

GRETCHEN WHITMER GOVERNOR STATE OF MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS LANSING

ORLENE HAWKS DIRECTOR

MICHIGAN BOARD OF PHARMACY RULES COMMITTEE WORK GROUP MEETING

MINUTES MAY 6, 2019

The Michigan Board of Pharmacy Rules Committee Work Group, met on May 6, 2019, at 611 West Ottawa Street, Upper Level Conference Center Room 5, Lansing, Michigan 48933.

CALL TO ORDER

Andria Ditschman called the meeting to order at 1:01 p.m.

ATTENDANCE

Members Present:	Nichole Cover, R.Ph. Patricia Keim, R.Ph. (arrived 2:15 p.m.) Charles Mollien, PharmD, JD Kathleen Pawlicki, MS, FASHP James Stevenson, PharmD
Members Absent:	None
Staff Present:	Andria Ditschman, Analyst, Boards and Committees Section Stephanie Wysack, Board Support, Boards and Committees Section
Public Present:	 Greg Baran – Barn Consulting, LLC Rose Baran - Self Amy Drumm – Michigan Retailers Association Deeb Eid – Self Marla Ekola – Michigan Health & Hospital Association and Michigan Society of Health-System Pharmacists Paige Fults – Michigan Health & Hospital Association Tomson George – Walgreen Co. Farah Jalloul – Michigan Pharmacists Association Joel Kurzman – National Association of Chain Drug Stores Bryan Liptak – Sparrow/Michigan Pharmacists Association Jonathan McLachlan – Alliance Rx Walgreens Prime Chris Meny – Blue Cross Complete of Michigan

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> Tisha Peterson – Michigan Society of Pharmacy Technicians/Munson Healthcare System Kathleen Reed – Dykema Gossett, PLLC Brian Sapita – Michigan Pharmacists Association Pam Sarau – Ascension Health/ Macomb-Oakland Hospital Sharon Smith – Ross Education, LLC Betsy Weihl – RWC Advocacy

WELCOME

Ditschman explained that Departmental leadership has mandated that all rules committee meetings will be open to the public in order to receive input on the rules draft from the public earlier in the rulemaking process. Ditschman reminded the public that the Rules Committee will make the final recommendation on the rules to the Board. Ditschman provided the link in a handout to receive email blasts that can be found by going online to www.michigan.gov/bpl and clicking on the email link at the bottom of the screen.

Ditschman indicated that item 3.C. Animal Euthanasia and Sedation will not be open for discussion at today's meeting as the Board has not voted to open the rules. She stated that comments could still be submitted to her for discussion at a future Rules Committee Work Group meeting.

Ditschman explained the plan for the flow of the meeting.

RULES DISCUSSION – Copies of Draft Rules is attached.

A. Controlled Substances

R 338.3138 Opioids and other controlled substances awareness training standards for prescribers and dispensers of controlled substances; requirements.

Ditschman explained that the requirement for opioid awareness training went into effect on January 4, 2019.

Ditschman identified two issues that were being addressed in the rule:

- **Provision (1):** The word "currently" was added in order to help clarify who this rule applies to.
- **Subrule (iv):** Removing the word "patients" to allow the rule to also apply to veterinarians whose "patients" are animals and cannot speak for themselves.
- **Provision (5):** Added in order to exclude the need for opioid training for licensees who solely prescribe for the purpose of research on animals.

Ditschman indicated that the rule does say how that the training is a one-time training, however, the licensee may need to attend multiple continuing education activities to cover all of the topics listed in the rule.

Cover noted that the opioid training does not apply to licensees who are renewing in June 2019.

Rose Baran asked when the rule would go into effect for licensees and when the training needed to be completed. Ditschman indicated that it would be required for licensees at the end of their first full 2-year renewal cycle after the rule goes into effect.

Ekola asked how this rule is different than the rule requirement for pain management. If the opioid training is completed prior to the requirement, would it count? Cover indicated that it is a one-time training for licensure and not continuing education. Pain management is continuing education. Ditschman indicated that similar to human trafficking, where some health professions are giving credit for human trafficking as continuing education in addition to it being recognized as a one-time, non-continuing education training, the onetime opioid awareness training may be used to meet a continuing education requirement if the Board allows it. Ditschman answered that an opioid awareness training activity that meets all of the requirements in the rule would be accepted even if taken before the effective date of the rule.

