Michigan Office of Administrative Hearings and Rules
611 W. Ottawa Street
Lansing, MI 48909
Phone: 517-335-8658 Fax: 517-335-9512

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:
Andria Ditschman

Phone number of person completing this form:
517-290-3361

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

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

2. Rule Set Information

MOAHR assigned rule set number:
2020-82 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 R 338.3135 and require physician's assistants to meet the opioid training requirements that apply to controlled substances licensees because they hold a controlled substance license; expand the individuals who must take the opioid training; require individuals to take the opioid training by July 1, 2022; exempt an individual licensed under section 7303 of the code, MCL 333.7303, who prescribes or dispenses controlled substances only for research on animals from taking the opioid training; clarify that R 338.3162b requires additional information to be submitted to the Prescription Drug Monitoring Program (MAPS) database; clarify rules regarding electronic transmission of prescriptions pursuant to section 17754a of the Public Health Code; update the controlled substances schedules; update rules related to the opioid crisis; clarify licensing provisions; evaluate the need for a separate license to treat a drug-dependent person; clarify when inventories and records are required; update prescription requirements; clarify dispensing and distribution requirements; and clarify refilling of prescriptions.

4. Summary of proposed rules:

The proposed revisions to the rules will: adopt the federal schedule of controlled substances; clarify when a controlled substance license is required; modify the requirements for opioids and other controlled substances training; modify the licensure requirements for prescribers who provide maintenance or detoxification treatment in the course of their professional practice or who are registered with the DEA to provide such treatment; clarify when a licensee may prescribe, dispense, and administer a controlled substance to a drug dependent individual; clarify "significant" loss; clarify when an inventory of controlled substances is required; modify record retention to two years for most records and 5 years for an original prescription; provide the requirements for electronic transmission of prescriptions; provide the process for a waiver from the mandate to electronically transmit a prescription; and modify reporting to the electronic system for monitoring.

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

Marquette Mining Journal – August 15, 2021; Flint Journal – August 15, 2021; Grand Rapids Press – August 19, 2021

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

9/1/2021

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

9/9/2021 01:00 PM at Location: G. Mennen Williams Building Auditorium , 525 W. Ottawa Street, Lansing, Michigan

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=1208

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

Kerry Przybylo, Manager; Andria Ditschman, Senior Policy Analyst; and Stephanie Wysack, Board Support.

10. Persons submitting comments of support:

The following persons submitted comments in support:
Adam Carlson, Vice President, Advocacy, Michigan Health & Hospital Association (MHA)
Deeb Eid, Advisor, Pharmacy Regulatory Affairs, CVS Health
Timothy Gammons, President, Michigan Society of Addiction Medicine (MISAM)
Julie Novak, Chief Executive Officer, Michigan State Medical Society (MSMS)

11. Persons submitting comments of opposition:

The following persons sent comments in writing:
Rose Baran, PharmD
Barry Cargill, President & CEO, Michigan HomeCare and Hospice Association (MHHA)
Adam Carlson, Vice President, Advocacy, Michigan Health & Hospital Association (MHA)
Deeb Eid, Advisor, Pharmacy Regulatory Affairs, CVS Health
Timothy Gammons, President, Michigan Society of Addiction Medicine (MISAM)
Alicia Mankowski, Pharmacy Compliance Specialist, Meijer
Charlie Mollien
Julie Novak, Chief Executive Officer, Michigan State Medical Society (MSMS)
Brian Sapita, Director of Government Affairs, Michigan Pharmacists Association (MPA)

Kolinda Lambert and Lori Smoker Young, Hospice Care of Southwest Michigan, testified at the public hearing.

