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:
2020-128 LR

Title of proposed rule set:
Pharmacy - General Rules

3. Purpose for the proposed rules and background:

The purpose of the Pharmacy – General Rules is to encompass all the necessary requirements for licensing and regulating the practice for pharmacists, pharmacies, and manufacturers and wholesale distributors of drugs and devices. The rules include parts for general provisions, pharmacist licenses, pharmacy licenses, manufacturer licenses, wholesale distributor licenses, and the practice of pharmacy.

The purpose of the proposed rules is to: establish any additional licensure requirements for a remote pharmacy and provide a procedure to request a waiver from the 10 mile rule for a remote pharmacy, pursuant to PA 4 of 2020; modify the requirements in the rules to require mandatory electronic transmission of a prescription and add the criteria for a waiver from electronic transmission, pursuant to PA 134 of 2020; establish licensure requirements for a wholesale distributor-broker and modify the activities allowed by an out-of-state pharmacy that is not licensed as a pharmacy in this state, pursuant to PA 142 of 2020; update rules affected by any other modified Public Health Code (Code) provisions; review practical experience requirements and limited licensure; review pharmacy ownership and licensure requirements; review the need for telehealth regulations; sanitation regulations; licensure reciprocity; and update definitions.

4. Summary of proposed rules:

The proposed revisions to the rules will: require preceptors to report internship hours; require an applicant who has failed the NAPLEX or the MPJE to review the material in a preparation course or with an instructor; clarify that an applicant who has completed the FPGEC certification has met the English proficiency requirement; allow an applicant for licensure by endorsement to obtain a license in this state if he or she either holds a license in another state or holds a license in Canada and meets additional requirements; add requirements for relicensure; establish the requirements for a remote pharmacy license; provide a waiver process from the 10 mile requirement for remote pharmacies; require any pharmacy that will provide sterile compounding in this state to submit an onsite physical inspection and report completed no more than 18 months before the application; clarify that a pharmacy that starts or resumes sterile compounding must apply to the Department and submit the required inspection report; require a pharmacy, manufacturer, wholesale distributor, and wholesale distributor-broker that is closing to maintain records; clarify the process for renewal versus relicensure; add the requirements for a facility manager for a manufacturer; adopt the federal exclusions to the definition of wholesale distribution; add the licensure and record keeping requirements for a wholesale distributor-broker; reduce the time from 3 years to 2 years before a prescription may be electronically duplicated; provide the requirements for electronic transmission of prescriptions; provide the process for a waiver from the mandate to electronically transmit a prescription; and clarify that if final product verification is delegated, then both the pharmacist and technician must record their initials.

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

Marquette Mining Journal – August 31, 2021; Flint Journal – August 31, 2021; Grand Rapids Press – August 31, 2021

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

9/15/2021

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

9/21/2021 01:00 PM at 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=1254

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

Kerry Przybylo, Manager; Andria Ditschman, Senior Policy Analyst; and LeAnn Payne, Board Support.

10. Persons submitting comments of support:

Deeb D. Eid, PharmD, RPh, Advisor, Pharmacy Regulatory Affairs, CVS Health submitted a comment in support.

11. Persons submitting comments of opposition:

The following persons sent comments in writing:
Rose M. Baran, PharmD
Deeb D. Eid, PharmD, RPh, Advisor, Pharmacy Regulatory Affairs, CVS Health
Charlie Mollien
Julie L. Novak, Chief Executive Officer, Michigan State Medical Society (MSMS)
Jon Pritchett, PharmD., RPh., BCSCP, Pharmacy Program Director, Accreditation Commission for Health Care (ACHC)
Brian Sapita, Director of Government Affairs, Michigan Pharmacists Association (MPA)

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	Mollien		"Written" is used throughout the rules without a definition. Add a definition making it clear that "written" allows for paper or electronic forms.	The Board agrees with the comment that the term "written" should be added to the definitions with clarification that the term allows for paper or electronic forms.	R 338.501(1)(l)

2	Sapita/MPA		Regarding R 338.505 subsection 2 which specifies “prelicensure inspection”. Subsection 1 references both applicants and license holders but subsection 2 now excludes inspections of license holders. We suggest removing this language and keeping the original language.	The Board agrees with the comment that subrules (1) and (2) are inconsistent with the addition of “prelicensure” in (2) and, therefore, “prelicensure” should be deleted as in the original language, and additional language should be added to (2), “Inspections in provision (1) must not extend to any of the following information, however, the information is subject to a disciplinary investigation.”	R 338.505(2)

3	Eid/CVS Health		Add “and explanation” and “or otherwise not readily available to patients” to (b) to strengthen the outcome of the rule.	The Board agrees with the comment to modify (b) as it will ensure the Department/Board has a clearer understanding of the services that will be offered rather than just a “list”. The addition of “or otherwise not readily available to patients” to 2(b) ensures the application is inclusive of services that may not be readily available to patients currently.	R 338.531a (2)(b)
4	Pritchett/ACHC		Requiring an inspection within 18 months of application presents a problem with the previously approved PCAB process. Accreditations with ACHC are provided on a 36-month cycle, which aligns with accreditation programs provided in other areas of the healthcare industry as well as requirements issued by the Centers for Medicare and	The Board agrees with the comment that the rule should be modified to allow for virtual inspections by deleting “onsite” and “physical” from (a) as a virtual inspection can cover the same issues as an in-person inspection with the bulk of the inspection being conducted by review of documents. The Board agrees that a pharmacy that has been accredited should	R 338.534(3)