Rose Baran asked if the certificate, showing proof of the training, would need to be kept forever. Ditschman indicated that the proof would need to be maintained as long as the rule was in effect. Cover indicated that CPE Monitor provided through the National Association of Boards of Pharmacy (NABP) may have the ability to track the certificate for opioid training as well.

The change to the Controlled Substances Rules will be voted on by the Board at the June 12, 2019 meeting.

B. Pharmacy Technicians

R 338.3651 Pharmacy technician licensure; eligibility; examination.

Ditschman indicated that the Department received comments from the Michigan Health & Hospital Association and the National Association of Chain Drug Stores and if anyone at the meeting today was from those organizations, they should feel free to raise their comments when we get to those sections of the rules.

Ditschman clarified that when drafting the rules, the Department did not want to be redundant in covering what is already covered under the statute. In doing that, MCL 333.16174 will be referenced often to cover basic licensure requirements such as age, application, fees, fingerprinting, and license verifications.

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Subrule (c) and (d): Ditschman indicated that these have both been added in order to address the dates in which human trafficking and English proficiency will be required.

Pawlicki questioned if everything for obtaining pharmacy technician licensure has been included as she did not see anything addressing pharmacy technician education. She felt that there should be expectations and standards added in order to protect the public. She also wanted a requirement for approved education added.

Ditschman indicated that pharmacy technician education beyond graduating from high school or equivalent is not required in the statute. However, passing the examination is required. Additional training is a requirement that could be added to continuing education. Cover confirmed that the statute does not allow for pharmacy education to be added. Ditschman will follow-up with the Department regarding the need for an educational component for licensure.

Fults felt that sterile compounding should be added to approved programs.

Rose Baran questioned whether the word "or" should be added to the first sentence of Provision (1) to then read "....., or holding a temporary pharmacy technician license...."

Rules Committee members agreed to add "or" to the rule.

R 338.3652 Temporary License.

Ditschman indicated that the provisions for the temporary license in the general statute is more specific then the pharmacy technician statute.

Provision (1): Ditschman indicated that the wording nonrenewable has been added to encourage the individual to obtain full licensure.

Ditschman indicated that provisions from the general statute were not added and she provided some examples.

Reed asked which statute was Ditschman referring to. Ditschman clarified that she was referencing the general provision of the statute that applies to all temporary licensed health professions, MCL 333.16181.

Reed indicated that she believed that all the provisions in the general provisions of the Public Health Code regarding the temporary license would apply to the pharmacy technician temporary license.

Pawlicki indicated that she felt that a temporary license would be important when obtaining pharmacy technician training and be required. Ditschman indicated that it is not required to obtain a temporary license for training under the statute. Pawlicki

expressed concern that the temporary license is not required when an individual is in training and the possible impact on public/patient safety.

Cover questioned how many temporary licenses are actually issued by the Department. She also indicated that requiring a temporary license for training purposes isn't something that can be managed, and that the Department just has to trust that the pharmacies are doing their due diligence in their hiring practices.

Reed suggested referencing the general provisions of the statute in the rule as a way to include all provisions as opposed to listing them all.

Stevenson indicated referencing the statute was not necessary. Mollien stated that there would be no harm in not referencing the general statute but felt that some provisions should be listed. The statutory provisions will be sent to the Rules Committee for review.

R 338.3653 Licensure by endorsement.

Ditschman indicated that changes were made to the rule to require the examination and make the rule similar to the pharmacy endorsement rule.

Cover felt that the changes cleaned up the concerns that she had. Stevenson agreed.

Subrule (d): Ekola asked whether certification through the Pharmacy Technician Certification Board (PTCB) needed to be maintained once licensure was obtained.

Cover stated that if PTCB certification was not maintained, it could cause licensure issues with other states.

Ditschman indicated that some license types have timeframe requirements on when the examination was taken.

Ekola asked if PTCB certification needed to be active when applying. Cover indicated yes.

Greg Baran asked if the process of a pharmacy technician applying using PTCB certification was different than a pharmacy technician applying using an employer-based exam. Mollien indicated no.

Ditschman asked whether it was important to add a timeframe on when the examination was taken. She indicated that a retesting requirement could be added, similar to the one that is required for relicensure.

