

GRETCHEN WHITMER

# STATE OF MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS LANSING

ORLENE HAWKS

# MICHIGAN BOARD OF PHARMACY RULES COMMITTEE WORK GROUP MEETING

# MINUTES JUNE 12, 2019

The Michigan Board of Pharmacy Rules Committee Work Group, met on June 12, 2019, at 611 West Ottawa Street, Upper Level Conference Center Room 3, Lansing, Michigan 48933.

#### **CALL TO ORDER**

Andria Ditschman called the meeting to order at 12:13 p.m.

#### **ATTENDANCE**

**Members Present:** Nichole Cover, R.Ph.

Charles Mollien, PharmD, JD James Stevenson, PharmD

**Members Absent:** Patricia Keim. R.Ph.

Kathleen Pawlicki, MS, FASHP

**Staff Present:** Andria Ditschman, Analyst, Boards and Committees Section

Stephanie Wysack, Board Support, Boards and Committees Section

Public Present: Dhafer Almaklani - Self

Rosalie Baran - Self Deeb Eid – Self

Marla Ekola – Michigan Health & Hospital Association and Michigan

Society of Health-System Pharmacists

Paige Fults – Michigan Health & Hospital Association Farah Jalloul – Michigan Pharmacists Association

Joel Kurzman – National Association of Chain Drug Stores

Eric Roath – Spartan Nash

Brian Sapita – Michigan Pharmacists Association

Larry Wagenknecht – Michigan Pharmacists Association

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#### WELCOME

Ditschman explained that comments received since the last meeting had been forwarded to the Rules Committee for review.

RULES DISCUSSION – A copy of the Pharmacy Technicians draft rules, used during discussion, is attached.

R 338.3665 Performance of activities and functions; delegation.

Ditschman inquired whether "product verification by a pharmacy technician" violates the statutory requirement that the pharmacist handle dispensing.

Stevenson stated that dispensing encompasses everything that the pharmacist does as part of their scope of practice. The rule states that once the parameters are checked by the pharmacist, that the pharmacy technician can fill the prescription with the correct product.

Wagenknecht stated that the person dispensing at a pharmacy depends on each pharmacy's process. The pharmacy technician assumes the responsibility from the pharmacist.

Ekola stated that the automatic systems have checks and balances built in.

Ditschman asked if there were sufficient safety measures included in the proposed language.

Baran stated that the rule is not Tech-Check-Tech. The rule is written so that one pharmacy technician can do the verification alone.

Cover suggested that some of the Tech-Check-Tech language be used, specific to the type of pharmacy environment.

Mollien stated he would like language added to cover all pharmacy settings. Cover agreed.

Eid stated that the term Tech-Check-Tech is old but other states use the same concept, just under a different name. He stated that the term is outdated and is only specific to pharmacy technicians, whereas in other states it is not specific to technicians. He stated that it is important that the rule specify a delegation task.

Wagenknecht stated that as long as the pharmacist is involved in the process, the critical position is covered.

Ditschman stated that proposed language could be sent to her.

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Ditschman asked whether the requirements should be different for community and institutional settings.

Mollien stated that the language should be the same for community and institutional settings.

Ditschman asked if the language should be modified to have more than one person provide the final verification and define product verification. Cover indicated no.

Ekola asked how this rule would fit into the retail side. Cover stated that the pharmacy technician is checking what the pharmacist has already done. Other states have good language regarding the procedure and Cover will get that to Ditschman.

**Subrule (b)(i):** Baran asked if the individual has passed the Pharmacy Technician Certification Board (PTCB) certification exam 30 years ago, would they need to retake it. Stevenson clarified that pharmacy technicians need to have a current certification from PTCB.

Eid stated that there are training programs available specifically for pharmacy technicians and product verification.

Ekola stated that training in product verification is a good idea and felt that it should be added in addition to the PTCB certification exam.

Cover questioned whether a designation could be added to the pharmacy technician license for a product verification endorsement. Ditschman indicated that there are no endorsements currently so the pharmacist would have to make the call regarding the qualifications of the pharmacy technician handling product verification.

Ditschman asked what type of training should be included in the rule.

Cover stated that the pharmacist has the discretion to use the pharmacy technician for product verification based on the experience of the pharmacy technician to handle the task. Mollien agreed.

Stevenson stated he would like nationally recognized training included.

Mollien indicated having current PTCB certification is important. He stated that maybe a timeframe on experience should be added before the pharmacy technician is allowed to perform product verification.

Ekola wondered if pharmacists felt that they had autonomy in filling prescriptions and with delegating tasks. Cover indicated that they do. Cover stated that within the pharmacy system that she works for, the individual's access for certain tasks is built into the system

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at sign-in. However, it was agreed that small pharmacies may not have these limitations built into the system.

Wagenknecht stated that additional requirements for pharmacy technicians are important. He indicated that community pharmacies are on the horizon.

Eid stated that there are four studies available that cover all the requirements regarding certification and training in product verification for pharmacy technicians. He provided them to Ditschman.

