MICHIGAN BOARD OF PHARMACY
APRIL 8, 2020 MEETING

APPROVED MINUTES

In accordance with the Open Meetings Act, 1976 PA 267, as amended, the Michigan Board of Pharmacy met on April 8, 2020. The meeting was held via teleconference, pursuant to Executive Order 2020-15.

CALL TO ORDER

James Stevenson, PharmD, Vice Chairperson, Acting Chairperson, called the meeting to order at 10:05 a.m.

ROLL CALL

Members Present: Charles Mollien, PharmD, JD, Chairperson (arrived 10:10 a.m.)
James Stevenson, PharmD, Vice Chairperson
Cynthia Boston, BHS, R.Ph.T.
Kathleen Burgess, Public Member
David Hills, Public Member
Kelli Oldham, Public Member
Kathleen Pawlicki, MS, FASHP (left 10:56 a.m.)
Grace Sesi, PharmD
Sandra Taylor, R.Ph.
Maria Young, R.Ph.

Members Absent: None

Staff Present: Andria Ditschman, Senior Policy Analyst, Boards and Committees Section
Kiran Parag, Senior Analyst, Compliance Section
Jacob Poynter, Analyst, Licensing Division
Michele Wagner-Gutkowski, Assistant Attorney General
Stephanie Wysack, Board Support, Boards and Committees Section

APPROVAL OF AGENDA

MOTION by Pawlicki, seconded by Oldham, to approve the amended agenda as presented.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, Oldham, Pawlicki, Sesi, Taylor, Young, Stevenson
Nays: None

MOTION PREVAILED

APPROVAL OF MINUTES

MOTION by Taylor, seconded by Sesi, to approve the March 12, 2020 meeting minutes as written.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, Oldham, Pawlicki, Sesi, Taylor, Young, Stevenson
Nays: None

MOTION PREVAILED

REGULATORY CONSIDERATIONS

None.

OLD BUSINESS

None.

NEW BUSINESS

Pharmacy Technician Training Program Examination Modification

Diplomat

MOTION by Hills, seconded by Sesi, to approve the Pharmacy Technician Training Program Examination Modification.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, Oldham, Pawlicki, Sesi, Taylor, Young, Stevenson, Mollien
Nays: None

MOTION PREVAILED

Continuing Education

Stevenson directed the Board to the list of continuing education programs for consideration (Attachment #1).

MOTION by Pawlicki, seconded by Taylor, to approve the continuing education programs.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, Oldham, Pawlicki, Sesi, Taylor, Young, Stevenson, Mollien
Nays: None

MOTION PREVAILED

Mollien stepped in as Chairperson.

Rules Discussion

Ditschman provided an overview of the Pharmacy General Rules – ORR 2018-039 LR, Public Comment Summary (Attachment #2).

MOTION by Sesi, seconded by Young, to approve the modifications as proposed by the Rules Committee and the Board at today's meeting.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, Oldham, Sesi, Taylor, Young, Stevenson, Mollien
Nays: None

MOTION PREVAILED

Ditschman provide an overview of some changes that were made to the Pharmacy Technicians draft rules (Attachment #3).

MOTION by Taylor, seconded by Hills, to approve the Pharmacy Technicians draft rules as presented and modified at today's meeting.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, Oldham, Sesi, Taylor, Young, Stevenson, Mollien
Nays: None

MOTION PREVAILED

MOTION by Boston, seconded by Sesi, to open the Pharmacy General Rules and Controlled Substance rules as soon as the current sets have been promulgated.

A roll call vote was taken: Yeas: Boston, Burgess, Hills, Oldham, Sesi, Taylor, Young, Stevenson, Mollien
Nays: None

MOTION PREVAILED

Chair Report

None.

Department Update

Ditschman stated that the 116th NABP Annual Meeting being held May 14 – 16, 2020 will be virtual. They are still in need of a delegate from Michigan. Young stated that she was available to attend.

Ditschman recommended that the Board members review, at a minimum, Executive orders 2020-21, 2020-25, and 2020-30 , which are all relevant to the practice of pharmacy.

Ditschman stated that licensees renewing during the emergency declaration will not be required to provide proof of continuing education. She stated that work related to COVID-19 will count towards the continuing education requirements. She stated that continuing education audits are not being run at this time.

Ditschman stated that pharmacy technicians, holding a temporary license, that are unable to test due to COVID-19, will be given a six-month extension.

Ditschman stated that the Criminal Background Checks are still required for licensure as there are available locations where this can be completed.

Ditschman stated that testing for licensure as a pharmacist is still required. Poynter indicated that the authorization to test is given by the National Association of Boards of Pharmacy, not by the Department.

Ditschman stated that there have been many misstatements regarding the Department's guidance regarding prescribing medications. She clarified that the Department encourages pharmacies to continue to practice good faith dispensing during COVID-19. However, the Department does not support stock piling of medications.

For any questions/concerns regarding COVID-19, an individual should email the Department.

PUBLIC COMMENT

Marla Ekola from McLaren Greater Lansing stated that there will be Pharmacy Compounding Accreditation Board (PCAB) certificates that may expire during COVID-19.

Jamie Tharp from the Department of Pharmacy at the University of Michigan stated that the United States Pharmacopeia (USP) does not recommend the reuse of garb/face masks

for compounding. They recommend the use of clean masks. She would like direction from the Department on this issue.

ANNOUNCEMENTS

The next regularly scheduled meeting will be held June 10, 2020 at 10:00 a.m. at 611 West Ottawa Street, Upper Level Conference Center Room 3, Lansing, Michigan 48933.

ADJOURNMENT

MOTION by Boston, seconded by Taylor, to adjourn the meeting at 11:58 a.m.

A roll call vote was taken: Yeas: Boston, Oldham, Sesi, Taylor, Young, Mollien
Nays: None
Absent: Burgess, Hills, Stevenson

MOTION PREVAILED

Minutes approved by the Board on June 10, 2020.

Prepared by:
Stephanie Wysack, Board Support April 9, 2020
Bureau of Professional Licensing

PHARMACY CONTINUING EDUCATION REVIEW
April 8, 2020

RECOMMENDED APPROVAL(S)

SPECTRUM HEALTH MEDICAL CENTER – DEPARTMENT OF PHARMACY
- Pharmacy Grand Rounds (April 14 & 21, 2020) for pharmacists

ASCENSION ST. JOHN HOSPITAL, DEPARTMENT OF INPATIENT SERVICES
- Opioid and Controlled Substances Awareness Training for pharmacy technicians

SPECTRUM HEALTH MEDICAL CENTER – DEPARTMENT OF PHARMACY
- Pharmacy Grand Rounds (April 28, 2020) for pharmacists

SPECTRUM HEALTH MEDICAL CENTER – DEPARTMENT OF PHARMACY
- Pharmacy Grand Rounds (April 28, 2020) for pharmacy technicians

SPECTRUM HEALTH MEDICAL CENTER – DEPARTMENT OF PHARMACY
- Pharmacy Grand Rounds (May 19, May 26, June 2, and June 9, 2020) for pharmacists

SPECTRUM HEALTH MEDICAL CENTER – DEPARTMENT OF PHARMACY
- Pharmacy Grand Rounds (May 19, May 26, June 2, and June 9, 2020) for pharmacy technicians

Pharmacy General Rules - ORR 2018-039 LR
Public Comment Summary
Rules Committee's Recommendations and Board's Response to October 4, 2019 Public Comments

Testimony/Comments Received:

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

Rule 338.486 "Medical institution" and "pharmacy services" defined; pharmacy services in medical institutions.