Mollien didn't feel that there was a need to require retesting for individuals who are actively licensed in another state at the time of application. Cover agreed.

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Subrule (c): Pawlicki wanted clarification of whether the rule was only referring to licensure as registration was not addressed in the rule. Registrations is used in many states.

Registration will be added to the rule.

Subrule (d): Rose Baran indicated that this rule should reference R 338.3651(b), not R 338.3651(c). Ditschman will make the correction.

R 338.3654 Examination requirements; passing score; application process.

Ditschman explained the changes made to the rule. She pointed out that subrule (3)(c) was added as there is currently no minimum score requirement.

Provision (3): Pawlicki questioned how the Department knows that the employer-based examinations are assessing competency. She is not sure that she is comfortable with the current process of Board approval.

Cover indicated that there would need to be a legislative change in order to remove the employer-based examination option from the statute. The statute currently allows the pathway to full licensure where the licensee can work at any pharmacy, even if the employer-based examination was taken through a different pharmacy. She stated that taking an employer-based examination should only allow the individual to work at the pharmacy through which the examination was taken.

Ditschman indicated that the Department reviews the examination application/packet for the correct number of questions and that all types of required questions are included. Then the examination is provided to the Board's Pharmacy Technician Examination Review Committee member for review of each question to be sure the questions and correct answer are good examination questions.

Pawlicki questioned whether the Rules Committee could set the rules to define the design of the examination. Cover indicated that she had recently been on a conference call with the company that wrote a certain employer-based examination. She stated that she asked who wrote the examination as she had many questions that needed clarification. The company indicated that the exam was written by licensed pharmacists. Cover indicated that the Department has to trust that the employer is using individuals with the knowledge needed in order to write the examination.

Ditschman indicated that the Rules Committee could include additional requirements for examinations. Suggestions should be sent to her and they can be discussed at a future meeting.

Stevenson stated that he shared the same concerns as Pawlicki and Cover and that there could be a better approach.

Cover felt the biggest concern is a licensee to has the ability to work at any pharmacy after taking an employer-based examination.

Keim was concerned that there is only one examination given by an employer-based program, therefore it is easy to know which answer goes to which question, each time the examination is taken.

Pawlicki wondered if the Rules Committee could ask for questions to be pulled from a database.

Ditschman indicated that the Rules Committee could ask for multiple examinations and/or use of a question pool. She will review other states to see how they regulate examinations.

Peterson indicated that the PTCB exam pulls questions randomly, therefore the examination is not the same every time it is taken.

Reed pointed out that Rule 2 should read Rule 4. Ditschman will make the correction.

Subrule (3)(c): Peterson felt that using a minimum of 75% was low compared to the national passing rate. Keim indicated that 75% is the national, so it is standard.

Rose Baran wanted clarification if subrule (3)(c) meant 75% of the questions or 75% overall.

Mollien believed that the intent was to answer 75% of the questions correctly.

Cover believed that it meant 75% of the questions as the employer-based examinations that came to the Board were 100 questions in length. Ditschman indicated that some examinations have more than 100 questions, the minimum is 100.

The language will be changed to 75% of the questions on the test are answered correctly.

Provision (4): A question was posed about aligning this requirement with renewal of the pharmacy. Mollien indicated that this would be too difficult to monitor, especially for large corporations, with the license renewal date changes.

Provision (6) and (7): Stevenson questioned whether this meant that the current examination is approved. Ditschman indicated that currently an examination is approved until it is changed. Provisions (6) and (7) were written in an attempt to require a more frequent status update of the examinations.

Stevenson questioned whether an employer-based examination could submit an attestation ten years after receiving their initial approval and be able to continue to use

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the same examination. Ditschman indicated that proposed provisions (6) and (7) would require an attestation every 3 years.

Stevenson would like the examination reviewed on a more regular basis, possibly 5 years.

Mollien suggested adding more requirements to the attestation.

Ditschman confirmed that the Rules Committee would like for the examination to be reviewed by the Department every three years instead of an attestation.

No public comment was made.

The Rules Committee agreed with the changes in the rule as discussed.

R 338.3655 Approved pharmacy technician programs.

Ditschman explained the changes to the rules. She pointed out that during previous Rules Committee meetings, instead of listing the requirements for a program in subrule (1)(d), the Rules Committee wanted all programs to be accredited for consistency and to be sure all programs were appropriately training pharmacy technicians.

