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:
517-241-9255

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

Name of Department Regulatory Affairs Officer reviewing this form:
Deidre O'Berry

2. Rule Set Information

MOAHR assigned rule set number:
2018-39 LR

Title of proposed rule set:
Board of Pharmacy - General Rules

3. Purpose for the proposed rules and background:

The current Pharmacy – General Rules are incomplete, disorganized, and difficult to use. The draft rules have been reorganized and substantially rewritten to provide for rules that encompass all the necessary requirements for licensing and regulating the practice for pharmacists, pharmacies, and manufacturers and wholesale distributors of drugs and devices. The draft rules include parts for general provisions, pharmacist licenses, pharmacy licenses, manufacturer licenses, wholesale distributor licenses, and the practice of pharmacy. Part 1 of the proposed pharmacy rules pertains to definitions, resale of drugs and devices, and inspections of applicants and licensees. Part 2 of the proposed pharmacy rules pertains to licensure of pharmacists. This part includes the rules pertaining to training for identifying victims of human trafficking, educational limited licenses, internship requirements, preceptor licenses, examinations, pharmacist licensure by examination and endorsement, and relicensure. Part 3 of the proposed pharmacy rules pertains to pharmacy licenses. This part includes the application requirements for pharmacies, sterile compounding services and the adoption by reference of standards that apply to these services, inspections, discontinuance and resumption of sterile compounding services, housing of a pharmacy, professional and technical equipment and supplies, closure of a pharmacy, and relicensure. Part 4 of the proposed pharmacy rules pertains to a manufacturer license. This part includes licensure requirements for manufacturers of drugs and devices, persons to whom drugs or devices may be sold, adoption by reference of a federal regulation on good manufacturing practices for finished pharmaceuticals, closure of a manufacturer, and relicensure. Part 5 of the proposed pharmacy rules pertains to a wholesale distributor license. This part includes the determination of a pharmacy as a wholesale distributor, the licensure requirements for wholesale distributors of drugs and devices, persons to whom drugs or devices may be sold, wholesale distributor practices, recordkeeping and policy requirements for wholesale distributors, facility requirements, examination of drugs and devices, closure of a wholesale distributor, and relicensure. Part 6 of the proposed pharmacy rules pertains to the practice of pharmacy. This part includes pharmacy services by medical institutions, prescription drug labeling and dispensing, prescription drug receipts, noncontrolled prescriptions, a customized patient medication packages, prescription records, prescription refill records, automated devices, professional responsibility of a pharmacist, and a hospice emergency drug box.

4. Summary of proposed rules:

The current Pharmacy – General Rules will be substantially rewritten and reorganized to provide for rules that encompass all the necessary requirements for licensing and regulating the practice for pharmacists, interns, preceptors, pharmacies, manufacturers, and wholesale distributors. The proposed revisions modify the parts pertaining to general provisions, pharmacist licenses, pharmacy licenses, manufacturer licenses, wholesale distributor licenses, and the practice of pharmacy.

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

Marquette Mining Journal – September 18, 2019; Flint Journal – September 19, 2019; Grand Rapids Press – September 19, 2019.

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

10/4/2019

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

10/4/2019 09:00 AM at G. Mennen Williams Building - Auditorium , 525 W. Ottawa Street, Lansing, MI

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=56

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

Kerry Przybylo, Manager; Andria Ditschman, Senior Policy Analyst; Weston MacIntosh, Senior Policy Analyst; Dena Marks, Senior Policy Analyst; Kimberly Catlin, Board Support; LeAnn Payne, Board Support; and Stephanie Wysack, Board Support.

10. Persons submitting comments of support:

There were no comments in support.