Rule Numbers	Commenter	Comment
Section (1)(a)	Eid/Ferris	Add "home of the aged" to the definition of "medical institution" as LARA has a Division of Adult Foster Care and Homes for the Aged. Provides inclusivity.

Section (3)	Baran/Ferris	Delete “inpatients” and replace with “patients of a medical institution” and delete “who is on the premises”. Removing “who is on the premises” does not allow the technicians to remain in the pharmacy working while the pharmacist is at meeting in the hospital or on the floor or etc. This negates the original intent to allow the pharmacist to be in the hospital but not in the pharmacy and let the technicians remain to continue drug preparation for the pharmacist review. This allows the pharmacist of small hospitals to attend meetings and other issues outside of the pharmacy but on the hospital premises. This would enable small hospitals to stay open and serve the public health of the community.
	Sapita/MPA	Do not remove “who is on the premises.”
Rules Committee Response	(1)(a): The Rules Committee does not agree with the comment to add “home of the aged” to the definition of “medical institution,” as the definition includes “health facility,” which under Article 17 of the Public Health Code includes a home for the aged. (3): The Rules Committee agrees with the comments to not remove “who is on the premises.”	

R 338.486 “Medical institution” and “pharmacy services” defined; pharmacy services in medical institutions.

Rule 16. (1) As used in this rule:

(a) "Medical institution" means a hospital, skilled nursing facility, county medical care facility, nursing home, **freestanding surgical outpatient facility, hospice,** or other health facility ~~which~~ **that** is licensed or approved by the state**,** ~~and~~ which directly or indirectly provides or includes pharmacy services.

(b) "Pharmacy services" means the direct and indirect patient care services associated with the practice of pharmacy.

(2) Pharmacy services **in a medical institution must** ~~shall~~ be directed and provided by a licensed pharmacist.

(3) Pharmacy personnel who assist the pharmacist by performing delegated functions in the care of ~~inpatients~~ **patients of a medical institution** shall be supervised by a pharmacist who is on the premises of the medical institution.

(4) The pharmacist who directs the pharmacy services shall develop, implement, supervise, and coordinate ~~all of~~ the services provided, including, at a minimum, all of the following:

(a) Dispensing medications in a form that minimizes additional preparation before administration to the patient, including the admixture of parenterals.

(b) Obtaining the prescriber's original medication order, a direct carbonized copy, an electromechanical facsimile, or other electronic order transmission. Security measures ~~shall~~ **must** be in place to ensure that system access by unauthorized individuals is not allowed.

(c) Interpreting and reviewing the prescriber's medication orders and communicating problems with these orders to the ~~physician or nurse~~ **prescriber** before administration of first doses. If the interpretation and review will cause a medically unacceptable delay, then a limited number of medications may be stocked at the patient care areas for the administration of first doses. ~~These medications~~ **Medications** ~~shall~~ **must** be provided in a manner that ensures security and immediate availability, such as sealed or secured medication kits, carts, or treatment trays. A pharmacist shall routinely inspect the medications and, after use, shall verify the contents and replace the medications as necessary.

(d) **Delegating the stocking of an automated device. Technologies must be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing bar-coding or another board-approved error prevention technology that complies with R 338.3154.**

(e) Monitoring medication therapy to promote positive patient outcomes while evaluating clinically significant chemical and therapeutic incompatibilities.

~~(e)~~ **(f)** Establishing the specifications for the procurement of all pharmaceuticals and related biologicals and chemicals approved for use in the medical institution.

~~(f)~~ **(g)** ~~Not less than once every 6 months, inspecting~~ **Inspecting** all areas in the medical institution where medications are stored to verify compliance with the standards for the safe use and storage of the medications**, not less than once every 6 months**.

~~(g)~~ **(h)** Maintaining proper security for all medications stored or kept within the medical institution.

~~(h)~~ **(i)** Providing educational programs regarding medications and their safe use.

~~(i)~~ **(j)** Providing a method by which medications can be obtained during the absence of a pharmacist in a medical institution where a pharmacist is not available 24 hours a day. The method shall minimize the potential for medication error. During the absence of a pharmacist, the services of a pharmacist ~~shall~~ **must** be available on an on-call basis. Only a limited number of medications that are packaged in units of use ~~shall~~ **must** be available. The medications ~~shall~~ **must** be approved and reviewed periodically as deemed necessary, but not less than once a year, by an appropriate interdisciplinary practitioner committee of the medical institution. The medication ~~shall~~ **must** be kept in a securely locked, substantially constructed cabinet or its equivalent in an area of limited access in a centralized area outside the pharmacy. Each medication ~~shall~~ **must** be labeled to include the name of the medication, the strength, the expiration date, if dated, and the lot number. A written order and a proof of removal and use document ~~shall~~ **must** be obtained for each medication ~~united~~ **unit** removed. The order and document shall be reviewed by the pharmacist within 48 hours of removing medication from the cabinet or its equivalent. The pharmacist who directs pharmacy services in the medical institution shall designate

the practitioners who are permitted to remove the medication. A pharmacist shall audit the storage locations as often as needed to guarantee control, but not less than once every 30 days.

(5) Upon recommendation of an interdisciplinary ~~practitioners~~ **practitioners'** committee, the pharmacist who directs pharmacy services in the medical institution shall adopt written policies and procedures to promote safe medication practices, to conduct medication utilization review, to approve medications for the medical institution's formulary or medication list, and to promote positive patient outcomes. A pharmacist shall meet with the committee at least quarterly to conduct assigned responsibilities.

(6) A pharmacy shall ensure that every medication dispensed is identified with its name and strength labeled on the container in which it is dispensed or on each single unit package. A pharmacy that is engaged in drug distribution to medical institutions which use unit-of-use packaging shall place identification on the label of its package to allow the package to be readily traced. The name of the patient, or a unique identifier, ~~shall~~ **must** be labeled on the medication container. The container may be the individual ~~patients'~~ **patient's** assigned medication drawer. The directions for use ~~shall~~ **must** be on the label of the container if the directions are not communicated in another effective manner. If the medication is to be self-administered, then directions for use ~~shall~~ **must** be on the container. The ~~preceding~~ provisions of this subrule are minimum labeling standards only and do not supersede other applicable laws or rules.

(7) A pharmacist shall ~~personally~~ supervise the destruction of unused portions of prescription medication, other than controlled substances under part 71 of the code, dispensed to patients. However, medications in single-unit packages and intravenous solutions which are designed to be tamper-evident and which show no evidence that tampering has occurred may be returned to stock. Medications that leave the medical institution or its legal affiliates may not be returned to stock for ~~redispensing~~ **dispensing**.

