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

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ShaltryJ1@michigan.gov

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

2. Rule Set Information

MOAHR assigned rule set number:
2022-8 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, manufacturers, wholesale distributors, and wholesale distributor-brokers. The rules include parts for general provisions, pharmacist licenses, pharmacy licenses, manufacturer licenses, wholesale distributor licenses, wholesale distributor-broker licenses, and the practice of pharmacy.

The purpose of the proposed rules is to: implement section 17744f of the Public Health Code (Code), MCL 333.17744f, regarding dispensing emergency supplies of insulin, pursuant to PA 36 of 2021; clarify the internship requirements; clarify the regulations regarding compounding accreditation, inspections, and applicable standards; update rules affected by any other modified Code provisions or federal regulations; review refill requirements; review the professional and technical equipment and supply requirements; review licensure requirements including the necessity of the Multistate Pharmacy Jurisprudence Examination; review the need for telehealth regulations; and update definitions.

4. Summary of proposed rules:

The proposed rules will be modified as follows: except for disciplinary inspections, inspections at the direction of the department will not involve purchasing data, other than shipment data and the current and historical selling price of the drug, or some research data; applicants will only be able to submit intern hours that are acquired through an educational program, under the personal charge of a preceptor, through a preapproved unconventional internship, or through an educational program outside of the United States; graduates of programs outside of the United States will be able to submit up to 1400 hours earned in an educational program experience if the hours are not completed through an approved educational program or under the person charge of a preceptor licensed in this state; preceptors in an educational program will not have to submit annual affidavits of hours; applicants for licensure by endorsement will no longer have to take the MPJE and instead will submit knowledge of the laws and rules affidavit; a PIC or facility manager who is unable to fulfill their duties for 120 consecutive days will appoint a new PIC or facility manager; an out-of-state pharmacy that will not compound sterile pharmaceutical products in this state may submit an inspection from NABP-VPP or a resident state board of pharmacy; an in-state pharmacy that will compound sterile pharmaceutical products will have a two-step inspection process that requires an inspection from the department and, within 6 months, an inspection to assess USP compliance or accreditation; a pharmacy that dispenses drugs will have a sink with running water, a refrigerator for drugs, and a telephone; a manufacturer will have the option of submitting an inspection from the FDA, the manufacturer's resident state board of pharmacy, or NABP drug distributor accreditation; a pharmacy intern who provides final product verification will record both the initials of the intern and supervising pharmacist; a pharmacy may locate an automated device as an extension of a pharmacy in additional locations with limitations; a pharmacy may locate a non-dispensing storage and pick-up device on the premises of the pharmacy; and a pharmacist may dispense an emergency supply of insulin.

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

The Flint Journal: April 30, 2023.
The Grand Rapids Press: April 30, 2023.
The Mining Journal: May 16, 2023.

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

6/1/2023

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

6/2/2023 09:00 AM 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=1367

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

Andria Ditschman, Departmental Specialist, Bureau of Professional Licensing.
Stephanie Wysack, Departmental Technician, Bureau of Professional Licensing.

10. Persons submitting comments of support:

There were no comments submitted of support.

11. Persons submitting comments of opposition:

The following individuals submitted comments in opposition with suggested changes:

Douglas Apple, Ascension Michigan; Rose Baran; Todd Belding, Sparrow; Ryan Bickel, Ascension Borgess;Gary Blake; Randy Burke; Alisha Cottrell, Ascension Michigan; Michelle Dehoorne; Deeb Eid, CVS Health; Rony Foumia; Denise Frank, Gates Healthcare Associates, Inc.; Mark Guzzardo; Lisa Herz; Lee King, Sparrow Health System; Bradley McCloskey, University Compounding Pharmacy; David Medina; Jasmine Mehta; David Miller, Keystone Pharmacy; Jessica Morris; Eric Roath, Michigan Pharmacists Association; Colleen Ryan; Renee Smiddy, Michigan Health & Hospital Association; Jamie Tharp, Pharmacy-Compounding Compliance, University of Michigan Health; Jeffrey Thomas, Ascension Rx; Chad Whitefield, University Compounding Pharmacy; and Maria Young, University Pharmacy.

12. Persons submitting other comments:

There were no other comments submitted in addition to those mentioned above.

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		There is no rule 338.588c in this rule set or the current rule set. Delete 338.588c.	The Board agrees that 338.588c is not the correct rule citation and R 338.486(4)(d) should be modified to specify R 338.588b.	R 338.486

2	Baran		Individual in this section (x) should be changed to "person".	The Board agrees with the comment that "individual" should be changed to "person" as a virtual manufacturer may be a company. Subdivision (x) in the draft that went to public hearing defined "virtual manufacturer" but due to renumbering in the draft due to other changes, "virtual manufacturer" is now (w).	R 338.501(1)(w)
3	Baran		Rule 338.7004 requires an individual applying for licensure or registration under article 15 of the code, MCL 333.16101 to 333.18838, except those seeking to be licensed under part 188 of the code to obtain Implicit Bias Training. Add at the end of (6): and rule 338.7004.	The Board agrees to add "and rule 338.7004" to clarify for applicants that they must attend the implicit bias training to receive an educational limited license.	R 338.513(6)