12. 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 change	Rule number & citation changed
1	Novak/MSMS		Subrules (3) and (8) appear to be both duplicative and contradictory. For clarity purposes, MSMS suggests that activities requiring a separate controlled substance licenses be included in subrule (3), while exceptions to that requirement be addressed in subrule (8) and (9).	To provide clarity to the rule, activities requiring a separate controlled substance license, will be included in subrule (3), while exceptions to that requirement will be addressed in subrules (8) and (9).	R 338.3132 (3) and (8)
2	Novak/MSMS and Carlson/MHA		To help provide clarity, MHA recommends referencing the Drug Treatment Program Prescriber	To provide clarity, the rule will be modified to state that the Drug Treatment Program Prescriber license	R 338.3137

			License, so providers understand which license is being discussed. MSMS believes that the Department should eliminate proposed Rule 37. With the proposed elimination of the requirement to have a separate controlled substance license for prescribing, dispensing, or administering a controlled substance to a drug dependent person in a drug treatment and rehabilitation program under Rule 32, proposed Rule 37 is both moot and confusing. It is also duplicative of proposed Rule 63, which requires compliance with federal law to provide treatment to a "drug-dependent individual."	is eliminated not waived.	

3	Baran		Other than the beginning inventory the rule does not state the annual inventory must be kept at the licensed location. Add to (5) "at the licensed location."	To add clarity, the phrase "at the licensed location" will be added to the rule.	R 338.3151 (5)
4	Baran		As voided DEA 222 forms must be kept at the licensed location pursuant to 21 CFR 1305.17, "or voided" should be added to the rule.	For consistency with federal regulations, the phrase "or voided" will be added to the rule.	R 338.3153 (a)
5	Eid/CVS Health		The term "sales receipt" be further defined to provide clarity and to explain whether sales receipts may be stored electronically or not.	To clarify, the phrase "in electronic or paper form" will be added to (c).	R 338.3153 (c)
6	Sapita/MPA		We feel that it is a cumbersome requirement to have our institutional pharmacists input their license number every time they check the machines. We would like to see the verbiage requiring the "license number" to be removed completely.	The requirement will be modified to "identification" instead of "name and license number."	R 338.3154 (5)(h)(vi)

7	Mankowski Novak/MSMS Carlson/MHA		For consistency, align the rule with the Code and the Pharmacy General Rules which also addresses electronic transmission of prescriptions.	Effective Date/Subrules (1) and (3): The Public Health Code mandates electronic transmission of prescriptions as of October 1, 2021 but requires that the Department delay the implementation date of the mandate to the date established by the Federal Centers for Medicare and Medicaid Services for electronic transmission of prescription for controlled substances. Therefore, the effective/enforced date will be the date the mandate is enforced by the Federal Centers for Medicare and Medicaid Services. The requirement that a prescriber is unable to meet the requirements of section 17754a(1) or (2) of the code /Subrule (4) (b): A typographical error that requires a prescriber to meet both (1) and	R 338.3162a (1), (3), (4), and (5)

				(2) will be changed to (1) or (2) for consistency with the Pharmacy General Rules and the Code. A dispensing prescriber/Subrule (4)(b)(i): In the Pharmacy General Rules, the basis for a waiver that "the prescriber and dispensing pharmacy are the same entity" was modified to "if the prescription is dispensed by a dispensing prescriber." For consistency, the change will also be made in the CS rules. CMS waiver is automatic state waiver/Subrule (4)(a): The Code requires that if a CMS waiver is granted then the Department shall also grant a waiver. Subrule (5) will be modified to allow for a waiver without meeting other requirements if the CMS waiver has been granted. Professional judgment/Subrule	