Subrule (1)(d): Ditschman inquired if the Rules Committee had questions regarding the new language of accreditation.

Pawlicki would like programmatic accreditation in order to be more specific.

Cover indicated that she didn't want to require the specific number of hours in the program. Length doesn't matter necessarily if the program has the content. Pawlicki and Mollien agreed.

Pawlicki suggested using the wording "or equivalent." Ditschman indicated that this would require the Board to review each program that was submitted as "equivalent."

Mollien indicated that he found that the Accreditation Commission for Health Care (ACHC) has approved pharmacy technician programs. Pawlicki questioned whether the program was accredited or equivalent. Mollien was unsure.

Smith indicated that PTCB recognizes accreditation through the Accrediting Bureau of Health Education Schools (ABHES).

George asked if the proposed rules would require a shift to the Board approving the programs. Ditschman clarified that the proposed rule would allow a program that is accredited to automatically be Board-approved, so no additional review by the Board would be necessary.

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Mollien indicated that he would like to have standardization, but the standards could be varying. The Board may have to approve the programs with standards that are set in advance.

Ditschman indicated that the Rules Committee could recommend specific accreditation entities to be included in the rules. They would remain in the rules until the rules were opened up again.

Cover indicated that standards can change over time and that research should be done to find entities that provided accreditation before any decision is made on this rule.

A Ferris State University representative inquired what evidence existed to support accredited versus non-accredited programs. Mollien clarified that the use of accredited means it meets minimum standards.

Ditschman indicated that this will be discussed at a future Rules Committee Work Group meeting along with removing the attestation and having a 3-year program review.

Mollien questioned if the individual cannot test unless his or her education is accredited, why would the attestation be necessary.

Pawlicki asked when an accredited program would be needed. Ditschman indicated that the only requirement of licensure is to have passed the examination. However, if there is a program in Michigan, the proposed rules would require that it be accredited. The accreditation requirement would be set for a specific date in the future.

Mollien wondered what was the point of putting program requirements in the rules if not required for licensure. Cover clarified that a standard needed to be set in order to protect the public and for the future.

Mollien stated that the temporary license should be linked to the program. Ditschman indicated that in order to work as a student, without a license, the employer must have a Board approved program. Therefore, the Board should have standards to review the program.

Mollien stated that there was a disconnect between the employer program and the employer examination and that they should be tied together.

Ditschman indicated that this rule will continue to be discussed at the next Rules Committee Work Group meeting.

R 338.3657 Requirements for relicensure; pharmacy technician.

Ditschman explained that there are two tables, the first for licensees who are lapsed in Michigan and do not hold an active license in another state. The second is for those

licensees who allowed their Michigan license to lapse and hold an active license in another state.

Pawlicki questioned why there isn't a fingerprinting requirement for licensees who have been lapsed for less than three years. Ditschman explained that is because the individual just had the fingerprints done recently for his or her initial license.

Subrule (1)(d): Pawlicki asked what the two years meant. Ditschman indicated that the two years corresponds with the timeframe the Department will hold an application after it is received. The license is not issued until proof of the continuing education is received by the Department.

Subrule (1)(e): Mollien questioned why relicensure required current examination when endorsement did not. Ditschman explained that relicensure only requires a current examination if an individual has been unlicensed for 3 years. Currently, endorsement only requires an examination if licensed in another state for less than 5 years. This requirement is similar to the requirements for other health professions. The proposed rule requires that anyone applying for endorsement must have been licensed in the other state by examination. For endorsement, an individual who has been practicing in another state with a clean license does not need to retake the examination to be licensed in Michigan.

R 338.3660 English proficiency.

Ditschman explained that English proficiency is required in the general provisions of the Public Health Code, and the Public Health Code – General Rules. This is being added to each health profession rule set.

No public comment was made.

The Rules Committee agreed with the proposed rule as presented.

R 338.3661 License renewals; continuing education requirements.

Ditschman indicated that the rule is currently in a table format to be consistent with the pharmacy rules, it was changed to the format presented. Ditschman pointed out that the language regarding continuing education in ethics and jurisprudence and waiver is new.

Subrule (1)(d)(i): Mollien thought that this should be law driven as opposed to ethics. Ditschman indicated it was written exactly as it is in the pharmacy rules.