Cover stated that if Tech-Check-Tech language is used, it should be written similar to the language used by PTCB.

Ditschman will draft language for the next work group meeting.

## R 338.3655 Approved pharmacy technician programs.

Ditschman stated that she had received multiple comments questioning the process of approval of pharmacy technician programs.

**Provision (1):** Stevenson stated that the Board should not decide what programs are appropriate. If the program is approved by the U.S. Department of Education, that should be adequate.

Ditschman asked whether the Rules Committee believed that pharmacy technician employer-based programs should also be accredited. Mollien stated they should.

Baran stated that she didn't believe that the statute was as specific as the rules. Ditschman indicated that approval of pharmacy technician programs is already included in the rule, and the Rules Committee is attempting to clarify the approval and reapproval process.

Almaklani asked if there were entities that accredited employer-based programs. The Rules Committee all indicated that there were.

Eid questioned whether accreditation actually made a difference in the safety of the public. Currently North Dakota is the only state that requires it. Ekola stated that the military also requires accreditation.

Mollien stated that accreditation establishes a minimum standard and oversight in order to protect the public. Further, accreditation adds the professional piece to licensure. Cover added that accreditation offers consistency and the ability to be prepared.

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Cover will provide Ditschman with information from other states as to their requirements for reviewing programs.

Eid questioned how a new accreditation standard would affect pharmacy technicians that are already licensed. Ditschman clarified that the accreditation would not affect them, since they are already licensed, but they would be affected by the new product verification training requirement. Ditschman indicated that programs will ultimately have to meet the accreditation requirements in order for the pharmacy technician program to obtain approval in Michigan. However, a pharmacy technician would still only have to pass an examination to be licensed as is required in the law.

Mollien stated that 2 years would be a good time to provide for programs to become compliant with the accreditation standard as the accreditation process is quick.

## R 338.3654 Examination requirements; passing score; application process.

**Subrule (3)(c):** Ditschman indicated that at the last meeting there were questions regarding the 75% requirement, and she inquired if there were thoughts on the number.

Eid stated that he felt that there is more to the passing score then just the 75%. There is a lot going on behind the scenes. Wagenknecht agreed.

Mollien stated that what goes on behind the scenes doesn't need to be looked at when determining what a passing score should be. Stevenson agreed.

Wagenknecht stated that if programs have to meet the U.S. Department of Education standards by 2022, then if the exam doesn't meet those requirements, it is no longer consistent with the rules. He stated that 75% is a good number.

Mollien questioned whether it would help to give the option of "or meeting accreditation requirements."

**Subrule (3)(a):** Ditschman stated she would confirm the number of questions required in statute.

#### R 338.3661 License renewals; continuing education requirements.

**Provision (1):** Baran questioned how the 2-year cycle, plus the extra months, affect audits. Will the 2-year cycle include the extra time that is allowed due to changing the system. Ditschman will check on the auditing process on the 2-year cycle during the change from set cycle dates to the new issuance dates.

#### **ADJOURNMENT**

Ditschman indicated that the draft of the controlled substance rules is still in process. The centralized prescription processing and animal euthanasia and sedation rules are are

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open and comments are welcome. The pharmacy continuing education rules and general pharmacy rules are almost ready for a public hearing.

Ditschman adjourned the meeting at 1:28 p.m.

Prepared by: Stephanie Wysack, Board Support Bureau of Professional Licensing

June 24, 2019

#### DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

#### **DIRECTOR'S OFFICE**

#### PHARMACY TECHNICIANS

Filed with the Secretary of State on

These rules become effective immediately upon filing with the Secretary of State unless adopted under section 33, 44, 45a(6), or 48 of 1969 PA 306. Rules adopted under these sections become effective 7 days after filing with the Secretary of State.

(By authority conferred on the director of the department of licensing and regulatory affairs by sections **16145**, 16148, **16184**, **16201**, **16204**, **16205**, <del>17707</del>, 17731, 17739, 17739a, 17739b, and 17739c, of 1978 PA 368, as amended, MCL 333.16145(3), 333.16148, **333.16184**, **333.16204**, **333.16205**, <del>333.17703</del>, <del>333.17707</del>, 333.17731, 333.17739, <del>333.17339a</del> **333.17739a**, 333.17739b, and **333.**17739c and Executive Reorganization Order Nos. <del>1996-1</del> **1991-9**, 1996-2, 2003-1, and 2011-4, MCL <del>330.3101</del> **338.3501**, 445.2001, 445.2011, and 445.2030)

R 338.3651, R 338.3653, R 338.3655, R 338.3657, R 338.3659, R 338.3661, R 338.3663, and R 338.3665 of the Michigan Administrative Code are amended, and R 338.3652, R 338.3654, R 338.3660, and R 338.3662 are added as follows:

R 338.3651 Pharmacy technician licensure; eligibility; examination.