(8) The licensed pharmacist who directs pharmacy services in the medical institution shall make the policies, procedures, and written reports required by this rule available to the board ~~of pharmacy~~, upon request.

Board Response	The Board

Rule 338.501 Definitions.

Rule Numbers	Commenter	Comment
Section (1)(d)	Sullivan/Michigan Surgical Hospital	Requests not adopting USP 797 and 800 and urges the Board to consider having MIOSH adopt USP 800 as an occupational health standard so it can be equally applied to all professions.
Section (1)(j)	Sapita/MPA	"Virtual manufacturer" is not defined in the statute and should be.
Rules Committee Response	(1)(d): This comment is more appropriate for R 338.531 and R 338.533. (1)(j): The Rules Committee made no recommendation on the comment as the comment was withdrawn.	

(d) "Compounding" means the preparation, mixing, assembling, packaging, and labeling of a drug or device by a pharmacist under any of the following circumstances:

(i) Upon the receipt of a prescription for a specific patient.

(ii) Upon the receipt of a medical or dental order from a prescriber or agent for use in the treatment of patients within the course of the prescriber's professional practice.

(iii) In anticipation of the receipt of a prescription or medical or dental order based on routine, regularly observed prescription or medical or dental order patterns.

(iv) For the purpose of or incidental to research, teaching, or chemical analysis and not for the purpose of sale or dispensing.

(e) "Compounding" does not include any of the following:

(i) Except as provided in section 17748c of the code, MCL 333.17748c, the compounding of a drug product that is essentially a copy of a commercially available product.

(ii) The reconstitution, mixing, or other similar act that is performed pursuant to the directions contained in approved labeling provided by the manufacturer of a commercially available product.

(iii) The compounding of allergenic extracts or biologic products.

(iv) Flavoring agents added to conventionally manufactured and commercially available liquid medications. Flavoring agents must be nonallergenic and inert, not exceeding 5% of a drug product's total volume.

(j) "Virtual manufacturer" means a person who engages in the manufacture of prescription drugs or devices and meets all of the following:

(i) Owns either of the following:

(A) The new prescription drug application or abbreviated new prescription drug application number.

(B) The unique device identification number, as available, for a prescription device.

(ii) Contracts with a contract manufacturing organization for the physical manufacture of the drugs or devices.

(iii) Is not involved in the physical manufacture of the drugs or devices.

(iv) At no time takes physical possession of or stores the drugs or devices.

(v) Sells or offers for sale to other persons, for resale, compounding, or dispensing of, drugs or devices, salable on prescription only.

Board Response	The Board

Rule 338.503 Prescription drugs and devices; return or exchange for resale prohibited.

Rule Numbers	Commenter	Comment
Add Section (d)	Baran/Ferris	Add to this rule the return of drugs for a manufacturer recall that is down to the patient level or when the wrong medication was dispensed to the patient. This then would align with 21 CFR part 1317. Add: (d) The provisions of subsection (1) shall not apply to drugs returned when the wrong medication was dispensed to the patient or in the instance of a drug recall. In no instance may returned drugs be reused or returned to active stock. This would encourage the removal of harmful drugs.
Rules Committee Response	The Rules Committee agrees with the comment to add "(d) Drugs returned when the wrong medication was dispensed to the patient or in the instance of a drug recall. In no instance may returned drugs be reused or returned to active stock." The addition of this language will allow the return of drugs in 2 additional circumstances that are not currently in the rules, subject to any controlled substances exceptions or limitations.	

R 338.503 Prescription drugs and devices; return or exchange for resale prohibited.

Rule 3. (1) Prescription drugs or devices that have been dispensed and have left the control of the pharmacist must not be returned or exchanged for resale.

(2) This rule does not apply to any of the following:

(a) A pharmacy operated by the department of corrections or under contract with the department of corrections or a county jail, as provided in section 17766d of the code, MCL 333.17766d.

(b) A pharmacy or charitable clinic that participates in the program for the utilization of unused prescription drugs, as provided in section 17775 of the code, MCL 333.17775.

(c) A pharmacy or health facility that participates in the cancer drug repository program, as provided in section 17780 of the code, MCL 333.17780.

(d) Drugs returned when the wrong medication was dispensed to the patient or in the instance of a drug recall. Subject to R 338.486(7), in no instance may returned drugs be reused or returned to active stock.

Board Response	The Board

Rule 338.505 Inspection of applicants and licensees.

Rule Numbers	Commenter	Comment
R 338.505	Baskerville	This draft rule mentions that the approved entity may enter any facility that is eligible for inspection "at reasonable times". The statement about the time needs to be more specific because "reasonable" is largely open to interpretation. Add 9:00 a.m.-5:00 p.m. after the phrase "reasonable times". It should read "…may enter between the reasonable times of 9:00 a.m. and 5:00 p.m., any building…"
Section (e)	Carlson/MHA	Modify to: (e) Research data. (f) Information gathered by a licensed health facility for quality improvement or professional practice review.
Rules Committee Response	The Rules Committee does not agree with the comment limiting the accessibility for inspections due to safety concerns. (e): The Rules Committee agrees with the comment to add (f) above.	

R 338. 505 Inspection of applicants and licensees.

Rule 5. The board, board inspector, board agent, or approved entity pursuant to R 338.532, may enter at reasonable times, any building, place, or facility that is owned or controlled by any applicant for, or holder of, a license to make an inspection to enable the board to determine if the applicant possesses the qualifications and competence for the license sought or to determine whether a license holder is and has been complying with the code and rules. The inspection must concern only matters relevant to the applicant's or license holder's practice of pharmacy, manufacturing, and wholesale distributing of drugs and devices saleable by prescription only.

(1) The inspection must not extend to any of the following information:

(a) Financial data.

(b) Sales data other than shipment data.

(c) Pricing data.

(d) Personnel data other than data as to the qualifications of personnel performing functions subject to the acts and rules enforced by the board.

(e) Research data.

(f) Information gathered by a licensed health facility for quality improvement or professional practice review.

(2) An applicant or license holder shall permit and cooperate with the inspection.

Board Response	The Board

Rule 338.511 Training standards for identifying victims of human trafficking; requirements.

Rule Numbers	Commenter	Comment
	Eid/Ferris	It is not clear if this training is required for a limited license, see R 338.513.
Section (3)	Sapita/MPA	Rule not consistent with CE rules – consider same verbiage.
Rules Committee Response	The Rules Committee agrees with the comment to clarify that a limited licensee must meet the human trafficking training requirement. No change to this rule is necessary. A reference to R 338.511, which requires the training, is recommended in R 338.513. (3): The rules committee agrees with the comment that the dates in this rule and the dates in the pharmacist CE rules must be consistent. No change to this rule is necessary.	

R 338.511 Training standards for identifying victims of human trafficking; requirements.

