Michigan Office of Administrative Hearings and Rules
MOAHR-Rules@michigan.gov

AGENCY REPORT TO THE JOINT COMMITEE ON ADMNINISTRATIVE RULES (JCAR)

1. Agency Information

Agency name:
Licensing and Regulatory Affairs

Division/Bureau/Office:
Bureau of Professional Licensing

Name of person completing this form:
Jennifer Shaltry

Phone number of person completing this form:
517-241-3085

E-mail of person completing this form:
ShaltryJ1@michigan.gov

Name of Department Regulatory Affairs Officer reviewing this form:
Elizabeth Arasim

2. Rule Set Information

MOAHR assigned rule set number:
2022-6 LR

Title of proposed rule set:
Pharmacy - Controlled Substances

3. Purpose for the proposed rules and background:

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 proposed rules will: clarify the requirements for controlled substance prescriptions; address transferring prescriptions between pharmacies; clarify the schedules of controlled substances; clarify the the requirements related to investigations of suspected theft or significant loss of a controlled substance; address comments made by the public; and update provisions pursuant to changes in the Public Health Code.

4. Summary of proposed rules:

The proposed rules will be modified as follows:

For schedules, the proposed changes adopt the federal schedule subject to drugs scheduled by the state after January 6, 2022, and the rules promulgated by the Michigan Board of Pharmacy; remove Brorphine and Gabapentin as exceptions to the federal schedule; remove Pentazocine from Schedule 5 to Schedule 4; provide an exception to the federal scheduling for isomers, Salvia Divorum, Salvinorum A, Synthetic Cannabinoids, and Synthetic Cathinones.

For controlled substances licensure, the proposed changes require a designated prescriber to have a controlled substance license for a health facility if substances are stored there without an on-site pharmacy or an automated device stocked by a pharmacy and provide an exception to licensure for an emergency kit that contains controlled substances.

For records, the proposed rules permit an electronic duplicate of the original paper prescription, which will become the original prescription, 2 years from the last dispensing date; require a pharmacy that holds an additional license for an automated dispensing system, that dispenses controlled substances, to store inventories and schedule order forms at the licensed location of the automated device; and clarify that if a controlled substance is dispensed from an automated device, documentation maintained on-site in the pharmacy must include the automated device's manufacture's name, model number, and the name and address of the facility where the automated device is located.

For controlled substance prescriptions, the proposed changes clarify that a paper prescription is not required to have preprinted numbers representing the quantity next to a box or line; require that the professional designation for the prescribing practitioner be stored electronically; allow a prescriber to seek waiver of electronic prescription transmission requirements if the prescriber can attest that he or she intends, within 12 months, to not regularly practice their licensed profession for financial gain or as a means of livelihood; and clarify that the prescriber must deliver to the dispensing pharmacist a written prescription postmarked within 7 days after the date the prescription was dispensed, or electronically transmit the prescription under R 338.3162a.

For controlled substance distributions, the proposed changes require a licensee to provide written notification to the department 15 days before controlled substances are transferred.

5. List names of newspapers in which the notice of public hearing was published and publication dates:

The Flint Journal, September 21, 2023
The Grand Rapids Press, September 21, 2023
The Mining Journal, September 23, 2023

6. Date of publication of rules and notice of public hearing in Michigan Register:

10/15/2023

7. Date, time, and location of public hearing:

10/16/2023 09:00 AM at UL-3 , 611 W. Ottawa Street, Lansing, Michigan or
https://ars.apps.lara.state.mi.us/Transaction/RFRTransaction?TransactionID=1365

8. Provide the link the agency used to post the regulatory impact statement and cost-benefit analysis on its website:

https://ARS.apps.lara.state.mi.us/Transaction/RFRTransaction?TransactionID=1365

9. List of the name and title of agency representative(s) who attended the public hearing:

Jennifer Shaltry, Specialist, Bureau of Professional Licensing.
Kerry Przybylo, Manager, Bureau of Professional Licensing.

10. Persons submitting comments of support:

None.

11. Persons submitting comments of opposition:

Rose Baran, Paul Chludzinski.

12. Persons submitting other comments:

Rose Baran, Martha O'Connor.