- Rule 1. Unless exempt pursuant to section 17739a of the code, MCL 333.177391, while a student currently in a pharmacy technician program approved by the board, or holding a temporary pharmacy technician license under R 338.3652 and section 17739b of the code, MCL 333.17739b, or holding a limited pharmacy technician license under section 17739c of the code, MCL 333.17739c, an applicant for licensure by examination as a pharmacy technician shall submit a completed application on a form provided by the department, together with the appropriate fee. In addition to meeting the requirements of the code and the requirements of section 16174 of the code, MCL 333.16174, administrative rules promulgated under the code, an applicant shall comply with all of the following requirements:
- (a) Have met the requirements specified in section 17739a(1)(b) and (c) of the code, MCL 333.17739a(1)(b) and (c). Have graduated from an accredited high school or comparable school or educational institution or passed the general educational development test or the graduate equivalency examination.
- (b) Unless exempt under section 17739a(4), MCL 333.17739a(4) of the code, have passed and provided proof to the department of passing any of the following examinations:
- (i) Examinations specified in section 17739a(1)(d)(i) and (ii) of the code, MCL 333.17739a(1)(d)(i) and (ii). The certified pharmacy technician examination given by the Pharmacy Technician Certification Board or the National Healthcareer Association.
- (ii) A nationally recognized **and administered** pharmacy technician certification examination that <del>covers the topics specified in section 17739a(1)(d)(iv) of the code, MCL 333.17739a(1)(d)(iv), and</del> has been approved by the board **under R 338.3655**.

- (iii) An employer-based training program examination with a minimum of 100 questions that covers the topics specified in section 17739a(1)(d)(iv) of the code, MCL 333.17739a(1)(d)(iv), and that has been approved by the board, pursuant to both of the following: under R 338.3654.
- (A) The employer submits to the department at least 60 days prior to administering the examination a completed application for approval of the examination, the examination, and the answers to the examination.
- (B) Approval of the examination shall be valid until the examination is changed.
- (c) Beginning March 16, 2021, an applicant shall submit proof of having completed training in identifying victims of human trafficking as required in R 338.3659.
- (d) Beginning June 1, 2020, an applicant shall meet the English proficiency requirement in R 338.3660.

#### R 338.3652 Temporary License.

- Rule 2. (1) Subject to the limitations in section 16181 of the code, MCL 333.16181, the department may issue a nonrenewable, temporary license to an applicant who has completed all requirements for licensure as a pharmacy technician required except passing the proficiency examination.
- (2) An applicant applying for a pharmacy technician temporary license shall submit a completed application on a form provided by the department, together with the appropriate fee.
- (3) The temporary license expires 1 year after the date the temporary license is issued.

### R 338.3653 Licensure by endorsement.

- Rule 3. (1) An applicant for licensure by endorsement shall submit a completed application on a form provided by the department, together with the requisite fee. An applicant who meets the requirements of this rule is presumed to meet the requirements of section 16186 of the code, MCL 333.16186.
- (2) In addition to meeting the requirements of the code and administrative rules promulgated under the code, an applicant shall satisfy both all of the following requirements:
- (a) Have met the requirements specified in section 17739a(1)(b) and (c) of the code, MCL 333.17739a(1)(b) and (c). Graduate from an accredited high school or comparable school or educational institution or passed the general educational development test or the graduate equivalency examination.
  - (b) Satisfy the requirements in section 16174 or the code, MCL 333.16174.
  - (b) (c) Meet 1 of the following requirements:
- (i) If Hold a licensed pharmacy technician license or registration by examination in another state that is currently active and in good standing. less than 5 years in another state,
- (d) submit Submit proof that the applicant passed 1 of the approved examinations specified in R 338.3651(b).
- (ii) If holds an active licensed license in good standing as a pharmacy technician for 5 or more years in another state, within 30 days prior to filing an application for licensure in this state, the applicant is presumed to meet the requirements of section 17739a(1)(d) of the code, MCL 333.17739a(1)(d).
  - (e) Beginning June 1, 2020, meet the English proficiency requirement in R 338.3660.
- (f) Beginning March 16, 2021, submit proof of having completed training in identifying victims of human trafficking as required in R 338.3659.