Rule 11. (1) Pursuant to section 16148 of the code, MCL 333.16148, an individual seeking licensure or who is licensed shall complete training in identifying victims of human trafficking that meets the following standards:

(a) Training content must cover 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 reviewed 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 must 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 apply for license renewals beginning in January 1, 2020 and for initial licenses issued after November 13, 2022.

Board Response	The Board

Rule 338.513 Educational limited license; application and renewal; practices.

Rule Numbers	Commenter	Comment
Section (1)(a)	Sapita/MPA	Remove "90 days" and replace with "180 days."
Section (2)(a)	Baskerville	The rule only allows renewal of a limited education license within 90 days after graduating from an approved educational program. Ninety days is not enough time because if a graduate does not pass the NAPLEX, they must wait 45 days to take the exam again. The window is tight, and it should be longer to accommodate more graduates. Modify 1a and 2a to 180 days instead of 90 days.
Section (3)	Sapita/MPA	Replace with "An educational limited licensee must engage in the practice of pharmacy under the supervision of a pharmacist preceptor as defined in section 17708(1) of the code and only under the personal charge of a pharmacist."

Section (4)	Roath/SpartanNash	In the context of the Proposed Rule 13, this subrule seems to require that an educational limited licensee (pharmacy intern) only practice under the direct personal supervision of a pharmacist licensed as a preceptor. Previously, this requirement only extended to pharmacy interns working towards the intern hours required to obtain their full pharmacist license. The language, as proposed, would create a barrier for pharmacy interns seeking to gain additional experience through paid internships aside from what is required by their academic programs. Also, this seems to conflict with Rule 15 (3) which creates provisions for a pharmacy intern to submit hours that were *not* conducted under the personal charge of a preceptor licensed in the state. As such, we recommend that Rule 13, Subrule (4) be removed from the rules as proposed.
Add Section (6)	Baran/Ferris Eid/Ferris	Need to add the human trafficking requirement. Add: (6) Applicants need to complete the training in human trafficking for licenses issued after November 13, 2022 as required in Rule 338.511. CE requirements do not apply for student pharmacists or interns. It is not clear whether the human trafficking training is required.
Rules Committee Response	(1)(a) and (2)(a): The Rules Committee agrees with the comment to replace "90 days" with "180 days." (3)(4): The Rules Committee agrees with the comments that the rules should be clarified to indicate that a licensee may engage in the practice of pharmacy only under the personal charge of a pharmacist. However, if the licensee wants to count the hours towards the required internship they must also be acting under a preceptor. The Rules Committee does not agree with the proposed language in either comment to (3) or (4) above. (6): The Rules Committee agrees with the comment to add the requirement of the human trafficking training.	

R 338.513 Educational limited license; application and renewal; practices.

Rule 13. (1) An applicant for an educational limited license shall submit to the department a completed application on a form provided by the department with the requisite fee. In addition to satisfying the requirements of sections 16174 and 17737 of the code, MCL 333.16174 and MCL 333.17737, the applicant shall establish either of the following:

(a) That he or she is actively enrolled in, or is within 180 days of having graduated from, an approved educational program.

(b) That he or she has successfully passed the foreign pharmacy graduate equivalency examination administered by the national association of boards of pharmacy (NABP) Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr., Mount Prospect, IL 60056, https://nabp.pharmacy/programs/fpgec/ **.**

(2) The educational limited license must be renewed annually.

(a) At the time of renewal, the applicant shall submit verification to the department that he or she is actively enrolled in, or is within 180 days of having graduated from, an approved educational program. The educational limited license is valid for 1 year.

(b) If an applicant is a graduate of a non-accredited college or school of pharmacy at the time of renewal, the applicant shall submit verification to the department from his or her preceptor that the applicant is currently in an internship program under the preceptor's supervision. The educational limited license is valid for 1 year and may be renewed 1 time.

(3) An educational limited licensee may engage in the practice of pharmacy only under the personal charge of a pharmacist.

(4) An educational limited licensee shall verify that his or her pharmacy preceptor holds a valid preceptor license prior to engaging in the practice of pharmacy if the internship hours will be submitted to the department for credit.

(5) An educational limited licensee shall notify the board within 30 days if he or she is no longer actively enrolled in an approved educational program.

(6) An applicant for an educational limited license shall meet the requirements of R 338.511.

Board Response	The Board

Rule 338.515 Internship requirements.

Rule Numbers	Commenter	Comment
Section (c)	Carlson/MHA	In the section for "Internship requirements," we trust the Board will carefully review and consider who it will allow to verify hours. We understand allowing more than a licensed pharmacy preceptor or approved education program for future flexibility but currently, the MHA does not see a category of "others" who are qualified to do this.
	Sapita/MPA	Remove "or other person previously approved by the board."
Section (3)	Sapita/MPA	Remove "personal charge" replace with "supervision of."
Rules Committee Response	The Rules Committee does not agree to delete the reference to "other person" and the comment is withdrawn. As a change is being made to R 338.513 the comment to (3) is withdrawn.	

R 338.515 Internship requirements.

Rule 15. (1) An internship must be a minimum of 1,600 hours.

(a) Not more than 40 hours per week may be earned.

(b) An unconventional internship requires prior board approval and is limited to a maximum of 400 hours, with a maximum of 16 hours earned per week, and not more than 40 hours earned per week when the intern's pharmacy school is not in session. "Unconventional internship" means an educational program of professional and practical experience involving the pharmacy or related pharmaceutical experiences which, through on-the-job training, provides knowledge useful to the practice of the profession of pharmacy.

(c) The preceptor, an approved education program, or other person previously approved by the board shall verify the hours.

(2) The internship must provide professional and practical experience.

(3) If an internship is not completed through an approved educational program or under the personal charge of a preceptor, the individual shall petition the board for approval of hours.

(4) An individual shall obtain an educational limited license pursuant to R 338.513 before starting an internship that includes the practice of pharmacy in this state.

Board Response	The Board

Rule 338.519 Examinations adoption; passing scores; reexamination.

Rule Numbers	Commenter	Comment
Section (4)	Sapita/MPA	After "examinations" add "within 3 attempts" after "after" add "the third."
Section (4) – (6)	Baran/Ferris	Modify (4). This section should be deleted as even the NABP allow for 5 attempts before any remediation is needed. This would be very costly and increase the pressure on passing this exam. No other health profession has this strict requirement. Also, none of the Great Lakes States have this strict requirement. One allows 2 failures, 2 allow 3 failures and the others follow the NABP. Suggest adding back language that would allow 5 attempts, suggested language: (4) An applicant who has not received a passing score on the NAPLEX and or MPJE examinations after 5 attempts shall provide certification from an approved education program certifying that he or she satisfactorily completed courses that provide a thorough review of the area or areas that he or she failed in the most recent examination. To be able to mandate this NABP has to provide to the applicant the areas they failed in, which I believe is not done currently.
Add to Section (4)	Daman/Ferris	Modify after (4) as follows: (5) An applicant who has not received a passing score on an examination that measures his or her