			Medicaid Services (CMS). A survey occurs prior to each new accreditation cycle, thus a survey roughly every 36 months. This creates a misalignment with the Michigan licensure schedule of renewal every 2 years; some pharmacies, depending on where they are in their accreditation cycle, will not be scheduled for a survey within the 18 months preceding renewal of their licensure. ACHC requests that the rule be returned to requiring either evidence on a current accreditation or a physical inspection and corresponding report completed within 18 months of application. We would also like to see clarification about acceptance of the use of virtual surveys during a public	not have to submit an inspection within 18 months before the date of an application. The Board will add the following language to (3) "unless accredited by a national accrediting organization, recognized by the board, an … .	

			health emergency, as the issues surrounding COVID-19 appear to be ongoing.		
5	Mollien		Clarify if the FDA certification requirement is necessary and if it is necessary whether it should only apply to distributions of blood and blood products.	In response to the comment to delete (h), add “if required by the FDA” to the rule.	R 338.563(2) (h)

6	Mollien		Add “board” to (6). These rules create a significant public health and safety gap that allows introduction of counterfeit medications into the closed distribution supply chain. To close this gap, clarify in this rule that any purchasing pharmacy using a wholesale distributor-broker to facilitate a transaction from a pharmacy not licensed in Michigan shall request the transaction history, transaction statement, or transaction information for the drugs supplied.	To address the safety concern in the comment, the Board adds the proposed language to (6) and as (8) requires additional record requirements, (8) must be referenced in (6).	R 338.569(6) and (8)
7	Mollien		The rules are missing the record retention requirements applicable to pharmacies related to non-control drug and device acquisition and distribution records. ADD	The Board agrees with the comment that for consistency with the controlled substances rules, a rule regarding pharmacy acquisition and distribution records should be added.	R 338.583a

			Pharmacy Acquisition and Distribution Records (1) A pharmacy must keep and make available for inspection all acquisition and distribution records for prescription and non-prescription drugs and devices, such as invoices, packing slips or receipts, for 5 years. All records, which may be electronic, must be readily retrievable within 48 hours. (2) Acquisition and distribution records must include the following information: (a) The source of the prescription drugs or devices, including the name and principal address of the seller or transferor and the address from which the prescription drugs or devices were shipped. (b) The identity and quantity of the prescription			

MCL 24.242 and 24.245

			drugs or devices received, if applicable, and distributed or disposed of. (c) The dates of receipt, if applicable, and distribution of the prescription drugs or devices.		
8	Baran Novak/MSMS		Change 338.584 (1)(g) to "Issue date of the prescription." The prescriber will not know the date the prescription was dispensed when issuing a prescription.	The Board will replace "dispensed" with "issued."	R 338.584(1)(g)
9	Mollien		Align the Pharmacy General rule with the CS rule regarding electronic transmission of prescriptions.	CMS waiver is automatic state waiver/Section (4)(a): The Code requires that if a CMS waiver is granted then the Department shall also grant a waiver. Subrule (4) will be modified to allow for a waiver without meeting other requirements if the CMS waiver has been granted.	R 338.584a (4)(a)

10	Novak/MSMS		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 338.584a (3)
11	Novak/MSMS		Recommends the effective dates between the rules sets and the Code be consistent.	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.	R 338.584a (1) and (3)

12	Novak/MSMS		Identify examples of qualifying "exceptional circumstances" as follows: (iii) The prescriber demonstrates attests to exceptional circumstances including, but not limited to, the following: A. Prescribing fewer than "X" prescriptions per year. B. Intention to cease practice within the next twelve months. C. Limited practice due to an illness or other unforeseen event. Clarify that the prescriber may declare or formally certify in writing such as with an attestation as to the exceptional circumstances, instead of using the word "demonstrate."	Exceptional circumstances will be further clarified by adding circumstances suggested in (B) and (C). However, (A) will not be added as this basis is really a claim for economic hardship, which is already in the rule. The rule will read "The prescriber demonstrates by attesting to exceptional circumstances including, but not limited to, the following: …"	R 338.584a (4)(b)(iii)

13	Sapita/MPA		We believe the use of "on site" is confusing since after 2 years the prescription information can be kept electronically. We suggest that "on site" be removed from this subsection entirely.	"On site" will be deleted in (e).	R 338.587(4) (e)
14	Eid/CVS Health		Add in clarifying language to allow for use of automated devices as patient pick-up options within the premises of a licensed pharmacy. Add this language: A secured, lockable, and privacy enabled automated device located on the premise of the licensed pharmacy may be utilized as a means for patient's or an agent of the patient to pick up prescription medications when and if a pharmacy is closed.	The comment will be added as it clarifies that a pharmacy may use an automated device within the pharmacy. The following changes also need to be made: delete "and if a pharmacy is closed;" add "only" and "non-controlled;" and modify "used" to "under control."	R 338.588(3)

13.Date report completed:

10/7/2021