- (2) (3) In addition to meeting the requirements of subrule (1) of this rule, an applicant's license shall be verified, on a form supplied by the department, by the licensing agency of another any state of the United States in which the applicant holds a current license or ever held a license as a pharmacy technician. This includes, but is not limited to, showing proof of any disciplinary action taken or pending disciplinary action imposed upon the applicant. Verification must be sent directly to the department from the licensing agency and include the record of any disciplinary action taken or pending against the applicant.
- R 338.3654 Examination requirements; passing score; application process.
- Rule 4. (1) A nationally recognized pharmacy technician proficiency certification examination and an employer-based training program proficiency examination must be approved by the board.
- (2) A nationally recognized pharmacy technician proficiency certification examination shall cover the topics specified in section 17739a(1)(d)(iv) of the code, MCL 333.17739a.
- (3) An employer-based training program proficiency examination shall comply with the following:
  - (a) Include a minimum of 100 questions.
  - (b) Cover the topics specified in section 17739a(1)(d)(iv) of the code, MCL 333.17739a.
- (c) Require 75% of the questions on the examination be answered correctly to pass the examination.
- (4) An application for examination board approval shall comply with the following:
- (a) The applicant shall submit to the department a completed application on a form provided by the department and a copy of the exam with the correct answers clearly identified for each question.
- (5) Board approval of a proficiency examination after promulgation of these rules will expire 5 years after the date of approval. Subsequent board approval shall be pursuant to the requirements of this rule.
- (6) Board approval of a proficiency examination approved before promulgation of these rules will expire on the day it was approved in 2022. Subsequent board approval shall be pursuant to the requirements of this rule.
- (7) A modification to a proficiency examination during its approval term must be submitted to the department for board approval pursuant to the requirements of this rule.
- R 338.3655 Approved pharmacy technician programs.
- Rule 5. (1) Pursuant to sections 16171(a), 17739(2), and 17739a(1) of the code, MCL 333.16171(a), MCL 333.17739(2), and MCL 333.17739a(1), a student in an approved pharmacy technician program is exempt from, and not eligible for, licensure while in the program. Any of the Beginning April 1, 2023, the following pharmacy technician programs are considered board-approved for this purpose:
- (a) A pharmacy technician program that is accredited by the accreditation council for pharmacy education (acpe) (ACPE).
- (b) A pharmacy technician program that is offered by a pharmacist education program that is accredited by the accreditation council for pharmacy education (acpe) ACPE.
- (c) A An accredited comprehensive curriculum-based pharmacy technician education and training program conducted by a school that is licensed pursuant to the Proprietary Schools Act,

- 1943 PA 148, MCL 395.101 to 395.103, that has been approved by the board under subrule (3) of this rule.
- (d) A An accredited pharmacy technician employer-based training program utilized by a pharmacy or employer that includes specific training in the functions, specified in MCL 333.17739(1), required to assist the pharmacist in the technical functions associated with the practice of pharmacy that has been approved by the board under subrule (3) of this rule.
- (2) The contents of the training programs offered under subdivisions (c) and (d) of subrule (1) of this rule include, at a minimum, all of the following:
- (a) The duties and responsibilities of the pharmacy technician and a pharmacist, including the standards of patient confidentiality, and ethics governing pharmacy practice.
- (b) The tasks and technical skills, policies, and procedures related to the pharmacy technician's position pursuant to the duties specified in section 17739(1) of the code, MCL 333.17739(1), and R 338.3665.
- (c) The pharmaceutical medical terminology, abbreviations, and symbols commonly used in prescriptions and drug orders.
- (d) The general storage, packaging, and labeling requirements of drugs, prescriptions, or drug orders.
- (e) The arithmetic calculations required for the usual dosage determinations.
- (f) The essential functions related to drug, purchasing, and inventory control.
- (g) The recordkeeping functions associated with prescriptions or drug orders.
- (3) To gain approval under subdivisions (c) and (d) of subrule (1) of this rule, an **applicant** application shall **submit an application** be submitted to the department on a form provided by the department, along with an attestation form that verifies compliance with the information required by subrule (2) of this rule and an overview of the pharmacy technician training program.
- (4) The pharmacy technician training program, employer, or pharmacy shall maintain the following records for 3 years after a student completes or leaves the program:
- (a) A record of a student's pharmacy technician training and education shall be maintained by the pharmacy technician training program, employer, or pharmacy specified in subrule (1) of this rule for a period of 2 years and shall include both of the following including:
  - (a)(i) The full name and date of birth of the pharmacy technician student.
- (b)(ii) The starting date of the pharmacy technician education **training** program and date the student successfully completed the program.
  - (b) The program syllabus and activities performed in the program.
- (5) A student shall complete the pharmacy technician training program within 2 years of beginning the program.
- (6) A student in a board approved pharmacy technician program is exempt from, and not eligible for, licensure while in the program.
- R 338.3657 Requirements for relicensure; pharmacy technician.
- Rule 7. (1) An applicant **for relicensure** whose Michigan pharmacy technician license has lapsed, under the provisions of section 16201(3) or (4) of the code, MCL 333.16201(3) or (4), and is not currently licensed in another state may be relicensed by submitting a completed application on a form provided by the department, together with the appropriate fee, and complying with the following requirements:

(1) Length of period of lapsed license For a	Lapsed	Lapsed more
pharmacy technician who has let his or her license	0-3 Years	than 3 years
lapse and who is not currently licensed in another	0-3 1 cars	than 5 years
state:		
(a) Application and fee Application and fee: Submit		
a completed application on a form provided by the		
department, together with the requisite fee.	V	V
(b) Good moral character: Establish that he or she		
is of good moral character as defined under		
sections 1 to 7 of 1974 PA 381, MCL 338.41 to	V	V
338.47.		
(c) Submit fingerprints: Submit fingerprints as		
required under section 16174(3) of the code, MCL 333.16174.		V
(d) Continuing education Continuing education:		
Submit proof of having completed 20 hours of		
continuing education specified in R 338.3661(1)(a)(i)	V	V
which was completed within the 2-year period	V	V
immediately preceding the date of the application for		
relicensure. However, if the continuing education		
hours submitted with the application are deficient,		
the applicant shall have 2 years from the date of		
the application to complete the deficient hours.		
The application will be held, and the license will		
not be issued until the continuing education		
requirements have been met.		
(e) Examination: Within 2 years of the		
period immediately preceding the application for		V
relicensure, pass 1 of the examinations specified in R		
338.3651(b)(i to iii).		
(f) Beginning in 2021, an applicant shall submit	V	V
proof of having completed training in identifying		
victims of human trafficking as required in R 338.3659.		
(g) Verification: Submit verification from the		
licensing agency of all other states of the United	$\sqrt{}$	V
States in which the applicant has ever held a		
license to practice as a pharmacy technician.		
Verification must include the record of any		
disciplinary action taken or pending against the		
applicant.		