		theoretical and practical knowledge of pharmacy after 5 attempts shall not take the examination a sixth or subsequent time, unless the applicant can demonstrate to the board that he or she has complied with all of the following: (a) Enrolled as a student in a pharmacy education program approved by the board. (b) Taken courses which would provide a thorough review of those areas failed on the applicant's most recent examination. (c) Submitted certification to the board from the pharmacy education institution that the courses have been satisfactorily completed. (6) An applicant who fails to pass the NAPLEX shall wait at least 45 days to retest or comply with the current waiting period established by NABP, whichever is later. An applicant who has not achieved a passing score on the NAPLEX shall not take the NAPLEX more than 2 times in a 12-month period. (7) An applicant who fails to pass the MPJE shall wait at least 30 days to retest or comply with the current waiting period established by NABP, whichever is later. (8) An applicant shall not sit for either exam specified in subrule (5) or (6) of this rule more than 5 times, unless he or she successfully repeats an approved education program, as specified in R 338.521(2)(a)(i), or successfully repeats the foreign pharmacy graduate equivalency examination committee certification program administered by the NABP, and provides proof of completion to the board.
Section (4)	Carlson/MHA	Under the "Practice of Pharmacy" Section, the new North American Pharmacist Licensure Examination (NAPLEX) and Michigan Multistate Pharmacy Jurisprudence Examination (MPJE) passing requirements raised some apprehension among hospital membership. While we respect the proposal to safeguard competent pharmacists to enter the workforce, the MHA wants to ensure qualified candidates are not inadvertently vetted out. Other variables, including education, prior employment, internships, residencies and skills which are valuable to hospitals are not defined by exams alone. Additionally, one day of poor performance during a test can happen, and students deserve another try before they are required to provide satisfactorily completed courses information to the Board. Modify to: (4) If an applicant for licensure fails to pass either of these examinations within 3 attempts, he or

		she shall provide the board, after the third failed attempt and prior to retesting, certification from an approved education program certifying that he or she satisfactorily completed courses that provide a thorough review of the area or areas that he or she failed in the most recent examination. This is more reasonable than after each failed exam and also aligns with the "3exam 12-month" cap outlined in (5).
Section (4)	Eid/Ferris and Osborne/Ferris	Keep as written in R 338.474a (1-3) or remove (4) in the proposed rule. National pass rates in 2018 for NAPLEX were 89.4% for first time attempts and the Michigan rate was 92.59% and the National pass rates for the MPJE for 2018 were 83.76% for first time attempts and the Michigan rate was 92%. This change seems unnecessary. This potentially places a financial burden on a sizable portion of student pharmacists. Ohio, Indiana does not have this requirement and Illinois allows for three attempts before requiring remedial education. There is no sound evident that adding this educational requirement after each failure will improve passing rates. Osborne suggested this language: R 338.519 Examinations adoption; passing scores; reexamination. Rule 19. (1) The board adopts the North American pharmacist licensure examination (NAPLEX) developed and administered by the NABP. (2) The board adopts the Michigan multistate pharmacy jurisprudence examination (MPJE) that is developed and administered by NABP. (3) The passing score for the NAPLEX or the MPJE accepted for licensure will be the passing score established by the NABP. ~~(4) If an applicant for licensure fails to pass either of these examinations, he or she shall provide the board, after each failed attempt and prior to retesting, certification from an approved education program certifying that he or she satisfactorily completed courses that provide a thorough review of the area or areas that he or she failed in the most recent examination.~~ **(4) An applicant who has not received a passing score on an examination that measures his or her theoretical and practical knowledge of pharmacy after 5 attempts shall not take the examination a sixth or subsequent time, unless the applicant can demonstrate to the board that he or she has complied with all of the following:** **(a) Enrolled as a student in a pharmacy education program approved by the board.**

		(b) Taken courses which would provide a thorough review of those areas failed on the applicant's most recent examination. **(c) Submitted certification to the board from the pharmacy education institution that the courses have been satisfactorily completed.** (5) An applicant who fails to pass the NAPLEX shall wait at least 45 days to retest or comply with the current waiting period established by NABP, whichever is later. An applicant who has not achieved a passing score on the NAPLEX shall not take the NAPLEX more than 3 times in a 12-month period. (6) An applicant who fails to pass the MPJE shall wait at least 30 days to retest or comply with the current waiting period established by NABP, whichever is later. (7) An applicant shall not sit for either exam specified in subrule (5) or (6) of this rule more than 5 times, unless he or she successfully repeats an approved education program, as specified in R 338.521(2)(a)(i), or successfully repeats the foreign pharmacy graduate equivalency examination committee certification program administered by the NABP, and provides proof of completion to the board.
Section (7)	Baran/Ferris	This section as currently written would require the applicant to completely redo the pharmacy degree and not just the sections they failed. Yet a foreign graduate would not have to do so.
Rules Committee Response	The Rules Committee agrees with the comment to: • Modify (4) to "within 3 attempts" not 1 attempt. • Modify (7) to require an applicant to take a pharmacy law course in an educational program or redo the program depending on which examination they have failed 5 times. • Delete the reference to the foreign pharmacy graduate equivalency examination certification program as a foreign graduate should be held to the same standard if they are failing the examinations. The Rules Committee disagree with the other comments as too restrictive.	

R 338.519 Examinations adoption; passing scores; reexamination.

Rule 19. (1) The board adopts the North American pharmacist licensure examination (NAPLEX) developed and administered by the NABP.

(2) The board adopts the Michigan multistate pharmacy jurisprudence examination (MPJE) that is developed and administered by NABP.

(3) The passing score for the NAPLEX or the MPJE accepted for licensure will be the passing score established by the NABP.

(4) If an applicant for licensure fails to pass either of these examinations, within 3 attempts, he or she shall provide the board, after ~~each failed~~ the third attempt and prior to retesting, certification from an approved education program certifying that he or she satisfactorily completed courses that provide a thorough review of the area or areas that he or she failed in the most recent examination.

(5) An applicant who fails to pass the NAPLEX shall wait at least 45 days to retest or comply with the current waiting period established by NABP, whichever is later. An applicant who has not achieved a passing score on the NAPLEX shall not take the NAPLEX more than 3 times in a 12-month period.

(6) An applicant who fails to pass the MPJE shall wait at least 30 days to retest or comply with the current waiting period established by NABP, whichever is later.

(7) An applicant shall not sit for ~~either~~ the NAPLEX ~~exam~~ specified in subrule (5) ~~or (6)~~ of this rule more than 5 times, unless he or she successfully repeats an approved education program, as specified in R 338.521(2)(a)(i), ~~or successfully repeats the foreign pharmacy graduate equivalency examination committee certification program administered by the NABP,~~ and provides proof of completion to the board.

(8) An applicant shall not sit for the MPJE specified in subrule (6) of this rule more than 5 times, unless he or she successfully repeats an approved pharmacy law course in an educational program, as specified in R 338.521(2)(a)(i), and provides proof of completion to the board.

Board Response	The Board

Rule 338.521 Pharmacist licensure by examination.