11. Persons submitting comments of opposition:

The following persons submitted public comments: Rose M. Baran, PharmD, MA, Assistant Professor, College of Pharmacy, Ferris State University; Alyssa R. Baskerville, PharmD Candidate; Adam Carlson, Senior Director, Government & Political Affairs, Michigan Health & Hospital Association (MHA); Thomas R. Clark, RPh, MHS, BCGP, Senior Director, Board of Pharmacy Specialties (bps); Maher Daman, PharmD, Ferris State University; Deeb D. Eid, PharmD, Assistant Profession, Ferris State University; Justin Kuhns, PharmD, Lab Director, Portage Pharmacy; Joel Kurzman, Director, State Government Affairs, National Association of Chain Drug Stores (NACDS); Bradley McCloskey, PharmD, President/CEO; Neal Mehta, Pharm D; Ned Milenkovich, PharmD, JD, Much Shelist, P.C.; Joseph C. Osborne, PharmD, Candidate, Ferris State University; Scott Popyk, Health Dimensions/member MPA and International Academy of Compound Pharmacists; Eric Roath, PharmD, MBA, Clinical Care Coordinator, SpartanNash; Brian Sapita, Government Affairs Manager, Michigan Pharmacists Association (MPA); Tom Sullivan, Michigan Surgical Hospital and Insight for Neurosurgery and Neurological Sciences; Larry Wagenknecht, Pharmacist, FMPA, FAPhA, Chief Executive Officer, MPA; and Neal Watson, Member Liaison, National Association of Boards of Pharmacy (NABP).

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	Rose M. Baran		Removing "who is on the premises" does not allow the technicians to remain in the pharmacy working while the pharmacist is at meeting in the hospital or on the floor. This negates the original intent to allow the pharmacist to be in the hospital but not in the pharmacy and let the technicians remain to continue drug preparation for the pharmacist review. This allows the pharmacist of small hospitals to attend meetings and other issues outside of the pharmacy but on the hospital premises. This would enable small hospitals to stay open and serve the public health of the community.	The Board agrees with the comments to not remove "who is on the premises" as it would negate the original intent of the provision to allow the pharmacist to be in the hospital but not in the pharmacy.	R 338.486(3)
2	Ned Milenkovich, PharmD, JD,		USP has indicated they intend to classify	The Board agrees with the comment to exclude	R 338.501(1) (e)(iv)

	Much Shelist, P.C.		all flavorings of conventionally manufactured medications as nonsterile compounding. Fourteen state boards of pharmacy have language on their books excluding flavoring from the definition of compounding. The request is to implement a regulation excepting the safe administration of flavorings added to conventionally manufactured medications from the definition of compounding. The Board can achieve this by narrowing the use of flavoring agents to conventionally manufactured and commercially available liquid medications and by setting conditions to ensure safe administration of flavorings (flavoring agents must be nonallergenic and inert, not exceeding 5% of a drug product's	flavoring agents as an exception to the compounding rule as long as there is no other product manipulation.		

			total volume).		
3	Rose M. Baran		Add to this rule the return of drugs for a manufacturer recall that is down to the patient level or when the wrong medication was dispensed to the patient. This then would align with 21 CFR part 1317. Add: (d) The provisions of subsection (1) shall not apply to drugs returned when the wrong medication was dispensed to the patient or in the instance of a drug recall. In no instance may returned drugs be reused or returned to active stock.	The Board agrees with the comment to add the language recommended to (d). The addition of this language will allow the return of drugs in 2 additional circumstances that are not currently in the rules, subject to any controlled substances exceptions or limitations.	R 338.503(2)(d)
4	Brian Sapita, Government Affairs Manager, Michigan Pharmacists Association (MPA)		The rule as written is not consistent with the continuing education (CE) rules – consider same verbiage.	The Board agrees with the comment that the dates in this rule and the dates in the pharmacist CE rules should be consistent.	R 338.511(3)
5	Brian Sapita, Government Affairs Manager, MPA		Remove “90 days” and replace with “180 days.” Ninety days is not enough time.	The Board agrees with the comment to replace “90 days” with “180 days” as more time is necessary.	R 338.513(1)(a) and (2)(a)
6	Brian Sapita, Government		Replace with “An educational	The Board agrees with the comments	R 338.513(4)