Cover stated that, as a conferee, she has been asking for more and more licensees to complete an ethics requirement, based on the complaints that are received. She would like for subrule (1)(d)(i) to stay as written.

Pawlicki questioned whether the language that is in subrule (1)(d)(i) was changed to read the same in the pharmacy rules. Ditschman confirmed the language is the same.

Greg Baran suggested changing the language to read one hour in ethics or jurisprudence.

Ekola suggested listing ethics and jurisprudence as two separate requirements in order to provide clarification. It does not currently clarify that the one hour has to include both ethics and jurisprudence. Ditschman indicated that the one hour needs to include both ethics and jurisprudence.

Stevenson indicated that the language was clear.

Peterson indicated that the Michigan Society of Pharmacy Technicians (MSPT) would be able to come up with a course that would include both ethics and jurisprudence.

Cover wanted the language to be consistent with the pharmacy rule language.

The Rules Committee agreed with the proposed rule as presented.

Subrule (1)(d)(iv): Stevenson stated that there should be a conversation about this rule if the intent is to take 3 prescribing hours and 17 hours in other areas. Ditschman indicated that the language is included in the current rule. The intent is for 17 hours to be in any combination. This provision can be changed or removed.

Stevenson indicated that subrule (1)(d)(iv) was not necessary and could be removed.

The Rules Committee agreed to remove subrule (1)(d)(iv).

R 338.3662 Format of acceptable continuing education for licensees.

Ditschman indicated that this table covered the categories for the required continuing education that was listed under existing R 338.3661. Ditschman gave a brief overview of the rule.

Cover asked that the continuing education requirement, giving credit for retaking the examination be removed. Ditschman indicated that it has been removed. Ditschman stated that the statute states "may" to give credit for retaking the examination. Therefore, the Rules Committee may delete this option.

Peterson wondered if the Rules Committee would consider giving credit for the compounding specialty exam that PTCB is preparing.

Cover thought that the table did not need to be so specific and that some items such as the examination could be covered under a more general heading of professional

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development. She would like to research other states to see how they give credit.

Mollien suggested adding the PTCB to activity code (a) in order to give credit for the compounding examination. Cover stated that this would open the door to other entities requesting to be added to the rule.

Ekola questioned if it was common for individuals to take the non-traditional route in obtaining continuing education. Ditschman indicated that the categories included in the table are used for other health professions but was not sure how often each category is used by licensees. Non-traditional continuing education allows for licensees to access a variety of training.

Cover stated that all professionals have a minimum amount of continuing education that they are required to complete. Providing more options allows for a broader range of courses to be taken.

Greg Baran questioned why the Michigan Pharmacists Association (MPA) was listed when the courses that they provide are already accredited/approved through the Accreditation Council for Pharmacy Education (ACPE). If they can be listed, other entities should have the opportunity to be added as well. Ditschman indicated that the language was pulled from the pharmacy rules and that the full Board has already approved that set of rules which includes ACPE. However, the rules are not final and additional entities could be added. Typically, the entities are nationally recognized or entities that licensees use for continuing education purposes.

Mollien felt that the MPA should be removed from the list in activity (a).

The Rules Committee agreed to remove MPA from activity (a).

R 338.3663 Continuing education providers; standards for approval.

Ditschman indicated that this rule is similar to the pharmacy rule and will be discussed at the next meeting.

R 338.3665 Performance of activities; delegation.

Ditschman indicated that she had received requests to add final verification by pharmacy technicians to the rule. Therefore, she added "...., and provide product verification,....." She asked the Rules Committee for input on this language.

Pawlicki noted that there was no language to cover quality control.

Keim questioned why there would be a need to add the new language.

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Cover indicated that she is the pharmacy representative on the facility side of licensing and that they are working on a Tech-Check-Tech model that would have pharmacy technicians checking each other's work. She stated that the new language aligned with the facility side.

Ditschman indicated that the statute is clear regarding the limitations on a pharmacy technician's activities. The proposed language allows the pharmacy technicians to participate in product verification. There is language in the General Pharmacy Rules regarding verification in a health system. However, that language does not allow a pharmacy technician to handle final product verification as proposed in this draft.

Cover felt that it should be written to be broad.

Pawlicki stated that regardless of the setting, the rule should be written in order to allow for transparency.

Ditschman inquired whether the Rules Committee wanted additional requirements in this provision relating to verification.