Rule Numbers	Commenter	Comment
Section (2)(i)	Carlson/MHA	Under the "Pharmacist licensure by examination" section, it is important to note that Canadian Council for Accreditation of Pharmacy Programs uses different criteria than the Accreditation Council for Pharmacy Education. Modify to: A professional degree from a school of pharmacy accredited by the Accreditation Council for Pharmacy Education or the Canadian council for accreditation of pharmacy programs.
	Sapita/MPA	Remove "Canadian council for accreditation of pharmacy programs." The Canadian

		Healthcare System is significantly different than that of the United States and should be removed from the rules.
Rules Committee Response	(2)(i): The Rules Committee agrees with the comment to delete the reference to the Canadian Council for Accreditation of Pharmacy Programs as it is not equivalent to ACPE.	

R 338.521 Pharmacist licensure by examination.

Rule 21. (1) An applicant for licensure as a pharmacist by examination shall submit to the department a completed application on a form provided by the department with the requisite fee.

(2) In addition to meeting the requirements of section 16174 of the code, MCL 333.16174, an applicant for licensure shall satisfy all of the following requirements:

(a) Earned either of the following:

(i) A professional degree from a school of pharmacy accredited by the American council of pharmaceutical education ~~or the Canadian council for accreditation of pharmacy programs~~.

(ii) A foreign pharmacy graduate examination committee certificate administered by the NABP.

(b) Successfully passed the MPJE and the NAPLEX.

(c) Completed an internship as set forth in R 338.515.

(3) An applicant's license shall be verified by the licensing agency of any state of the United States in which the applicant holds or has ever held a license to practice pharmacy. This includes, but is not limited to, showing proof of any disciplinary action taken or pending against the applicant.

Board Response	The Board

Rule 338.523 Pharmacist license by endorsement; requirements.

Rule Numbers	Commenter	Comment
Add	Watson/NABP	Mirror the license by exam rules to require the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) under the License by Endorsement as follows: That he or she has successfully passed the foreign pharmacy graduate equivalency examination administered by the national association of boards of pharmacy (NABP) Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr., Mount Prospect, IL 60056, https://nabp.pharmacy/programs/fpgec/ .

		AND: A foreign pharmacy graduate examination committee certificate administered by the NABP.
Rules Committee Response	The Rules Committee agrees with the suggested change to require passing the examination and meet the FPGEC requirements.	

R 338.523 Pharmacist license by endorsement; requirements.

Rule 23. (1) An applicant for licensure as a pharmacist by endorsement shall submit to the department a completed application on a form provided by the department 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) An applicant shall satisfy all of the following requirements:

(a) Establish that the he or she is currently licensed in another state and was initially licensed by examination in another state or he or she successfully passed the foreign pharmacy graduate examination administered by NABP and he or she has obtained a foreign pharmacy graduate examination committee certificate administered by the NABP.

(b) Pass the MPJE as required under R 338.519.

(c) Have his or her license verified by the licensing agency of any state of the United States in which the applicant holds or has ever held a license to practice pharmacy. This includes, but is not limited to, showing proof of any disciplinary action taken or pending against the applicant.

(d) Submit the MPJE examination score report and NABP licensure transfer report to the department.

Board Response	The Board

Rule 338.525 Relicensure of a pharmacist license; requirements.

Rule Numbers	Commenter	Comment
	Eid/Ferris	Questions what happens to applications when the new CE requirements become effective and shouldn't the one-time trainings be required for relicensure?
Section (1)(f) and (g)	Sapita/MPA	Remove "or outside of Michigan."
Rules Committee Response	The Rules Committee agrees with the comment to clarify that relicensure will not be granted until the continuing education requirements are met, and that to meet relicensure an applicant must meet the one-time training requirements. (1)(f) and (g): The comment to remove " or outside of Michigan" is withdrawn.	

R 338.525 Relicensure of a pharmacist license; requirements.

Rule 25. (1) An applicant for relicensure whose pharmacist license has lapsed, under the provisions of sections 16201(3) or (4), and 17733 of the code, MCL 333.16201(3), MCL 333.16201(4), and MCL 333.17733, as applicable, may be relicensed by complying with the following requirements as noted by (x):

(1) For a pharmacist who has let his or her license lapse and who is not currently licensed in another state:	License lapsed 0-3 years	License lapsed more than 3 years, but less than 8 years	License lapsed 8 or more years
(a) Application and fee: submit to the department a completed application on a form provided by the department, with the requisite fee.	X	X	X
(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 MCL 338.47.	X	X	X
(c) Submit fingerprints: submit fingerprints as required under section 16174(3) of the code, MCL 333.16174(3).		X	X
(d) Continuing education: submit proof of having completed 30 hours of continuing education that satisfy R 338.3041 to R 338.3045 in the 2 years immediately preceding the date of application for relicensure. However, if the continuing education hours submitted with the application are	X	X	X

deficient, the applicant has 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) Pass MPJE: retake and pass the MPJE as provided in R 338.519.		**X**	**X**
(f) Practical experience: complete 200 hours of practical experience under the personal charge of a currently licensed Michigan pharmacist in or outside of Michigan, within 6 months of applying for relicensure.		**X**	
(g) Practical experience: complete 400 hours of practical experience under the personal charge of a currently licensed Michigan pharmacist in or outside of Michigan, within 6 months of applying for relicensure.			**X**
(h) Examination: pass the NAPLEX within 2 years before applying for relicensure, as provided in R 338.519.			**X**
(i) Verification: submit verification from the licensing agency of all other states of the United States in which the applicant has ever held a license to practice pharmacy. Verification must include the record of any disciplinary action taken or pending against the	**X**	**X**	**X**

applicant.			

(2) For purposes of subrule (1)(f) and (g) of this rule, an applicant may be granted a nonrenewable limited license to complete the practical experience.

(3) To demonstrate compliance with subrule (1)(f) or (g), the supervising pharmacist shall provide verification to the department of the applicant's completion of the experience on a form provided by the department.

(4) For a pharmacist who has let his or her pharmacist license lapse, but who holds a current and valid pharmacist license in another state:	**License lapsed 0-3 Years**	**License lapsed more than 3 years, but less than 8 years**	**License lapsed 8 or more years**
(a) Application and fee: submit to the department a completed application on a form provided by the department, with the requisite fee.	**X**	**X**	**X**
(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 MCL 338.47.	**X**	**X**	**X**
(c) Submit fingerprints: submit fingerprints as required under section 16174(3) of the code, MCL 333.16174(3).		**X**	**X**
(d) Continuing education: submit proof of having completed 30 hours of continuing education that satisfy R 338.3041 to R 338.3045 in the 2 years immediately preceding the date of application for relicensure. However, if the continuing education hours submitted with the application are deficient, the applicant has 2 years from the date of the application to complete the deficient hours.	**X**	**X**	**X**

The application will be held and the license will not be issued until the continuing education requirements have been met.			
(e) Examination: retake and pass the MPJE as provided in R 338.519.		**X**	**X**
(e) Verification: submit verification from the licensing agency of all other states of the United States in which the applicant holds or has ever held a license to practice pharmacy. Verification must include the record of any disciplinary action taken or pending against the applicant.	**X**	**X**	**X**

Board Response	The Board

Rule 338.531 Pharmacy license; applications; requirements.

