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

REQUEST FOR RULEMAKING (RFR)

Under the Administrative Procedures Act (APA), 1969 PA 306, the agency that has the statutory authority to promulgate rules must electronically file an RFR with the Michigan Office of Administrative Hearings and Rules (MOAHR) before initiating any changes or additions to the rules. Please submit the RFR to orr@michigan.gov.

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

2. Rule Set Information:

Title of proposed rule set:	Pharmacy – Controlled Substances
Rule number(s) or range of numbers:	R 338.3101 – 338.3199q
Included in agency's annual regulatory plan as rule to be processed in current year?	Yes

3. Estimated timetable for completion, or statutory deadline, if applicable:

1 year.

4. Describe the general purpose of these rules, including any problem(s) the changes are intended to address:

The purpose of the Pharmacy - Controlled Substances Rules is to regulate the schedules, licenses, security, records, dispensing and administering, prescriptions, distributions, and administrative and disciplinary procedures for controlled substances. The draft rules will: clarify R 338.3135, which requires an individual seeking a controlled substance license or an individual who already has a controlled substance license to prescribe or dispense controlled substances to complete a 1-time training on opioids and controlled substances awareness; and R 338.3162b, which requires a pharmacist, dispensing prescriber, and veterinarian licensed in Michigan, to report data to an electronic drug monitoring system when they dispense schedule 2 to 5 controlled substances.

5. Cite the specific rule promulgation authority (i.e. agency director, commission, board, etc., listing all applicable statutory references. If the rule(s) are mandated by any applicable constitutional or statutory provision, please explain.

MCL 333.7301, MCL 333.7333a and Executive Reorganization Order No. 1991-9, MCL 338.3501; Executive Reorganization Order No. 1996-2, MCL 445.2001; Executive Reorganization Order 2003-1, MCL 445.2011, and Executive Reorganization Order 2011-4, MCL 445.2030.

6. Describe the extent to which the rule(s) conflict with, duplicate, or exceed similar regulations, compliance requirements, or other standards adopted at the state, regional, or federal level. Include applicable public act and statutory references.

Each state establishes its own requirements with respect to records and training a licensee to prescribe or dispense a controlled substance so there is no federal rule or standard set by a national or state agency that the proposed rules can duplicate or be in conflict with.

7. Is the subject matter of the rule(s) currently contained in any guideline, manual, handbook, instructional bulletin, form with instructions, or operational memo?

No. The subject matter of these rules is not currently contained in any guideline, handbook, manual, instructional bulletin, form with instructions, or operational memoranda.

8. Explain whether the rule(s) will be promulgated under Sections 44 or 48 of the APA or the full rulemaking process:

These rules will be promulgated using the full rulemaking process.

9. Do the rule(s) incorporate the recommendations of any Advisory Rules Committee formed pursuant to Executive Order 2011-5? If yes, explain.

The proposed rules do not incorporate any recommendation of any Advisory Rules Committee.

10. Is there an applicable decision record as defined in Section 3(6) and required by Section 39(2) of the APA? If so, please attach the decision record.

The Michigan Board of Pharmacy voted to open the rules at the regularly scheduled board meeting on October 10, 2018. Please see attached copy of the minutes from that meeting.

11. Reviewed by the following Departmental Regulatory Affairs Officer:

Liz Arasim
Department of Licensing and Regulatory Affairs

↓ To be completed by MOAHR ↓

Date RFR received:6-11-2019

☒ **Based on the information in this RFR, MOAHR concludes that there are sufficient policy and legal bases for approving the RFR.**

MOAHR assigned rule set number:	**2019-057 LR**
Date of approval:	**6/11/19**

☐ **Based on the information in this RFR, MOAHR is not approving the RFR at this time.**

Date of disapproval:	
Explanation:	