	Affairs Manager, MPA And Eric Roath, PharmD, MBA, Clinical Care Coordinator, SpartanNash		limited licensee must engage in the practice of pharmacy under the supervision of a pharmacist preceptor as defined in section 17708(1) of the code and only under the personal charge of a pharmacist." In the context of the Proposed Rule 13, this subrule seems to require that an educational limited licensee (pharmacy intern) only practice under the direct personal supervision of a pharmacist licensed as a preceptor. Previously, this requirement only extended to pharmacy interns working towards the intern hours required to obtain their full pharmacist license. The language, as proposed, would create a barrier for pharmacy interns seeking to gain additional experience through paid	that the rules should be clarified to indicate that a licensee may engage in the practice of pharmacy only under the personal charge of a pharmacist. However, if the licensee wants to count the hours towards the required internship they must also be acting under a preceptor. The Board does not agree with the specific proposed changes in either comment to (4).		

			internships aside from what is required by their academic programs. Also, this seems to conflict with Rule 15 (3) which creates provisions for a pharmacy intern to submit hours that were not conducted under the personal charge of a preceptor licensed in the state. As such, we recommend that Rule 13, Subrule (4) be removed from the rules as proposed.		
7	Rose M. Baran		Need to add the human trafficking requirement.	The Board agrees with the comment to add the requirement of the human trafficking training.	R 338.513(6)
8	Adam Carlson, Senior Director, Government & Political Affairs, Michigan Health & Hospital Association (MHA)		Under the "Practice of Pharmacy" Section, the new North American Pharmacist Licensure Examination (NAPLEX) and Michigan Multistate Pharmacy Jurisprudence Examination (MPJE) passing requirements raised some	The Board agrees with the comment to modify (4) to "within 3 attempts" not 1 attempt, as requiring retraining after only 1 attempt is too strict. The Board also has added (8) to separate the MPJE test from the NAPLEX which allows an	R 338.519(4)

			apprehension among hospital membership. While we respect the proposal to safeguard competent pharmacists to enter the workforce, the MHA wants to ensure qualified candidates are not inadvertently vetted out. Other variables, including education, prior employment, internships, residencies and skills which are valuable to hospitals are not defined by exams alone. Additionally, one day of poor performance during a test can happen, and students deserve another try before they are required to provide satisfactorily completed courses information to the Board. Modify to: (4) If an applicant for licensure fails to pass either of these examinations	applicant that fails the MPJE more than 5 times to take a pharmacy law course. The commenter suggested that the applicant satisfactorily complete courses. The Board agrees that for the MPJE repeating an entire program would not be the most beneficial to passing an examination on rules and the law.		

			within 3 attempts, he or she shall provide the board, after the third failed attempt and prior to retesting, certification from an approved education program certifying that he or she satisfactorily completed courses that provide a thorough review of the area or areas that he or she failed in the most recent examination.		
9	Rose M. Baran		This section as currently written would require the applicant to completely redo the pharmacy degree yet a foreign graduate would not have to do so.	The Board agrees to delete the reference to the foreign pharmacy graduate equivalency examination certification program, as a foreign graduate should be held to the same standard if they are failing the examinations.	R 338.519(7)

10	Adam Carlson, Senior Director, Government & Political Affairs, MHA And Brian Sapita, Government Affairs Manager, MPA		Remove "Canadian council for accreditation of pharmacy programs." The Canadian Healthcare System is significantly different than that of the United States and should be removed from the rules. Under the "Pharmacist licensure by examination" section, it is important to note that Canadian Council for Accreditation of Pharmacy Programs uses different criteria than the Accreditation Council for Pharmacy Education.	The Board agrees with the comment to delete the reference to the Canadian Council for Accreditation of Pharmacy Programs as it is not equivalent to Accreditation Council of Pharmacy Education (ACPE).	R 338.521(2)(i)