Mollien stated that it should stay as written.

Pawlicki liked the language but stated that some provisions should be included.

Keim did not want the language included as this would not be safe for the public and there are no requirements as to how many pharmacy technicians are under the authority of a pharmacist. Oversight may not be adequate.

Pawlicki stated that this would allow the pharmacist to delegate certain tasks to the pharmacy technicians, allowing the pharmacist to focus more on clinical work within the pharmacy.

Ditschman read the verification requirement from the general rules and the exception it allowed for medical institutions.

Stevenson stated that because the new language did not have any qualifiers, it was not appropriate. It should be clarified.

Fults stated that the language would be appropriate in a health system if a list of requirements was included. She had a list of suggested requirements that she will submit to Ditschman for review by the Rules Committee. These requirements are for in-patient settings only, not retail pharmacies.

Sarau indicated that guidance is covered under the Tech-Check-Tech model. Leaving the proposed new language would allow pharmacists to provide more clinical work and utilize the skills of the pharmacy technicians in other areas.

Ekola indicated that the language made her nervous and that the language could have a place as long as safeguards were put in place.

Kurzman is familiar with the Tech-Check-Tech model and supports of the language in order to allow the pharmacists to do more clinical work.

Rose Baran indicated that the way this rule is written it is broader than just health systems and would cover other settings such as nursing homes, etc.

Eid has a study regarding the Tech-Check-Tech model and will send to Ditschman for review by the Rules Committee. He liked that this allows for pharmacist to delegate in order to free up his or her time. However, it is a choice, not a requirement.

Cover indicated that this is another way to allow pharmacists to work at the top of their professions in utilizing the skills of the pharmacy technicians.

Reed pointed out that this rule is not about the Tech-Check-Tech model. It is about identifying who is doing the verification, not product verification alone. The pharmacy general rules removed the term "in patient" when referring to a medical institution. Cover agreed.

Keim indicated that she is not opposed to delegation.

Ekola stated that she is concerned about ensuring the pharmacy technicians are well trained pharmacy technicians in order to ensure that the public is safe.

Reed stated that delegation and supervision are defined in the statute and that the licensee could be charged with professional misconduct if not using due diligence.

Cover noted that in Ohio and Idaho, the professional misconduct can also come back on the facility in which the licensee worked if it is found that the facility was forcing the pharmacist to delegate.

ADJOURNMENT

Ditschman announced that there is another Rules Committee Work Group meeting on June 12, 2019, immediately following the full Board meeting.

Ditschman adjourned the meeting at 3:56 p.m.

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

May 13, 2019

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

BOARD OF PHARMACY

PHARMACY - CONTROLLED SUBSTANCES

Filed with the secretary of state on

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a(6) of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the board of pharmacy by sections 7201, 7219, section 7301, and 16204e-7333a of 1978 PA 368, MCL 333.7201, 333.7219, 333.7301, and 333.16204e 333.7333a and Executive Reorganization Order Nos. 1991-9, 1996-2, 2003-1, and 2011-4, MCL 338.3501, 445.2001, 445.2011, and 445.2030)

R 338.3135 and R 338.3162b of the Michigan Administrative Code is amended, as follows:

R 338.3135 Opioids and other controlled substances awareness training standards for prescribers and dispensers of controlled substances; requirements.

Rule 35. (1) Pursuant to section 7301 of the act, MCL 333.7301, an individual seeking a controlled substance license or who is **currently** licensed to prescribe or dispense controlled substances shall complete a 1-time training, offered after promulgation of this rule, in opioids and controlled substances awareness that meets the following standards:

(a) Training content must cover all of the following topics:

(i) Use of opioids and other controlled substances.

(ii) Integration of treatments.

(iii) Alternative treatments for pain management.

(iv) Counseling patients on the effects and risks associated with using opioids and other controlled substances.

(v) The stigma of addiction.

(vi) Utilizing the Michigan Automated Prescription System (MAPS).

(vii) State and federal laws regarding prescribing and dispensing controlled substances.

(viii) Security features and proper disposal requirements for prescriptions.

(b) Topics covered under subrule (1)(a) of this rule may be obtained from more than 1 program.

(c) 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 offered by a continuing education program or activity that is accepted by a licensing board established under article 15 of the act.

