing of Schedule 2 controlled substances and the dispensing of controlled substances in this state. Establishing an electronic system for monitoring schedule 2 to 5 drugs dispensed in this state by veterinarians, pharmacists, and dispensing prescribers is mandated by section 7333a of the Public Health Code, MCL 333.7333a. Since the rules are permitted and mandated by statute, private market-based systems cannot serve as an alternative. Each state is responsible for implementing its own laws and rules pertaining to training for controlled substances licenses and submittal of information to a prescription drug monitoring program used in each state. Private market-based systems are not used for regulating controlled substances training or collection of information by the state for drug monitoring. These are state functions, so a regulatory program independent of state intervention cannot be established.

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.

No alternatives were considered during rule development.

Additional Information:

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

Opioid and controlled substance training: The rules will explicitly inform licensees of the training requirements.

Electronic system for monitoring schedules 2, 3, 4, and 5 controlled substances: The rules will explicitly inform licensees of the specific type of information that must be submitted. In addition, instructions on how to use the electronic data transmittal process are on the Bureau of Professional Licensing website, https://www.michigan.gov/lara/0,4601,7-154-89334_72600_72603_55478---,00.html.

↓ **To be completed by MOAHR** ↓

PART 4: REVIEW BY MOAHR

Date RIS received:	6-21-2019

Date RIS approved:	**6/24/19**

Date of RIS disapproval:	
Explanation:	