11	Neal Watson, Member Liaison, National Association of Boards of Pharmacy (NABP)		Mirror the license by exam rules to require the Foreign Pharmacy Graduate Examination CommitteeTM (FPGEC®) under the License by Endorsement as follows: That he or she has successfully passed the foreign pharmacy graduate equivalency examination administered by the National Association of Boards of Pharmacy (NABP) Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr., Mount Prospect, IL 60056, https://nabp.pharmacy/programs/fpgec/ AND: A foreign pharmacy graduate examination committee certificate administered by the NABP.	The Board agrees with the suggested change to require passing the examination and obtaining the FPGEC certificate from NABP.	R 338.523(2)(a)

12	Deeb D. Eid, PharmD, Assistant Profession, Ferris State University		The commenter asked how CE requirements will be handled in processing applications for relicensure as well as requesting that the 1-time trainings be required.	The Board agrees with the comment to clarify that relicensure will not be granted until the continuing education requirements are met, and that to meet relicensure an applicant must meet the 1-time training requirements.	R 338.525(1)(d) and (4)(d)(1)(e) and (4)(e)
13	Rose M. Baran		Add USP Chapter 797 for consistency with Rule 338.533(1).	The Board agrees with adding USP 797 for consistency.	R 338.531(4)
14	Justin Kuhns, PharmD, Lab Director, Portage Pharmacy		Delete “and 800”.	The Board agrees with the comments to delete USP 800 from the rule until it is published in the compendium.	R 338.531(4)
15	Eric Roath, PharmD, MBA, Clinical Care Coordinator, SpartanNash		The adoption of these reference standards in conjunction with the clause in (4)(b) seems to imply that the standards are only applicable to pharmacies providing compounding services, though this is not explicit. Additionally, some of the guidance in the standards extend to practices beyond	Pursuant to the commenter’s concern, it is necessary to delete “sterile” to clarify that the rules apply to both sterile and non-sterile compounding. As the Board agrees with the comments to R 338.532 and R 338.533 to delete the term “sterile” as the rules should regulate sterile and non-sterile compounding, for consistency,	R 338.531(2)(g) and (i)

			compounding and it is unclear as to whether pharmacies operating under the purview of these standards would be required to comply with the full reference standard, or just the areas that apply to compounding practices. Additionally, recent comments at the NABP Annual meeting by a USP representative suggest that the USP's intent regarding general chapter 800 indicate that this guidance was intended to apply to compounding activities only. To provide additional clarification, we recommend that Rule 31, Subrule (4)(b) be modified to read: "A pharmacy that provides compounding services shall comply with all standards adopted in subrule (4) of this rule as they	"sterile" will also be deleted from R 338.531.		

			apply to compounding services as defined in Michigan law."		
16	Justin Kuhns, PharmD, Lab Director, Portage Pharmacy		The commenter has requested to delete the term "sterile."	The Board agrees with the comment to delete the term "sterile" from R 338.532 and R 338.533, as both rules should regulate sterile and non-sterile compounding. For consistency "sterile" will also be deleted from R 338.531.	R 338.532(1)
17	Deeb D. Eid, PharmD, Assistant Profession, Ferris State University		The commenter asked that the rules clarify how often an inspection should be submitted and whether the details of the inspection are required to be shared with the Department.	The Board agrees with the comment that the results of a pharmacy inspection should be required to be shared with the Department and does not agree that the rule should include a set expiration date of a certain amount of years for accreditation approvals. The inspection entity should submit the length of their accreditation approvals with their application as an approval entity.	R 338.532(3) (e) and (f)