(iv) Training obtained in an educational program that has been approved by a board established under article 15 of the act for initial licensure or registration, or by a college or university.

(d) Acceptable modalities of training include any of the following:

(i) Teleconference or webinar.

- (ii) Online presentation.
- (iii) Live presentation.

(iv) Printed or electronic media.

(2) After September 1, 2019, A a prescriber or dispenser shall not delegate, or allow by a practice agreement, or order the prescribing, dispensing, or administering of a controlled substance as authorized by this act to an advanced practice registered nurse, registered professional nurse, or licensed practical nurse, or any other licensee under article 15, unless the nurse until the advanced practice registered nurse, registered professional nurse, licensed practical nurse, or any other licensee under article 15 with this rule.

(3) The department may select and audit licensees and request documentation of proof of completion of training. If audited, an individual shall provide an acceptable proof of completion of training, including either of the following:

(a) A completion certificate issued by the training provider that includes the date, provider name, name of training, and individual's name.

(b) A self-attestation by the individual that includes the date, provider name, name of training, and individual's name.

(4) **Controlled substance licensees shall** The **complete the training as follows:**

(a) Licensees who are renewing a controlled substance license must complete the training by the end of requirements specified in this rule apply to controlled substance license renewals beginning with the first renewal cycle after the January 4, 2019. promulgation of this rule and for initial licenses issued after September 1, 2019.

(b) Applicants for an initial controlled substance license after September 1, 2019, must complete the controlled substance training prior to the application for licensure.

(5) Licensees who solely prescribe or dispense controlled substances to be used in research on animals are exempt from this rule.

R 338.3162b Electronic system for monitoring schedules 2, 3, 4, and 5 controlled substances.

Rule 62b. (1) Except as otherwise exempt under section 7333a of the code, MCL 333.7333a, A-a pharmacist, dispensing prescriber, and veterinarian licensed under Part 177 who dispenses a prescription drug which is a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by the state that dispenses in this state or dispenses to an address in this state a controlled substance listed in schedules 2 to 5 shall report to the department or the department's contractor by means of an electronic data transmittal process the following information for each prescription of a schedules 2 to 5 controlled substance prescription dispensed:

(a) The patient identifier, as defined in R 338.3102(1)(f). The following apply:

(i) An identification number, as specified in R 338.3102(1)(f)(iv)(A) or (B), is not required for patients under the age of 16.

(ii) If the patient is under 16 years of age, zeroes shall be entered as the identification number.

(iii) If the **medication is being dispensed for** patient is an animal, positive identification of the animal's owner (client) that meets the requirements of R 338.3102(1)(f)(iv), and the animal's name.

(b) The name of the controlled substance dispensed. The patient or client name, including first, middle (or initial if available), and last.

(c) The patient or client address, including street, city, state, and zip code.

(d) The patient or client phone number.

(e) The patient or client gender.

(f) The patient or client date of birth.

(g) The species code, according to ASAP standards.

(c) (h) The metric quantity of the controlled substance dispensed.

(d) (i) The national drug code number (ndc) of the controlled substance dispensed.

(e) (j) The date of issue of the prescription.

(f) (k) The date of dispensing.

(l) The number of refills authorized.

(m) The refill number of the prescription fill.

(g) (n) The estimated days of supply of the controlled substance dispensed.

(h) (o) The prescription number assigned by the dispenser.

(p) The prescription transmission form code according to ASAP standards that indicates how the pharmacy received the prescription.

(q) The prescription payment type.

(r) The electronic prescription reference number if applicable.

(s) The patient location code when receiving pharmacy services, according to ASAP standards.

(i) (t) The dea registration number of the prescriber and the dispensing pharmacy.

(j) The Michigan license number of the dispensing pharmacy.

(u) The first and last name of the person obtaining the dispensed controlled substance.

(v) The identifier of the person obtaining the dispensed controlled substance. Any of the following may serve as an acceptable identifier:

(i) A Michigan driver's license number.

(ii) An identification number obtained from a photo identification card issued by this state.

(iii) The number zero. Zeroes shall be entered as the identification number if the positive identification presented by the person does not include a license number or an identification number, as listed in this subdivision.

(w) Relationship of the person obtaining the dispensed controlled substance to the patient or animal.

(2) A pharmacist, dispensing prescriber, or veterinarian may presume that the patient identification information provided by a patient or a patient's representative is correct.

