

Michigan Office of Administrative Hearings and Rules

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**AGENCY REPORT TO THE
JOINT COMMITTEE ON ADMINISTRATIVE 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:

2020-29 LR

Title of proposed rule set:

Pharmacy Technicians

3. Purpose for the proposed rules and background:

The purpose of the Board of Pharmacy - Pharmacy Technicians Rules is to regulate the prelicensure programs, examinations, licensure, licensure renewal, relicensure, continuing education, and delegation of activities and functions for pharmacy technicians. The proposed rules are intended to: clarify the type of examination required for licensure; clarify the licensure requirements; clarify the requirements for licensure by endorsement; clarify the requirements for a temporary license; add the minimum requirements for a pharmacy technician education or training program; clarify the requirements for relicensure; clarify the continuing education requirements; clarify the process for review of continuing education; and clarify the activities and functions that may be delegated to a pharmacy technician's scope of practice.

4. Summary of proposed rules:

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The proposed rules will clarify the requirements and process of applying for a pharmacy technician license; require Board approved pharmacy technician programs to be accredited; limit the time a pharmacy technician student may participate in pharmacy technician activities while in a pharmacy technician program; review pharmacy technician employer programs and examinations every 5 years; require all applicants for relicensure to show good moral character and submit their fingerprints; require all applicants to take human trafficking training; require continuing education to be met with courses and programs instead of taking a proficiency examination; require 1 hour in ethics and jurisprudence in each renewal cycle; modify the continuing education approval process; and allow pharmacy technicians to assist in technology assisted final product verification.

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

Marquette Mining Journal – January 5, 2021; Flint Journal – January 5, 2021; Grand Rapids Press – January 5, 2021

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

1/15/2021

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

1/19/2021 01:00 PM at The public hearing will be held virtually via Zoom to receive public comments while complying with measures designed to help prevent the spread of Coronavirus Disease 2019 (COVID 19). , [https://us02web.zoom.us/j/89584407954?](https://us02web.zoom.us/j/89584407954?pwd=R0ZmOGhNUmw5Z24xZ3g4a2UveGx4dz09)
pwd=R0ZmOGhNUmw5Z24xZ3g4a2UveGx4dz09 Password for video connection: 759646 Phone number: 877-336-1831 Conference Code for audio connection: 486917

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=157>

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; and LeAnn Payne, Board Support.

10. Persons submitting comments of support:

No persons submitted comments in support.

11. Persons submitting comments of opposition:

The following persons sent comments in writing:
Rose M. Baran, PharmD, MA, Assistant Professor, College of Pharmacy, Ferris State University;
Deeb D. Eid, PharmD, RPh; and
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:

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	Name & Organization	Comments made at public hearing	Written Comments	Agency Rationale for change	Rule number & citation changed
1	Deeb E. Eid		<p>Number (2) in this section is confusing because if you reference MCL 333.17739a (1) (d)(iv) the language is specific to “employer-based training program examination” within statute, so it does not line up with a nationally recognized exam as currently mentioned. Delete current proposed language for (2).</p>	<p>Delete (2) as the Public Health Code (Code) requires an employer-based proficiency examination to cover the topics listed in the Code, it does not require a national recognized pharmacy technician examination to cover the topics in the Code.</p>	<p>R 338.3654 (2)</p>

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2	Deeb D. Eid		<p>Certification exams are usually only accredited if they on the national level. Exams like PTCB and NHA go through their own set of accreditations for the exams themselves (ANSI and NCCA). Employer based training program exams would very unlikely reach this level of accreditation because they are not on the national level. Removal of “accreditor’s accreditation” in (4).</p>	<p>Delete (4) as a proficiency examination should not be required to meet program accreditation standards and, therefore, the provision should be deleted.</p>	R 338.3654 (4)