				(1)(c): The language in (1)(c) will be modified for consistency with the Code and Pharmacy General Rules by adding "validity" and deleting the last sentence. Delete Subrule (5): The Controlled Substances Rules include a provision that is duplicative of the Code and is not included in the Pharmacy General Rules. For consistency it will be deleted.	
8	Novak/MSMS and Carlson/MHA		Amend to recognize the exceptions to the mandate by adding, "unless an exception under section 17754 of the Code, MCL 333.17754a, applies, …"	The rule will recognize the exceptions to electronic transmissions permitted by MCL 333.17754a.	R 338.3162a (3)
9	Novak/MSMS		Identify examples of qualifying "exceptional circumstances as follows: (iv) The prescriber demonstrates attests to	The exceptional circumstances will be further clarified by adding circumstances suggested in A, C, and D, however, (A) will read "prescribing fewer	R 338.3162a (4)(b)(iii)(A)-(C)

			exceptional circumstances including, but not limited to, the following: A. Prescribing fewer than “X” prescriptions (combined controlled and non-controlled substances) per year. B. Utilizing electronic transmission for non-controlled substances but prescribing fewer than “Y” controlled substance prescriptions per year. (Note: The cost of the enhanced e-prescribing software for controlled substances is not fiscally responsible for some prescribers who rarely prescribe them.) C. Intention to cease practice within the next twelve months. D. Limited practice due to an illness or other unforeseen event.	than 100 controlled substances prescriptions per year or the number of controlled substances prescriptions used in the Federal Centers for Medicare and Medicaid Services waiver for electronic transmission of prescriptions for controlled substances, whichever is more.”	

10	Carlson/MHA		Clarify that the prescriber may declare of formally certify in writing such as with an attestation as to the exceptional circumstances, instead of having to demonstrate the exceptional circumstances.	The rule will read "The prescriber demonstrates by attesting to exceptional circumstances including, but not limited to, the following: …."	R 338.3162a (4)(b)(iii)

11	Mollien		The rules do not address or provide clarity for a definition of what a "cash" transaction is for purposes of reporting "the prescription payment type" under R 338.3162b(1)(q). The rule should add a definition or explain what payment types are considered "cash" under the ASAP 4.1 reporting requirements, which should include cash prices at U&C and, only for purposes of reporting to MAPS, any discount card used that is not regulated under the Insurance Code (e.g., GoodRx, etc.)	The phrase "cash discount cards are considered cash transactions" will be added.	R 338.3162b (1)(q)
12	Novak/MSMS		Rule 63 be eliminated or significantly revised for better clarity and consistency with federal law. This proposed Rule is confusing and uses terminology that is inconsistent with	Pursuant to the comments the following changes are made to the rule: Drug dependent person: Throughout the rule "Drug dependent person" will be modified to "individual with	R 338.3163

			similar federal laws regarding the authorized prescribing, administering and dispensing of controlled substances to an individual for treatment of substance use disorder. Furthermore, the term "drug-dependent individual" is not defined in the Proposed Rule Set and is not acknowledged by the Public Health Code. MSMS questions whether there is a more appropriate and person-first reference to these individuals than "drug-dependent individual."	substance use disorder." Practitioner: Throughout the rule, the various terms, licensee, health professional, and prescriber, will be modified for consistency to practitioner. Behavior allowed/Subrule (1): The rule will be modified to state the behavior that is allowed instead of what is prohibited. "Drug treatment and rehabilitation program"/Subrules (1)(b) and (3)(b): This term is not defined in the Code. It will be modified to "program" which is defined in the Mental Health Code, MCL 330.1260(1)(i). Align with federal regulations: To further align the rule with the federal regulations (b)(i) has been divided into two provisions (b) and (c) to clarify that the limitations of a one-day supply of medicine and no more than 3 days	

				only apply to acute withdrawal not participation in a program. Further, (2) has been modified for consistency with federal regulations to refer to "hospital or similar setting.	
13	Sapita/MPA		Regarding R338.3165 subsection 2(c) which specifies "dispensing pharmacist". We believe this would cause undue hardship on our relief pharmacists who may work at different pharmacies each day. Would the dispensing relief pharmacist have to check each place of work to ensure compliance with this rule?	"Dispensing pharmacist" and "pharmacist" will be modified to "pharmacy."	R 338.3165

13.Date report completed:

10/6/2021