### Michigan Office of Administrative Hearings and Rules

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# 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:

Elizabeth Arasim

#### 2. Rule Set Information

MOAHR assigned rule set number:

2019-22 LR

Title of proposed rule set:

Pharmacy - Continuing Education

3. Purpose for the proposed rules and background:

The Pharmacy Continuing Education rules pertain to license renewals, continuing education requirements, approval of continuing education courses and programs, and acceptable continuing education activities. The draft rules have been reorganized and rewritten to provide the requirements necessary to aid a licensee in accumulating the continuing education credits necessary for license renewal.

R 338.3041: This rule pertains to license renewal and continuing education requirements. The proposed rule will add renewal of a special retired pharmacist license, require training for identifying victims of human trafficking, require training in opioids and other controlled substances awareness, and require 1 hour of continuing education in pharmacy ethics and jurisprudence. It will also clarify the courses that will satisfy the 1 hour of required pain and symptom management continuing education. The proposed rule will prohibit a licensee from earning credit for the same course twice within a renewal period and advise the licensee that his or her submission of an application for renewal constitutes his or her certification that he or she has complied with all continuing education requirements of this rule. The proposed rule will also advise a licensee that a continuing education waiver request must be received by the department before the expiration date of the license. R 338.3043: This rule pertains to approval of continuing education courses and programs. The proposed rule will establish additional requirements for an applicant seeking board approval of a continuing education course or program. The proposed changes include requiring submission of a "patient protection" form with the application if the course or program involves treating live patients, requiring submission at least 70 days before the course or program is to be conducted, and requiring that the course or program substantially meet an acceptable category of continuing education. The proposed rule will provide that the board may approve a program for 3 years and will also require reevaluation of an approved course or program if changes are made to the course or program. The proposed rules will provide the required information that the sponsor must include on the certificate or other proof of completion of the course or program that must be provided to the licensee. Finally, it will provide that the board may revoke approval for noncompliance with the rules. R 338.3044: This rule pertains to acceptable continuing education activities. The proposed rule will reorganize it into a more user-friendly format. The proposed rule will describe approved continuing education courses and programs, the number of continuing education hours that may be earned by completing each activity, and the licensee's duty to provide documentation of completion of the activity if audited. R 338.3045: This rule pertains to continuing education equivalents for a licensee residing or practicing in another state. This rule will be rescinded because the substance of the rule is included as an acceptable continuing education activity in R 338.3044(e).

#### 4. Summary of proposed rules:

Overview: The proposed changes will: require completion of training for identifying victims of human trafficking and training in opioids and other controlled substances awareness before renewal of the license; clarify that continuing education (CE) is only required if a licensee has been licensed for a full 2-year license cycle; require 1 hour of CE in pharmacy ethics and jurisprudence; clarify the pain and symptom management requirement; limit CE credit for taking the same CE course or program twice during 1 renewal period; require documentation of meeting CE requirements; require a waiver request prior to the expiration date of the license; modify CE approval standards; organize CE activities in a table; add CE activities for credit; require specific proof for CE; and rescind the CE rule regarding renewal requirements for a pharmacist who resides or practices in another state.

## 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. Allegan St, Lansing, MI 48909

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

https://dtmb.state.mi.us/ARS Public/Transaction/RFRTransaction?TransactionID=45

### 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:

Adam Carlson, Senior Director, Government & Political Affairs, Michigan Health & Hospital Association (MHA)

### 11. Persons submitting comments of opposition:

Rose M. Baran, PharmD, MA, Assistant Professor, College of Pharmacy, Ferris State University; Thomas R. Clark, RPh, MHS, BCGP, Senior Director, Board of Pharmacy Specialties (bps); Deeb D. Eid, PharmD, Assistant Profession, Ferris State University; Mary Anne McCoy, PhD, RN, ACNS, ACNP-BC, FAANP, President, Michigan Council of Nurse Practitioners (MICNP); Brian Sapita, Government Affairs Manager, 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	Brian Sapita, Government Affairs Manager, Michigan Pharmacists Association (MPA)		pharmacist's license" is not defined anywhere	The term "special retired pharmacist," refers to a special volunteer license for a pharmacist as authorized in section 16184 of the Public Health Code (Code), MCL 333.16184. The Board agrees to add "volunteer" to the term "special retired pharmacist license" to clarify that the license is the volunteer license authorized under the Code.	338.3041(1)
2	Rose M. Baran, PharmD, MA, Assistant Professor, College of Pharmacy, Ferris State University		Modify to read: "For license renewals beginning in 2020" The way it is currently written "Beginning with the first renewal cycle after November 13, 2017" is confusing.	The Board agrees with the comment to delete "with the first renewal cycle", as this language is confusing. The date that has been provided on the Department's website of 2020 is used in the rule.	338.3041(1) (b)