18	Justin Kuhns, PharmD, Lab Director, Portage Pharmacy		The commenter has requested to delete the term "sterile."	The Board agrees with the comment to delete the term "sterile" from R 338.532 and R 338.533, as the rules should regulate sterile and non-sterile compounding. For consistency "sterile" will also be deleted from R 338.531.	R 338.533(3), (4), (6)(c), (6)(e)
19	Justin Kuhns, PharmD, Lab Director, Portage Pharmacy		The commenter suggested the following language for (4): An outsourcing facility located in this state or that dispenses, provides, distributes, or otherwise furnishes sterile compounded pharmaceuticals in this state must shall be inspected and registered as an outsourcing facility by the United States Food and Drug Administration (FDA) prior to applying for a pharmacy license in this state.	The Board agrees with further expanding the term distributes" to "dispenses, provides, distributes, or otherwise furnishes."	R 338.533(4)

20	Justin Kuhns, PharmD, Lab Director, Portage Pharmacy		The commenter requested the deletion of (5) which allows an outsourcing facility to undergo an inspection by the board or a third party recognized by the board instead of only the FDA providing the inspections.	The Board agrees with the comment that only the FDA should inspect an outsourcing facility that handles compounded pharmaceuticals in this state which is registered as an outsourcing facility by the FDA and, therefore, deletes (5).	R 338.533(5)
21	Rose M. Baran		The commenter requested to reference the Federal Food, Drug, and Cosmetic Act 503B(10) and rule 338.582.	The Board accepts the comment to reference R 338.582 and patient specific drugs to the rule.	R 338.533(6)(d)
22	Justin Kuhns, PharmD, Lab Director, Portage Pharmacy		The commenter requested this language be added, “An outsourcing facility may compound drugs using bulk drug substances that appear on a list established by the Secretary identifying bulk drug substances for which there is a clinical need.”	The Rules Committee agrees with adding the language to (10).	R 338.533(8)

23	Brian Sapita, Government Affairs Manager, MPA		Remove "the NABP-VPP" replace with "a board approved accrediting organization."	The Board agrees with the comment to replace the existing language with "a board approved accrediting organization" instead of listing each organization in the rule as the rule would require modification every time a change was made.	R 338.534
24	Justin Kuhns, PharmD, Lab Director, Portage Pharmacy		Add "or outsourcing facility" to (1): "A sterile compounding pharmacy or outsourcing facility … ."	The Board agrees with the proposed change as it clarifies that an outsourcing facility must notify the Department if it ceases to provide sterile compounding.	R 338 535(1)
25	Justin Kuhns, PharmD, Lab Director, Portage Pharmacy		Add the following: "An outsourcing facility shall not resume providing sterile compounding services in this state until the outsourcing facility is approved by the department and verifies that it is compliant by an organization satisfying the requirements of R 338.533(4-10)."	The Board agrees with the proposed change to clarify that an outsourcing facility must notify the Department if it desires to resume sterile compounding.	R 338.535(4)

26	Brian Sapita, Government Affairs Manager, MPA		MPA believes that R 338.493a (3), proposed R 338.561(b), should not be deleted and should read, "if the total number of dosage units of all prescription drugs that are prepared or compounded by a pharmacy for resale, compounding, or dispensing by another person, as defined in section 1106 of the code, during any consecutive 12-month period is more than 5% of the total number of dosage units of prescription drugs prepared by the pharmacy during the 12-month period, then the pharmacy is a manufacturer as defined in section 17706(1) of the code."	The Board agrees that prior R 338.493a(3), proposed R 338.561(b), should not be deleted entirely from the rules. However, the Board moves R 338.561(b) to R 338.551(4) as the provision applies to a manufacturer license not wholesale license.	R 338.551(4)

27	Rose M. Baran		Delete (b) entirely as (b) is in violation of 333.17748a(7) and the Drug Quality and Security Act section 503A.	The Board does not agree with deleting (b) from the rules, but instead recommends moving (b) to R 338.551(4) as it applies to a manufacturer license and clarify (a) to make it consistent with the Drug Quality and Security Act.	R 338.561(b)
28	Rose M. Baran		Delete “or the reference "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products” from the rule. The rule was created before computer software was standard practice in pharmacy over 30 years ago. This terminology is no longer used on prescription labels because computers made it obsolete.	The Board agrees with the comment to delete "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products” from the rule, but does not agree with deleting the rule in its entirety as the use of generic needs to be disclosed if being used.	R 338.582(3)