4	Morris		Remove adoption of MPJE.	The Board agrees with the comments to remove adoption of the MPJE as the requirements to take the MPJE is being deleted in the rules. Removing the adoption of the MPJE in section (2) results in: deleting section (2), (5), and (8); renumbering the sections in the rule; and making additional changes to the language in section (3).	R 338.519(2), (3), (5) and (8)

5	Morris		Remove the MPJE requirement.	The Board agrees with the comments to remove the MPJE requirement for the reasons stated in the comments. For consistency with the licensure by endorsement rule, where the Board has proposed deletion of passing the MPJE and instead is requiring an attestation from the applicant, this same requirement should be added to this rule if the MPJE requirement is deleted. Because the previous subdivision (2)(f) will be deleted based on another comment, a new subdivision (2)(f) will be added requiring the applicant to submit an attestation to the department that the applicant has sufficient knowledge of the code and the board's rules to competently practice pharmacy in this state.	R 338.521(2)(f)

6	Ryan		Allow licensure by examination by new grads with a score transfer even though they may be licensed in another state.	The Board agrees with the comment to allow initial licensure by score transfer if the applicant has been licensed in another state for 1 year or less. Therefore, (2)(a) and (2)(a)(iii) must be modified to allow score transfer as an option.	R 338.521

7	Morris		Delete MPJE requirement.	The Board agrees with the comments to remove the MPJE requirement for the reasons stated in the comments. For consistency with section (4) of this rule and other licensure rules, where the Board has proposed deletion of passing the MPJE and instead is requiring an attestation from the applicant, this same requirement should be added to this rule if the MPJE requirement is deleted. Subdivision (1)(e) will be modified to require the applicant to submit an attestation to the department that the applicant has sufficient knowledge of the code and the board's rules to competently practice pharmacy in this state	R 338.525

8	Young		Delete reference to English language requirement as this should only be required with initial licensure.	Although the comment refers to R 338.525(1)(f) and (4)(g), it is clear from the content of the rules and the comment that the comment is intended to address R 338.521 (2)(f) and R 338.523(2)(g) concerning the English language requirement. The Board agrees to delete the English language requirement as it is only required for initial licensure.	R 338.521(2) (f) and R 338.523(2)(g)
9	Young		Adopt updated versions of USP with the exception of flavoring.	The Board recommends adopting the 2023 version of 795 and 797 with the exception of flavoring.	R 338.533(1)
10	Apple		Remove “not limited to.”	The Board agrees to remove the language “ not limited to.”	R 338.533(1)

11	Tharp		USP no longer provides free copies of compounding chapters. Pharmacies and licensees must purchase or subscribe to USP to gain access the chapters.	The Board agrees that the rule should state that there is a cost associated with obtaining the USP and that the Department can't provide copies to the public as pharmacies and licensees must purchase or subscribe to USP to gain access to the chapters.	R 338.533(2)
12	Tharp		The use of the phrase "current standards" is in conflict with the proposed fixed versions of USP being proposed in subrule (1) of this rule.	The Board agrees with the comment to delete the language that references "current standards" as well as "applicable" and instead will refer to the standards adopted above in the same rule.	R 338.533(3)

13	Tharp		Consider aligning this standard with the Sterile Compounding Pharmacy Licensing requirement in R 338.534a (2), An applicant for an in-state pharmacy license that intends to compound sterile pharmaceutical products shall complete both of the following: (a) Obtain an inspection from the department or its designee for the purpose of meeting R 338.536 and R 338.537 for initial licensure. (b) Within 6 months after initial licensure under this subrule, a pharmacy shall obtain, and provide to the department, a subsequent inspection to assess adherence to cGMP.	The Board agrees with the comment that there is a need for a two-step process for licensing outsourcing facilities that practice in this state. Therefore, the two-step process suggested in the comments is adopted in (5). The changes in (5) that apply to only outsourcing facilities located in this state, requires changing (4) to apply to out-of-state outsourcing facilities. This change differentiates between the process for an in-state facility, which needs a two -step process, and an out-of-state facility, which does not require the two-step process.	R 338.533(4) and (5)

14	Tharp		Recommend that revisions to cGMP standards be allowed for outsourcing facilities. Suggest deleting a fixed reference date (year) to cGMP standards: (b) Compound drugs pursuant to current good manufacturing practices for finished pharmaceuticals set forth in 21 CFR 211.1 to 211.208.	The Board agrees with the comment to delete the year in the citation and simply adopt the current version.	R 338.533(6) (b)