Rule Numbers	Commenter	Comment
	Eid/Ferris	Should there be a provision regarding the result when a pharmacist passes away. What happens to the pharmacy license? How often must an inspection be submitted? Are the details of the inspection required to be shared with the state? Is a pharmacy license renewal the same process as the initial process?
	Milenkovich/Much Shelist	USP has indicated they intend to classify all flavorings of conventionally manufactured medications as nonsterile compounding. Fourteen state boards of pharmacy have language on their books excluding flavoring from the definition of compounding. The request is to implement a regulation excepting the safe administration of flavorings added to conventionally manufactured medications from the definition of compounding. The Board can achieve this by narrowing the use of flavoring agents to conventionally manufactured and commercially available liquid medications and by setting conditions to ensure safe administration of flavorings (ie favoring agents must be nonallergenic and inert, not exceeding 5% of a drug product's total volume).

Section (3)	Baran/Ferris Sapita/MPA	This should be modified to: (3) The department shall issue only 1 pharmacy license per address. If an applicant has more than 1 location at which drugs are prepared, or dispensed, or prescriptions received, each address location shall obtain a separate license. This is to align with MCL 333.17722 and also require any location where prescriptions are dropped off for filling would need to be licensed. MPA recommends the language mirrors R 338.477 "If multiple locations under the same ownership exist at a single street address and share a central inventory, then only 1 license is required."
Section (4)	Baran/Ferris Kuhns/Portage Pharmacy Roath/SpartanNash	Add USP Chapter 797 to this to make it consistent with Rule 338.533(1). Delete "and 800". The adoption of these reference standards in conjunction with the clause in (4)(b) seems to imply that the standards are only applicable to pharmacies providing compounding services, though this is not explicit. Additionally, some of the guidance in the standards extend to practices beyond compounding and it is unclear as to whether pharmacies operating under the purview of these standards would be required to comply with the full reference standard, or just the areas that apply to compounding practices. Additionally, recent comments at the NABP Annual meeting by a USP representative suggest that the USP's intent regarding general chapter 800 indicate that this guidance was intended to apply to compounding activities only. To provide additional clarification, we recommend that Rule 31, Subrule (4)(b) be modified to read: "A pharmacy that provides compounding services shall comply with all standards adopted in subrule (4) of this rule as they apply to compounding services as defined in Michigan law."
Rules Committee Response	The Rules Committee does not agree with the comment to add a rule regarding the death of a PIC as there is already a rule regarding changes to a PIC. The Rules Committee does not agree with adding a time on inspections as this rule is regarding initial licensure not renewal. The rules committee agrees with the comment to exclude flavoring as an exception to the compounding rule as long as there is no other product manipulation. (3): The Rules Committee does not agree with the suggested comments and more discussion is needed.	

	(4): The Rules Committee members are split regarding the comment to delete USP 800 from the rule until it is published in the compendium. The Rules Committee members are split regarding whether to specifically refer to the USP chapters 795, 797, and 825 throughout the rules. The consensus is to continue discussion with the full Board. The Rules Committee suggested referencing the statutory requirement of complying with USP. The Rules Committee does not agree with modifying the rules to clarify that USP 800 applies to pharmacies that do not handle compounding or other entities such as offices and clinics.

R 338.531 Pharmacy license; applications; requirements.

Rule 31. (1) An applicant for a pharmacy license shall submit to the department a completed application on a form provided by the department together with the requisite fee.

(2) An applicant shall submit all of the following information:

(a) Certified copies of articles of incorporation or partnership certificates and certified copies of assumed name certificates, if applicable.

(b) Submission of fingerprints for the purpose of a criminal history background check required under section 17748(6) of the code, MCL 333.17748(6).

(c) Proof of registration or licensure from every state or province where the pharmacy is currently licensed or has ever held a license or registration.

(d) The name and license number of the pharmacist in this state designated as the pharmacist in charge (PIC) pursuant to section 17748(2) of the code, MCL 333.17748(2), who must have a valid and unrestricted license.

(e) The identity and address of each partner, officer, or owner, as applicable.

(f) A completed self-inspection form.

(g) If the applicant intends to provide sterile compounding services, proof of application with an entity that satisfies the requirements of R 338.532.

(h) An inspection report that satisfies the requirements of R 338.534.

(i) If the applicant is an in-state pharmacy that intends to compound sterile pharmaceutical products, the applicant shall submit to an inspection from an approved accrediting organization under R 338.532.

(j) If the applicant is a governmental entity, an individual must be designated as the licensee. The licensee and the pharmacist on duty shall be responsible for complying with all federal and state laws regulating the practice of pharmacy and the dispensing of prescription drugs.

(3) The department shall issue only 1 pharmacy license per address. If an applicant has more than 1 location at which drugs are prepared or dispensed, each address location shall obtain a separate license.

(4) The board approves and adopts by reference the compounding standards of the United States Pharmacopeia (USP), published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, MD 20852-1790. This includes, but is not limited to, USP Chapters 795 and 800.

(a) The standards adopted by reference in subrule (4) of this rule are available at cost at http://www.usp.org/compounding, or at cost **from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, MI 48909.**

(b) A pharmacy that provides compounding services shall comply with all standards adopted in subrule (4) of this rule.

Board Response	The Board

Rule 338.532 Sterile compounding accrediting organizations; board approval; inspection entities.

Rule Numbers	Commenter	Comment
	Eid/Ferris	Should there be a provision regarding the result when a pharmacist passes away. What happens to the pharmacy license? How often must an inspection be submitted? Are the details of the inspection required to be shared with the state? Is a pharmacy license renewal the same process as the initial process?
Section (1)	Kuhns/Portage Pharmacy	Modify as follows: (1) The board shall approve, under section 17748~~a~~ of the code, MCL 333.17748~~a~~, accrediting or inspection organizations ~~or inspection entities~~ for ~~pharmacies~~ entities that compound ~~sterile~~ pharmaceuticals according to standards adopted by reference in R 338.533. Add: (1)(a)"Entities" means pharmacies, physician private offices, dental private offices, podiatric private offices, veterinarian private offices, infusion centers, surgical outpatient facilities, hospitals, health facilities, and outsourcing facilities.
Rules Committee	(1): The Rules Committee does not agree with the suggested change to (1), as this would require a change to the Public	

Response	Health Code. The Rules Committee agrees with the comment that the results of pharmacy inspections should be required to be shared with the Department. The Rules Committee does not agree with the comment that the rule should include a set expiration date of a certain amount of years for accreditation approvals. The inspection entity should submit the length of their accreditation approval with their application for approval as an approval entity.

R 338.532 ~~Sterile~~ ~~compounding~~ Compounding accrediting organizations; board approval; inspection entities.