29	Rose M. Baran		Change the first sentence to: "A CPMP must be accompanied by any mandated patient information required under federal law." This would cover any medication guides required.	The Board agrees with the comment as it clarifies the provision.	R 338.585(2)(b)
30	Brian Sapita, Government Affairs Manager, MPA		Subrule (2) should be included in this section.	Subrule (2) will be added back in as it was deleted by error.	R 338.587(6)
31	Eric Roath, PharmD, MBA, Clinical Care Coordinator, SpartanNash		Statutory changes that have occurred since the original rules regarding the use of automated devices in healthcare settings, as well as the addition of Subrule (2)(h) in these proposed rules, creates the potential for automated devices to be used in locations outside a pharmacy but at the same physical address of the pharmacy. However, this is currently limited only to hospital settings. Given that hospital pharmacies do not have any differentiation in	The Board agrees with the comment to add the language "a pharmacy, or at the same physical address as the pharmacy provided that the location of the device is owned and operated by the same legal entity as the pharmacy."	R 338.588(2)

			license classification and, in some circumstances, have the ability to operate as outpatient facilities, this creates an environment where certain outpatient pharmacies are able to use these devices in capacities that are denied to pharmacies in the community practice setting. To address this discrepancy, we recommend that Rule 88, Subrule (2)(a) be modified to read "a pharmacy, or at the same physical address as the pharmacy provided that the location of the device is owned and operated by the same legal entity as the pharmacy."		
32	Eric Roath, PharmD, MBA, Clinical Care Coordinator, SpartanNash		The current definition "automated device" in the Michigan Public Health Code and in the rules as proposed encompasses	The Board agrees with the comment from Roath as this is current practice with a change of the term "patient" to "ultimate user."	R 338.588(3)

			several devices that may be used in workflow for tasks other than the delivery of a medication to patient or other healthcare provider (e.g., counting machines and packaging devices operated by pharmacy staff as part of the dispensing process). We feel that to register each of these devices with the department goes beyond the intent of the Board and the Department and will cause devices that do not require department oversight to be erroneously registered with the Department. To correct this, we recommend that Rule 88, Subrule (3) be modified to read: "A pharmacy that operates an automated device under this section to deliver a drug or device directly to a patient or other healthcare provider shall		

			notify the department of the automated device's location on a form provided by the department …"		
33	Brian Sapita, Government Affairs Manager, MPA		Remove "unless the prescriber's office is affiliate with a hospital consisted with section 17760 of code, MCL 333.17760." This is not relevant to this section.	Although the Board does not agree with the commenter's suggestion to delete MCL 333.17760 because the statutory provision it an exception to the rule, a reference to (2)(h) which details the circumstances that amount to the exception, is being added for clarification.	R 338.588(4)
34	Rose M. Baran		Rule 338.3154 does not identify what is "board-approved error-prevention technology" and refers back to rule 338.490 which is being rescinded by the new draft rules. 338.3154 and 338.490 go around in a circle without ever defining "board-approved error-prevention technology".	The Board agrees with the comment to delete the reference to R 338.3154 for the reasons noted by the commenter.	R 338.588(5)

35	Brian Sapita, Government Affairs Manager, MPA		After "pharmacy" add "or dispensing prescriber."	The Board agrees with the comments to provision (7).	R 338.588(7)(b)
36	Rose M. Baran		There is no longer an exception in R 338.486(3).	The Board does not agree with the comment that there is no longer an exception in R 338.486. However, as there are multiple exceptions in this rule there is a typographical error and the (3) should be deleted.	R 338.589(5)
37	Brian Sapita, Government Affairs Manager, MPA		After "prescriptions" add issued by an appropriate prescriber" and remove "of the attending physician."	The Board agrees with the comment to update the language.	R 338.590

13.Date report completed:

7/22/2020