<sup>(2)</sup> An applicant whose Michigan pharmacy technician license has lapsed and who holds a current and valid license in another state shall comply with all of the following:

<sup>— (</sup>a) Submit a completed application on a form provided by the department, together with the requisite fee.

- (b) Submit proof of having completed 20 hours of continuing education or passing an exam specified in R 338.3661(1)(d)(ii) which was completed within the 2-year period immediately preceding the application for relicensure.
- (c) An applicant's license shall be verified by the licensing agency of all other states or territories of the United States in which the applicant holds a current license or ever held a license as a pharmacy technician. If applicable, verification shall include the record of any disciplinary action taken or pending against the applicant.

(2) For a pharmacy technician who has let his or	Lapsed	Lapsed more
her license lapse, but who holds a current and	0-3 Years	than 3 years
valid pharmacy technician license in another state:		
(a) Application and fee: Submit a completed		
application on a form provided by the department,	$\sqrt{}$	$\sqrt{}$
together with the requisite fee.		
(b) Good moral character: Establish that he or she		
is of good moral character as defined under		$\sqrt{}$
sections 1 to 7 of 1974 PA 381, MCL 338.41 to		
338.47.		
(c) Submit fingerprints: Submit fingerprints as		
required under section 16174(3) of the code, MCL		$\sqrt{}$
333.16174.		
(d) Continuing education: Submit proof of having		
completed 20 hours of continuing education		
specified in R 338.3661(1)(a)(i) which was		
completed within the 2-year period immediately		$\sqrt{}$
preceding the date of the application for		
relicensure. However, if the continuing education		
hours submitted with the application are deficient,		
the applicant shall have 2 years from the date of		
the application to complete the deficient hours.		
The application will be held, and the license will		
not be issued until the continuing education		
requirements have been met.		,
(e) Beginning in 2021, an applicant shall submit		$\sqrt{}$
proof of having completed training in identifying		
victims of human trafficking as required in R		
338.3659.		
(f) Examination: Within 2 years of the period		$\sqrt{}$
immediately preceding the application for		
relicensure, pass 1 of the examinations specified in		
R 338.3651(b)(i to iii).		
(g) Verification: Submit verification from the		1
licensing agency of all other states of the United		$\sqrt{}$
States in which the applicant has ever held a		
license to practice as a pharmacy technician.		

Verification must include the record of any	
disciplinary action taken or pending against the	
applicant.	

- R 338.3659. Training standards for identifying victims of human trafficking; requirements.
- Rule 9. (1) Pursuant to section 16148 of the code, MCL 333.16148, an individual licensed or seeking licensure shall complete training in identifying victims of human trafficking that meets the following standards:
  - (a) Training content covering all of the following:
  - (i) Understanding the types and venues of human trafficking in the United States.
  - (ii) Identifying victims of human trafficking in health care settings.
- (iii) Identifying the warning signs of human trafficking in health care settings for adults and minors.
  - (iv) Resources for reporting the suspected victims of human trafficking.
  - (b) Acceptable providers or methods of training include any of the following:
- (i) Training offered by a nationally-recognized or state-recognized health-related organization.
  - (ii) Training offered by, or in conjunction with, a state or federal agency.
- (iii) Training obtained in an educational program that has been approved by the board for initial licensure, or by a college or university.
- (iv) Reading an article related to the identification of victims of human trafficking that meets the requirements of subdivision (a) of this subrule and is published in a peer review journal, health care journal, or professional or scientific journal.
  - (c) Acceptable modalities of training may include any of the following:
    - (i) Teleconference or webinar.
    - (ii) Online presentation.
    - (iii) Live presentation.
    - (iv) Printed or electronic media.
- (2) The department may select and audit a sample of individuals and request documentation of proof of completion of training. If audited by the department, an individual shall provide an acceptable proof of completion of training, including either of the following:
- (a) Proof of completion certificate issued by the training provider that includes the date, provider name, name of training, and individual's name.
- (b) A self-certification statement by an individual. The certification statement shall include the individual's name and either of the following:
- (i) For training completed pursuant to subrule (1)(b)(i) to (iii) of this rule, the date, training provider name, and name of training.
- (ii) For training completed pursuant to subrule (1)(b)(iv) of this rule, the title of article, author, publication name of peer review journal, health care journal, or professional or scientific journal, and date, volume, and issue of publication, as applicable.
- (3) Pursuant to section 16148 of the code, MCL 333.16148, the requirements specified in subrule (1) of this rule shall apply for license renewals beginning with the first renewal cycle after the promulgation of this rule March 16, 2016, and for initial licenses issued 5 or more years after March 16, 2021 the promulgation of this rule.