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3	Deeb D. Eid		<p>Numbers (5) and (6) are non-feasible because a national certification exam program (such as PTCB or NHA) is not going to submit an application to the Board. In addition, providing a copy of the examination with correct answers for a national certification exam (such as PTCB or NHA) would compromise the exam. Each of these companies have question bank systems, etc. so they would never be able to provide this to the board without completely compromising their entire business model. Removal of language relating to a nationally recognized certification exam in (5) and (6).</p>	<p>The questions on an accredited nationally recognized pharmacy technician proficiency examination do not need to be reviewed by the Board. The Board can rely on the accreditation process. Therefore, changes to (5) and (6) have been made as a nationally recognized pharmacy technician proficiency examination should be submitted by an application to the Department with proof of accreditation in order to be considered Board approved, and further that modifications to the examination do not need review by the Board. However, if the accreditation is lost, the examination will no longer be considered Board approved.</p>	R 338.3654 (5) and (6)
4	Deeb D. Eid		Educational	There needs to be	R 338.3655

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			<p>programs often are conducted by schools, colleges, vocational programs, and/or specific entities.</p> <ul style="list-style-type: none"> o Training programs are often conducted or held by employers, associations, and other entities. o Trainings can also be internal for employers and employers often do not have formal “education” programs. • There needs to be clear distinction within the language to ensure there is no mix up of expectations for this section. 	<p>a clear distinction within the language to ensure there is no mix up of expectations for this section.</p> <p>Adding “including an employer-based training program” helps to clarify that this type of program is considered a training program.</p> <p>Therefore, (a) will read:</p> <p>(a) A pharmacy technician program including an employer-based training program that is accredited by the accreditation council American Society of Health-System Pharmacists/Accreditation Council for pharmacy education Pharmacy Education (acpe) Pharmacy Technician Accreditation Commission (ASHP/ACPE).</p> <p>Add the United States Department of Education to broaden the entities that may offer accreditation.</p>	<p>(1)(a)</p>
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5	Deeb D. Eid		Move towards unifying language with other parts (U.S. Dept of Education) and delete “pharmacist.”	Add the United States Department of Education to broaden the entities that may offer accreditation.	R 338.3655 (1)(b)
6	Deeb D. Eid		<p>(4): There needs to be a clear distinction within the language to ensure there is no mix up of expectations for this section.</p> <p>(8): Of note, there are no published studies/evidence to showcase that accreditation standards lead to increased patient safety or to show that accredited vs non-accredited education or training leads to less harm.</p> <p>o Patient safety is the key piece to consider as accreditation is a costly, time extensive, and challenging process to maintain.</p>	<p>(4): There needs to be a distinction in the language to ensure there are clear expectations as it applies to different types of programs, therefore, (4) will be deleted and the language will be moved to (1) to apply to programs that are accredited.</p> <p>(8): Requiring all programs to be accredited, as required in (8), does not allow for the Board to consider other programs as well, therefore, deletion of (8) allows programs that are not accredited to still apply for approval.</p> <p>The deletion of (4) and (8) require a modification to (7) (delete the reference of (4) - (8) and replace with “this rule.”)</p>	R 338.3655 (4) and (8)
7	Brian Sapita		MPA would suggest that the	A reference to a second pharmacy	R 338.3665(i) and (v)

			<p>rules are more precise on the use of a second licensed pharmacy technician during the technology-assisted final product verification process. Currently as written we believe the rules could be misconstrued that a single pharmacy technician would be allowed to process an entire medication order from start to finish without any checks or balances. Our suggested wording changes are below: (i) A licensed pharmacy technician verifies the work of a second licensed pharmacy technician. (v) The technology-assisted final product verification after being verified by a second licensed pharmacy technician is</p>	<p>technician is needed in the rule to clarify that there will be two people involved in the process which allows the first pharmacy technician to process the prescription and the second licensed pharmacy technician to provide final verification. Therefore, (i) will read as follows: (i) "A second licensed pharmacy technician verifies the work of the first licensed pharmacy technician to perform final product verification." Further (v) will read as follows: "The second licensed pharmacy technician technology-assisted final product verification is subject to all of the following requirements:"</p>	
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			subject to all of the following requirements:		
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13.Date report completed:

5/6/2021