3	Rose M. Baran,	Modify to read:	The Board agrees	338.3041(1)
	PharmD, MA,	"For controlled	with the comment	(c)
	Assistant	substance license	to clarify that the	
	Professor,	renewals	opioid and	
	College of	beginning with	controlled	
	Pharmacy,	the 2021 renewal	substances training	
	Ferris State	cycles, an	is required only if	
	University	applicant for	the licensee is also	
		license renewal	applying for a	
		shall have	controlled	
		completed a 1-	substances license.	
		time training in	A specific	
		opioids and other	effective date has	
		controlled	been deleted, as R	
		substances	338.3135, which	
		awareness."	requires the opioid	
			training, is on hold	
			at the Joint	
			Committee on	
			Administrative	
			Rules.	
4	Rose M. Baran,	Rule 338.3041(d)	To provide for	338.3041(1)
	PharmD, MA,	requires the one	more time for	(d)(i)
	Assistant	hour in pharmacy	licensees to	, , , ,
	Professor,	ethics and	comply with the	
	College of	jurisprudence be	rule, the Board	
	Pharmacy,	obtained to renew	agrees with the	
	Ferris State	the license in	comment to clarify	
	University	2020. That	that 1 credit in	
	·	means the group	ethics and	
		of pharmacists	jurisprudence will	
		renewing with the	be effective	
		expiration date of	January 1, 2021.	
		June 30, 2020	·	
		will have less		
		than 6 months to		
		obtain this		
		requirement.		
		Would suggest		
		changing the		
		date, the start of		
		rule 338.3041(d)		
		to read		
		"Beginning in		
	1			
		2021"		

5	Brian Sapita, Government Affairs Manager, Michigan Pharmacists Association (MPA)	Rule should read "Emergency skills related to the health and safety of the patient pharmacy."  To clarify the rule, the Board agrees with the comment to modify the language to read "Emergency skills related to the health and safety of the patient."	(iv)
6	Rose M. Baran, PharmD, MA, Assistant Professor, College of Pharmacy, Ferris State University	This should be changed to read "A continuing education sponsoring organization, institution, or individual approved by the Michigan Pharmacists Association (MPA) or Michigan Health and Hospital Association, or national pharmacy organizations, or health system."  This would allow for more entities to provide continuing education for pharmacists.  To clarify the rule, the Board will modify the rule by deleting the provision referencing MPA, as MPA and any other entity that is approved by ACPE is included in subdivision (a) as accepted continuing education	338.3044(a)

7	Brian Sapita,	Pharmacy school The Board will	338.3044(a)
	Government	ACPE/CCAPP change "school" to	. ,
	Affairs	accreditation "program" in	
	Manager,	process is not subdivision (a) to	
	Michigan	similar to ACPE clarify that the	
	Pharmacists	accreditation for program must be	
	Association	CE hours. The ACPE or CCAPP	
	(MPA)	accreditation is approved, not the	
	,	based on different school.	
		criteria.	
		Recommend	
		removing the	
		ACPE and	
		CCAPP.	
8	Brian Sapita,	A preceptor may The Board agrees	338.3044(d)
	Government	not always have with the comment	` `
	Affairs	direct interaction that clarity is	
	Manager,	with the student. necessary in	
	Michigan	Some student subdivision (d).	
	Pharmacists	pharmacists may To clarify that it is	
	Association	not interact with a the Board's intent	
	(MPA)	preceptor at all. that the	
		How will the relationship	
		Board ensure that between the	
		this will not be preceptor and	
		abused? student must be in	
		Consider person, the term	
		removing "1 "in person" will be	
		intern – to- 1 added after "120	
		preceptor ratio." hours."	

### 13.Date report completed:

2/19/2020