R 338.3660 English proficiency.

Rule 10. (1) Beginning June 1, 2020, pursuant to section 16174(1)(d) of the code, MCL 333.16174, an applicant seeking initial licensure shall demonstrate a working knowledge of the English language if the applicant's educational or training program was taught outside the United States, unless exempted by subrule (3) of this rule.

- (2) To demonstrate a working knowledge of the English language, an applicant shall submit proof that he or she has obtained a total score of not less than 80 on the Test of English as a Foreign Language Internet Based Test (TOEFL-IBT) administered by the Educational Testing Service.
- (3) If an applicant's education or training program was taught in English within 1 or more of the following, he or she is exempted from the requirements of subrule (1) of this rule:
  - (a) Canada, except Quebec.
  - (b) England.
  - (c) Ireland.
  - (d) New Zealand.
  - (e) Australia.

R 338.3661 Continuing License renewals; continuing education or exam; renewal requirements.

- Rule 11. (1) A licensee seeking renewal of a pharmacy technician's license, who has been licensed for the 2-year period immediately preceding the end of the license cycle, shall at each renewal, comply with all of the following:
- (a) Complete and submit an Submit a completed application for renewal on a form provided by the department together with the requisite fee.
- (b) Pay the required renewal fee. Beginning June 1, 2020, meet the English proficiency requirement in R 338.3660.
- (c) Comply with R 338.3659. Submit proof of having completed training in identifying victims of human trafficking as required in R 338.3659.
- (d) If licensed for the entire 2-year period immediately preceding the application for renewal, Comply with 1 of the following:
- (i) Except as otherwise provided, complete at least 20 hours of continuing education courses or programs approved by the board under R 338.3662, during the 2 years immediately preceding the application for renewal, as follows:
  - (A) (i) One hour shall be in pharmacy ethics and jurisprudence.
- (ii) One hour shall be in pain and symptom management in the practice of pharmacy, which includes but is not limited to, courses in behavior management, psychology of pain, pharmacology, behavior modification, stress management, clinical applications, and drug interventions as they relate to professional practice.
  - (iii) One hour shall be in patient safety.
- (iv) No more than 12 hours of continuing education credit may be earned during a 24-hour period.
- (B) (vi) Credit for a continuing education program or activity that is identical to a program or activity that the licensee has already earned credit for during the renewal period shall not be

granted. An applicant for license renewal shall not earn credit for taking the same continuing education course or program twice during 1 renewal period.

(C) If audited, the licensee shall submit a copy of a letter or certificate of completion showing the licensee's name, number of continuing education hours earned, sponsor name or the name of the organization that approved the program or activity for continuing education credit, and the date on which the program was held, or activity completed.

(D) (vii) At least 5 of the continuing education credits shall be earned by attending live courses, programs or activities that provide for direct interaction with instructors, peers, and participants, including but not limited to lectures, meetings, symposia, real-time teleconferences or webinars, and workshops.

(E) Continuing education credit shall be earned as follows:

Sub	ects	Number of continuing
<del>Suo</del> j	<del>cets</del>	
		education hours required or
		permitted for each activity
A	Pain and symptom management relating to the practice of	Minimum: 1 hour
	pharmacy.	
₿	Patient safety.	Minimum: 1 hour
C	Pharmacy law.	Minimum: 1 hour
Đ	Pharmacy-related subject matter including the following	Minimum: 17 hours in any
	topics:	combination of D listed
	Medication or drug distribution.	subjects. Instruction in each D
	Inventory control systems.	listed subject is not required.
	Mathematics and calculations.	Example 1: Biology, 5 hours;
	Biology.	Drug repackaging, 4 hours;
	Pharmaceutical sciences.	Pharmacy operations, 8 hours;
	Therapeutic issues.	total: 17hours. Example 2:
	Pharmacy operations.	Prescription compounding, 17
	Pharmacology, drug therapy or drug products.	hours; total: 17 hours.
	Preparation of sterile products.	(Minimum: 7 hours in any
	Prescription compounding.	combination for an applicant
	Drug repackaging.	under subrule (4) of this rule.)
	Patient interaction or interpersonal skills and	
	communication.	

- (ii) Complete a proficiency examination as specified in R 338.3651(b)(i) to (iii).
- (2) Submission of an application for renewal shall constitute the applicant's certification of compliance with this rule. The licensee shall retain documentation of meeting the requirements of this rule for a period of 3 4 years from the date of applying for license renewal. Failure to comply with this rule is a violation of section 16221(h) of the code, MCL 333.16221(h).
- (3) An applicant who was originally licensed in Michigan less than one year before the renewal date is not required to comply with this rule.
- (4) An applicant for renewal who was originally licensed in Michigan more than one year but less than two years before the renewal date shall have accumulated ten hours of continuing education credits pursuant to these rules.