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**, 17707, 17731, 17739, 17739a, 17739b, and 17739c, of 1978 PA 368, as amended, MCL 333.16145(3), 333.16148, **333.16184**, **333.16201**, **333.16204**, **333.16205**, 333.17703, 333.17707, 333.17731, 333.17739, 333.17339a **333.17739a**, 333.17739b, and **333.**17739c and Executive Reorganization Order Nos. 1996-1 **1991-9**, 1996-2, 2003-1, and 2011-4, MCL 330.3101 **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 every the topics specified in section 17739a(1)(d)(iv) of the code, MCL 333.17739a(1)(d)(iv), and has been approved by the board **under R 338.3655**.

May 29, 2019

(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		,
state:		
(a) Application and fee Application and fee: Submit		
a completed application on a form provided by the	\checkmark	\checkmark
department, together with the requisite fee.		
(b) Good moral character: Establish that he or she		
is of good moral character as defined under	\checkmark	\checkmark
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		\checkmark
333.16174.		
(d) <u>Continuing education</u> 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	\checkmark	\checkmark
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 Examination: Within 2 years of the		
period immediately preceding the application for		\checkmark
relicensure, pass 1 of the examinations specified in R		
338.3651(b)(i to iii).		
(f) Beginning in 2021, an applicant shall submit	\checkmark	\checkmark
proof of having completed training in identifying		
victims of human trafficking as required in R		
338.3659.		
(g) Verification: Submit verification from the	I	
licensing agency of all other states of the United		\checkmark
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.		

(2) 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:

(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,	\checkmark	\checkmark
together with the requisite fee.		
(b) Good moral character: Establish that he or she		
is of good moral character as defined under	\checkmark	\checkmark
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		\checkmark
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		1
completed within the 2-year period immediately		\checkmark
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 definite hours		
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		
proof of having completed training in identifying	v	v
victims of human trafficking as required in R		
338.3659.		
(f) Examination: Within 2 years of the period		
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		
licensing agency of all other states of the United	\checkmark	\checkmark
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 shan be carried as follows.	
ects	Number of continuing
	education hours required or
	permitted for each activity
Pain and symptom management relating to the practice of	Minimum: 1 hour
pharmacy.	
Patient safety.	Minimum: 1 hour
Pharmacy law.	Minimum: 1 hour
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.
	Example 1: Biology, 5 hours;
	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.	
	Pain and symptom management relating to the practice of pharmacy. Patient safety. Pharmacy law. Pharmacy-related subject matter including the following topics: Medication or drug distribution. Inventory control systems. Mathematics and calculations. Biology. Pharmacy operations. Pharmacology, drug therapy or drug products. Preparation of sterile products. Prescription compounding. Drug repackaging. Patient interaction or interpersonal skills and

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

(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:

(a)	Completion of an approved continuing	The number of hours earned
(<i>a)</i>	education course or program related to the	will be the number of hours
	practice of pharmacy. A continuing	approved by the sponsor or the
	education course or program is approved,	approving organization.
	regardless of the format in which it is	approving organization.
	offered, if it is approved or offered for	If the activity was not approved
	continuing education credit by any of the	for a set number of hours, then 1
	following:	credit hour for every 50 minutes
	A pharmacy school accredited by	of participation may be earned.
	the Accreditation Council for	of participation may be carried.
	Pharmacy Education (ACPE) or the	No limitation on the number of
	Canadian Council for Accreditation	hours earned.
	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	
	program or activity for continuing	
	education credit, and the date on which the	
	program was held, or activity completed.	
(b)	Completion of postgraduate pharmacy	Twelve hours of continuing
	practice or administration courses offered	education will be earned for
	for credit in a pharmacy school accredited	each academic quarter credit
	by the ACPE or the CCAPP.	earned and 18 hours will be
		earned for each academic
	If audited, a licensee shall submit an	semester credit earned.
	official transcript that reflects completion	
	of the postgraduate pharmacy practice or	No limitation on the number of
	administration course and 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. 	Ten hours will be earned per publication. A maximum of 10 hours may be earned in each renewal period.
	If audited, a licensee shall submit a copy of the publication that identifies the licensee as the author or a publication acceptance letter.	
(f)	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 data of the presentation	earned in each renewal period.
(g)	date of the presentation. 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
	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.

(1) 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.