13. Identify any changes made to the proposed rules based on comments received during the public comment period:

	Name & Organization	Comments made at public hearing	Written Comments	Agency Rationale for Rule Change and Description of Change(s) Made	Rule number & citation changed
1	Baran		Commenter suggested updating the standard for a MAPS claim form referenced in the rule to ASAP 5.0 Standard for Prescription Drug Monitoring Programs.	The board agreed with the suggestion and updated the standard.	R 338.3102 (d) and R 338.3162c
2	Baran		Commenter suggested removing "vendor" from the definition of "NDC" to correspond with the definition found in 21 USC § 207.33.	The board agreed with the suggestion and modified the definition of "NDC" to correspond with the federal regulation.	R 338.3102(f)

3	Baran		Commenter suggested adding a tribal government identification number to the information making up a patient identifier in R 338.3102(h)(iv) and updating the reference in R 338.3162b to reflect the addition.	The board agreed that a tribal government identification number should be part of the patient identifier and added subparagraph (D). As a result of the additional subparagraph, the previous R 338.3102(h)(iv)(D) was renumbered to (E), and the reference in 338.3162b(1)(a)(i) was updated to reflect the change.	R 338.3102(h)(iv)(D) and (E) and R 338.3162b(1)(a)(i)
4	O'Connor		Commenter suggested removing unneeded language to clarify the definition of "isomer."	The board agreed with the suggestion to clarify the rule by removing unneeded language.	R 338.3111(3)(d)
5	O'Connor		Commenter suggested replacing references to the federal regulation with the specific information required for licensure, as some of the references no longer apply and their inclusion is confusing.	The board agreed with the suggestion to specify the requirements for licensure instead of referencing the federal regulation.	R 338.3132(5) and (7)
6	O'Connor		Commenter suggested that due to the state's direction to	The board agreed to require the substance abuse and controlled	R 338.3135(1), (2) and (5)

			accept the federal 8-hour substance abuse and controlled substances training in lieu of the training required under the rule, subrule (1)(a) should be corrected to require only the topics of utilizing the MAPS and state and federal laws regarding prescribing and dispensing controlled substances for licensees required to obtain a DEA registration. For licensees who are not required to obtain a DEA registration, the commenter suggested specifying all of the required training topics in subrule (5). Commenter suggested that the substance abuse and controlled substance training should be required for each licensure cycle rather than just one time.	substances awareness training for each licensure cycle, to remove topics duplicated by the federal training requirements for licensees required to have a DEA registration and continue to require all training topics for licensees not required to obtain a DEA registration.	

7	Baran		Commenter suggested increasing the time period for notifying the department of a suspected theft or significant loss of a controlled substance and submitting a copy of DEA form 106 or an equivalent document to the department to 45 days after completion of the investigation because the DEA provides 45 days from the discovery of the theft or loss to file DEA form 106.	The Board agreed that more time is needed to complete DEA form 106 before submitting it to the Department and modified the time period to notify the Department of the loss or theft to 45 days after completion of the investigation.	R 338.3141 (3)
8	Baran		Commenter opposed removing the words, "on site" from the rule because 21 CFR 1304.04(h) requires paper prescriptions to be kept at the pharmacy.	The board agreed with the comment and kept "on site" in the rule.	R 338.3153 (3)

9	Baran		Commenter suggested deleting the subrule because schedule 2 order forms and controlled substance inventories are already required to be kept at a pharmacy under federal law and R 338.3151(5) and 3153(1).	The board agreed with the comment that the subrule is unnecessary because a pharmacy is already required to keep schedule 2 order forms and controlled substance inventories on site. The board decided to remove the subrule.	R 338.3153 (6)
10	Chludzinski		Commenter questioned how a pharmacy may identify and store a prescriber's professional designation when a prescriber is not required to supply it.	The board agreed to clarify the rule by modifying subdivision (1)(b) to require the prescriber's professional designation be either written on the prescription or stored electronically in the pharmacy's automated data processing system and deleting subrule (6) requiring the professional designation to be stored electronically.	R 338.3161 (1)(b) and (6)

11	Baran		Commenter suggested modifying the rule to comply with the requirements for electronic prescribing under MCL 333.17754a because 333.17754 no longer applies.	The board agreed to update the rule to comply with MCL 333.17754a.	R 338.3162a

14.Date report completed:

3/8/2024