(3) A request for a waiver under section 16205 of the code, MCL 333.16205, must be received by the department before the expiration date of the license.

R 338.3662 Format of acceptable continuing education for licensees.

R 12. (1) The board shall consider all of the following as acceptable continuing education:

	FORMAT OF ACCEPTABLE CONTINUING EDUCATION ACTIVITIES		
(a)	Completion of an approved continuing education course or program related to the practice of pharmacy. A continuing education course or program is approved, regardless of the format in which it is offered, if it is approved or offered for continuing education credit by any of the following:  • A pharmacy school accredited by the Accreditation Council for Pharmacy Education (ACPE) or the Canadian Council for Accreditation of Pharmacy Programs (CCAPP).  • A continuing education sponsoring organization, institution, or individual approved by the ACPE.  • Another state board of pharmacy.  If audited, a licensee shall submit a copy of a letter or certificate of completion showing the licensee's name, number of hours earned, sponsor name or the name of the organization that approved the	The number of hours earned will be the number of hours approved by the sponsor or the approving organization.  If the activity was not approved for a set number of hours, then 1 credit hour for every 50 minutes of participation may be earned.  No limitation on the number of hours earned.	
	program or activity for continuing education credit, and the date on which the program was held, or activity completed.		
(b)	Completion of postgraduate pharmacy practice or administration courses offered for credit in a pharmacy school accredited by the ACPE or the CCAPP.	Twelve hours of continuing education will be earned for each academic quarter credit earned and 18 hours will be earned for each academic	
	If audited, a licensee shall submit an official transcript that reflects completion of the postgraduate pharmacy practice or administration course and number of	No limitation on the number of hours earned.	

semester or quarter credit hours earned.

(c)	Participation in a home study program offered through an ACPE-approved provider or other instructional approaches that include an evaluation component including, but not limited to, on-line continuing education programs and journal articles.	One hour will be earned for each hour devoted to a home study program.  A maximum of 20 hours per renewal period.
	If audited, a licensee shall submit an affidavit attesting to the number of hours the licensee spent participating in the home study program that includes a description of the activity.	
(d)	Renewal of a pharmacy technician license held in another state that requires continuing education for license renewal that is substantially equivalent in subject matter and total amount of required hours to that required in these rules if the licensee resides and practices in another state.	Twenty hours will be earned.  A maximum of 20 hours may be earned in each renewal period.
	If audited, a licensee shall submit proof of current licensure in another state and a copy of a letter or certificate of completion showing all of the following: the licensee's name, number of hours earned, the sponsor's name or the name of the organization that approved the program or activity for continuing education credit, and the date on which the program was held or the activity was completed.	
(e)	Initial publication of an article or a chapter related to the practice of pharmacy in either of the following:  • A pharmacy textbook.  • A peer reviewed journal.  If audited, a licensee shall submit a copy of the publication that identifies the licensee	Ten hours will be earned per publication.  A maximum of 10 hours may be earned in each renewal period.
(f)	as the author or a publication acceptance letter.  Presentation of a continuing education program approved by the board under R 338.3663 or subdivision (a) of this rule that is not a part of the licensee's regular job	Two hours for every 50 minutes devoted to presenting the program.

	description.	A maximum of 10 hours will be earned in each renewal period.
	If audited, a licensee shall submit a copy of the curriculum and a letter from the program sponsor verifying the length and date of the presentation.	
(g)	Attendance at a pharmacy-related program, which is approved by the board pursuant to R 338.3663.	The number of hours earned will be the number of hours approved by the sponsor or the approving organization.
	If audited, a licensee shall submit a copy of a letter or certificate of completion showing the licensee's name, number of hours earned, sponsor name or the name of the organization that approved the program or course for continuing	If the activity was not approved for a set number of hours, then 1 credit hour for every 50 minutes of participation may be earned.
	education credit, and the date on which the program was held or the activity was completed.	No limitation on the number of hours earned.

R 338.3663 Continuing education providers; standards for approval.

Rule 13. (1) Continuing education for pharmacy technicians that is offered or approved by any of the following providers **is approved by the board and** meets the requirements of R 338.3661(1):

- (a) A pharmacy technician educational program that has been approved pursuant to R 338.3655.
  - (b) A course or program approved by Another another state board of pharmacy.
  - (c) A program approved by the Accreditation Council for Pharmacy Education (ACPE).
- (2) A continuing education provider course or program that is not pre-approved under subrule (1) of this rule may be approved by the board. To be approved by the board, the provider shall comply with subrules (2), (3), and (4) of this rule, by submitting to the department a complete an completed application on a form provided by the department, and file it with the department for review no later than 60 70 days before the program date, and 70 days prior to the next regularly scheduled board meeting. A continuing education course or program conducted prior to board consideration and approval will be denied approval. The application and supporting documentation shall include all of the following information:
- (a) A program schedule, including **the** date of the program, topics, the name of **all** speaker speakers, and break times.
- (b) An explanation of how the program is being designed to further educate pharmacy technicians, including a short narrative describing the program content and the criteria for the selection of this topic.
  - (c) Copies of instructional objectives that have been developed.
  - (d) Copies of all promotional and advertising materials for the program.
- (e) The name, title and address of the program director and a description of his or her qualifications to direct the program.