15	Young		Update (1)(b): Most recent printed, and or unabridged computerized versions of the Michigan pharmacy laws and rules, plus at least 2 comprehensive pharmaceutical reference text(s). Which will encompass the general practice of pharmacy that pertains to pharmacology, drug interactions, drug composition, or other information necessary for the delivery of safe and effective practice of pharmacy.	The Board agrees that the language should be updated to include "unabridged computerized versions" of reference materials, and include "or other information necessary for the delivery of safe and effective practice of pharmacy".	R 338.537(1)(b)
16	Foumia		Pharmacies are now allowed to print and download copies of their pharmacy licenses. I don't think it is necessary to have closed pharmacies return these licenses as many times they are not even originally printed by the department.	The Board agrees with the comment that the license does not need to be returned to the Department.	R 338.538(1)

17	Baran		It places a burden on pharmacies that sell non-prescription drugs that it doesn't place on other retailers that sell non-prescription drugs that are not a pharmacy. It doesn't require the retailer to keep the records for non-prescription drugs as it does the pharmacy. This will increase cost for pharmacies. Delete "and non-prescription" from (1).	The Board agrees with the comment to delete non-prescription.	R 338.583a (1)

18	Roath		Additionally, MPA advocates for removing the limitation prohibiting a remote pharmacy from operating an automated device in subsection (1)(b). If a pharmacist is available, as required by subsection (1)(c), and a pharmacist may be available for real-time consult in subsection (1)(f), then a remote pharmacy should be permitted to operate an automated device. Further, the added safety features implemented by an automated device stocked and maintained by a pharmacist will enhance the safe delivery of medications in a remote pharmacy.	The Board agrees with the comment to allow an automated device at a remote pharmacy if consistent with the Code.	R 338.588a (1)(b)

19	Smiddy		The MHA suggests combining (f) and (c) subsections.	The Board agrees with the comment to combine (f) and (c) to simplify the rule. Combining (c) and (f) resulted in the revision of (d) through (g) and the removal of (h).	R 338.588a (1)(c)-(h)
20	Eid		We recommend simplifying (2) by adding the word “inside of” after “device” as shown below and deleting the word “on”, along with letter (b) for clarity and simplification.	The Board agrees with the comments to simplify the provision as suggested by Eid. The changes require deletion of “pharmacy meets both of the following:” from subrule (2) and “(a) The". Then, the remaining language from (2) (a) was incorporated into subrule (2).	R 338.588a (2) and (2)(a) and (2)(b)
21	Smiddy		The suggested modifications attempt to reduce confusion related if the pharmacist is the default standard for stocking the automated device, since there is not an explicit language referencing stocking by a pharmacist. Above statements reference	The Board agrees with the comments to simplify the rule.	R 338.588b (1), (1)(a), and (1)(b)

			‘controlled by a pharmacy’, not controlled by a pharmacist. In her written statement, Ms. Smiddy suggested revising R 338.588b as follows: (1) An automated device used by staff to administer store medications to registered patients intended for patient administration in any hospital, county medical care facility, nursing home, hospice, or another skilled nursing facility, as defined in section 20109(4) of the code, MCL 333.20109, must comply with all of the following: (a) The automated device must be supplied stocked, maintained, and controlled by a pharmacy that is licensed in this state. (b) If a pharmacist delegates the stocking of the			

			automated device is performed by non pharmacist personnel, then technologies must be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing bar-coding or another board-approved error-prevention technology that complies with R 338.3154.		
22	Baran		Add to (5) "Pharmacist delegation of acts, tasks, or functions shall be in compliance must comply with section 16215 of the code, MCL 333.16215, and be under the personal charge of the delegating pharmacist, except as provided in R 338.486 and 17742b of the code MCL 333.17742b."	The Board agrees that there are situations in addition to R 338.486 where a pharmacist delegates without personal charge and those rule and code sections should be added to this rule.	R 338.589(5)

23	Roath		MPA recommends the addition of language to clarify that although an emergency supply of insulin may only be dispensed once per qualified prescription, this does not change the ability of a pharmacy to issue three such emergency supplies per patient per year (MCL 333.17744f (2)).	The Board agrees to add the proposed language to (1)(c). Subdivision (c) was revised as a result of Mr. Roath's comment, but a new subdivision wasn't added.	R 338.591
24	Young		Add ability for the licensed Pharmacist to access pharmacy database from home or other remote location for remote order entry verification including performing a drug regimen review. If the pharmacy establishes controls to protect the privacy and security of confidential records.	The Board agrees that a pharmacist may access a pharmacy database and other necessary databases that a pharmacist uses with the added security to protect the confidentiality and integrity of a patient's protected health information. Subrule (7) was added in response to Ms. Young's statement.	R 338.589

25	Morris		Delete MPJE definition if delete the MPJE as a requirement.	The Board agrees to delete the requirement to take the MPJE in R 338.519, R 338.521, and R 338,523 in response to comments about deleting this requirement as noted later in this JCAR Report Therefore, the reference to the MPJE in the definitions should be deleted.	R 338.501(1) (q)-(x) M. Morris' comments to delete the MPJE requirement as noted in this JCAR Report results in deleting the MPJE definition in R 338.501.

14.Date report completed:

10/31/2023