- (f) A description of how the amount of continuing education credit to be awarded for this program was determined.
- (g) A description of how participants will be notified that continuing education credit has been earned.
- (h) A description of the physical facilities, lab, or pharmacy available to ensure a proper learning environment.
  - (i) A copy of the curriculum vitae for each instructional staff member.
- (j) A description of the delivery method or methods to be used and the techniques that will be employed to assure active participation.
  - (k) A copy of the post-test instrument that will be used for participant evaluation.
  - (l) A description of how post tests will be administered, corrected, and returned to participants.
- (m) A description of how post-test performance will influence the awarding of continuing education credit.
- (n) A description of how attendance will be monitored, including sample documents, and the name of the person monitoring attendance.
- (3) The continuing education program approved under subrule (2) of this rule shall meet all of the following:
- (a) Be an organized program of learning that that will contribute to the advancement and enhancement of professional competency and scientific knowledge in the practice of pharmacy and be designed to reflect the educational needs of pharmacy technicians.
- (b) Have a scientific and educational integrity and contain generally accepted pharmacy practices.
- (c) Have an outline which demonstrates consistency with the course description and reflects the course content.
- (d) Be taught in a manner appropriate to the educational content, objectives, and purpose of the program and allow suitable time to be effectively presented to the audience.
- (e) Provide instructors who have the necessary qualifications, training, and experience to teach the course.
  - (f) Provide for active participation and involvement from the participants.
- (g) Offer educational materials for each continuing education activity that will enhance the participant's understanding of the content and foster applications to pharmacy practice.
- (h) Include learning assessments in each activity that allow pharmacy technicians to assess their achievement of the learned content. Completion of a learning assessment is required for continuing education content.
- (4) Board approval shall be for a term of 3 years (term of approval) from the date of approval.
- (5) An approved continuing education course or program must be reevaluated by the board prior to any changes during the approval term, including but not limited to changes in the following:
  - (a) Instructors and speakers.
- (b) Continuing education course or program content, title, and number of continuing education hours to be awarded to participants.
- (c) Subject to subdivision (d) of this rule, all changes to a previously approved continuing education course or program must be submitted on required department forms at least 70 days prior to the date the continuing education course or program is offered to participants and 70 days prior to the next regularly scheduled board meeting to be considered for

approval by the board. Any changes to a submitted and previously approved continuing education course or program conducted prior to board reconsideration and approval will be denied approval.

- (d) Emergency changes to instructors and speakers that are unable to be submitted to the board at least 70 days prior to the date of the continuing education course or program may be reviewed by the department in consultation with the board chair or a continuing education board committee member when proof acceptable to the department is submitted with the change supporting the nature of the emergency.
- (e) The specific dates that the continuing education course or program will be offered do not require further board approval and may be changed without review by the board as long as the presentation dates are within the board's original 3-year term of approval.
- (4) (6) The program provider or sponsor of a course or program approved under subrule (2) of this rule shall issue certificates or letters of attendance that include all of the following:
  - (a) The name of the applicant and sponsor.
  - (b) The name of the program.
  - (c) The name of the attendee.
  - (d) The date of the program.
- (e) The Michigan continuing education approval number as assigned by the department and current approval term.
  - (f) The signature of the person responsible for attendance monitoring and his or her title.
  - (g) The number and type of hours attended awarded.
- (7) The provider or sponsor of a course or program shall maintain records of the information contained in subrule (6) of this rule for 5 years after the course or program is offered to participants.
- (8) The board may revoke the approval status of any approved continuing education course or program at any time the continuing education course or program fails to comply with these rules.
- R 338.3665 Performance of activities and functions; delegation.
- Rule 15. In addition to performing the functions described in section 17739(1) of the code, MCL 333.17739(1), a licensed pharmacy technician may also engage in reconstituting dosage forms as defined in 17702(4) of the code, MCL 333.17702(4) the following tasks, under the delegation and supervision of a licensed pharmacist:
- (a) Reconstituting dosage forms, as defined in 17702(4) of the code, MCL 333.17702.
- (b) Product verification, subject to all of the following requirements:
- (i) The pharmacy technician performing product verification has passed the pharmacy technician certification board (PTCB) certification exam and holds a current full pharmacy technician license in this state (not a temporary or limited license).
- (ii) Product verification by a pharmacy technician is limited to pharmacy services provided in a medical institution, as defined in R 338.486.
- (iii) The medical institution where a pharmacy technician performs product verification has in place policies and procedures governing pharmacy technician product verification.
- (iv) The pharmacy technician uses a technology-enabled verification system to perform product verification.
- (v) A pharmacy technician does not perform product verification for sterile compounding.