Rule 32. (1) The board shall approve, under section 17748a of the code, MCL 333.17748a, accrediting organizations or inspection entities for pharmacies that compound ~~sterile~~ pharmaceuticals according to standards adopted by reference in R 338.533.

(2) The department shall post on its website, the list of organizations approved under subrule (1) of this rule.

(3) An organization may petition the board for approval under subrule (1) of this rule. The petition must include, but not be limited to, all of the following:

(a) Requirements for accreditation or compliance.

(b) Requirements for inspectors.

(c) Training provided to inspectors.

(d) Copy of the most current inspection form.

(e) The length of accreditation.

(f) Agreement and plan to share results of inspections with the Department.

(4) If the board approves the petition, the approval is valid for 3 years from the date of approval. The organization may submit a petition that complies with subrule (3) of this rule to seek continuing approval.

(5) The board may rescind approval of an organization upon just cause. The rescission will not immediately affect the compliance of a pharmacy using the accreditation. Within 12 months of the rescission date or by the next licensure renewal date, whichever is later, the accreditation is void, and a pharmacy shall obtain accreditation or an inspection from an organization that satisfies subrule (1) of this rule.

Board Response	The Board

Rule 338.533 Sterile compounding standards and requirements; outsourcing facilities; requirements.

Rule Numbers	Commenter	Comment
	Popyk/Health Dimensions	Delete adoption of USP 795, 797, and 800.
Section (1) – (10)	Kuhns/Portage Pharmacy	Modify as follows: R 338.533 ~~Sterile~~ Compounding standards and requirements; ~~outsourcing facilities; requirements~~. Rule 33. (1) The board approves and adopts by reference the compounding standards of the United States Pharmacopeia (USP) Chapters 795 and 797., published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, MD 20852-1790. ~~This includes, but is not limited to, USP Chapters 795, 797, and 800.~~ **(2)** The board approves and adopts by reference the compounding standards of the United States Pharmacopeia (USP) Chapter 800 for entities engaged in compounding, preparing, or otherwise manipulating antineoplastic drugs. **(a)** "Entities" means pharmacies, physician private offices, dental private offices, podiatric private offices, veterinarian private offices, infusion centers, surgical outpatient facilities, hospitals, health facilities, and outsourcing facilities. **(b)** "Antineoplastic drugs" means substances identified as antineoplastic drugs by the National Institute of Occupational Safety and Health (NIOSH). **(3)** The standards adopted by reference in subrule (1) and (2) of this rule are available at cost at http://www.usp.org/compounding, or at cost from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, MI 48909. **(4)** A pharmacy, physician private office, dental private office, podiatric private office, veterinarian private office, infusion center, surgical outpatient facility, hospital, health facility, or outsourcing facility that provides ~~sterile~~ compounding services shall comply with all current standards adopted in subrule (1) and (2) of this rule. **(5)** An outsourcing facility located in this state or that dispenses, provides, distributes, or otherwise furnishes ~~sterile~~ compounded pharmaceuticals in this

		state ~~must~~ shall be inspected and registered as an outsourcing facility by the United States Food and Drug Administration (FDA) prior to applying for a pharmacy license in this state. **(6)** ~~An outsourcing facility must undergo an inspection by the board, or a third party recognized by the board if the outsourcing facility is registered with the FDA but has not received an FDA inspection as an outsourcing facility. Third party inspection providers approved by the board must be posted on the department's website~~. **(7)** A licensed outsourcing facility shall submit to the board a copy of the biannual report it provided to the FDA that identifies the drugs compounded in the previous 6-month period, including a drug's active ingredients, strength, and dosage form. **(8)** An outsourcing facility shall do all of the following: **(a)** Compound drugs by or under the supervision of a licensed pharmacist. **(b)** Compound drugs pursuant to current good manufacturing practices for finished pharmaceuticals set forth in 21 C.F.R. sections 211.1 to 211.208 (1978). **(c)** Ensure that a pharmacist or pharmacists who conducts or oversees ~~sterile~~ compounding at an outsourcing facility is proficient in the practice of ~~sterile~~ compounding and has acquired the education, training, and experience to maintain that proficiency by doing any of the following: **(i)** Participating in seminars. **(ii)** Studying appropriate literature. **(iii)** Consulting with colleagues. **(iv)** Being certified by a compounding certification program approved by the board. **(d)** Label compounded drugs with all of the following: **(i)** Required drug and ingredient information. **(ii)** Facility identification. **(iii)** The following or similar statement: "This is a compounded drug. For office use only" or "Not for resale." **(e)** Ensure that bulk drug substances used for ~~sterile~~ compounding meet specified FDA criteria. **(9)** An outsourcing facility may compound drugs that appear on an FDA shortage list, if

		the bulk drug substances used to compound the drugs comply with the criteria specified in this rule. **(10)** An outsourcing facility may compound drugs using bulk drug substances that appear on a list established by the Secretary identifying bulk drug substances for which there is a clinical need. The term "Secretary" means the Secretary of Health and Human Services of the United States.
Section (7)(c)(iv)	Clark/bps	Bps encourages the BOP to recognize bps Board Certification in Compounded Sterile Preparations as meeting the standards in (c)(iv) as " a compounding certification program approved by the board."
Section (7)(d)(i), (ii), and (iii)	Baran/Ferris	Modify to: "(d) label compounded drugs in compliance with the Federal Food, Drug, and Cosmetic Act 503B(10) and rule 338.582." The label must include the requirements of both the state and federal law. This would be easier to quote the federal law at **(7)(d)** instead of listing all of the following. "`(10) Labeling of drugs.-- ``(A) Label.--The label of the drug includes-- ``(i) the statement `This is a compounded drug.' or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug; ``(ii) the name, address, and phone number of the applicable outsourcing facility; and ``(iii) with respect to the drug-- ``(I) the lot or batch number; ``(II) the established name of the drug; ``(III) the dosage form and strength; ``(IV) the statement of quantity or volume, as appropriate;

		``(V) the date that the drug was compounded; ``(VI) the expiration date; ``(VII) storage and handling instructions; ``(VIII) the National Drug Code number, if available; ``(IX) the statement `Not for resale', and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement `Office Use Only'; and ``(X) subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient." Also, the label needs to meet the requirements in Rule 338.582, and it would be easier to state the rule number and not all the details in the rule.
Section (7)(a)	Carlson/MHA	"Supervision" is not defined in the Code or the rules. The Code and rules generally use "personal charge" in reference to needing the immediate presence of a pharmacist. Modify supervision to personal charge.
Rules Committee Response	Kuhn: The Rules Committee agrees with the comment to delete the term "sterile" from R 338.532 and R 338.533. 7(c)(iv): The Rules Committee does not agree with listing entities that provide accreditation. (5): The Rules Committee is split on whether to limit inspections to the FDA for outsourcing facilities that deal with compounded pharmaceuticals in Michigan. Kuhn: The Rules Committee recommends with the comment to add the language in (10) if the language is consistent with Federal law and is not already in the definition. 7(d)(i), (ii), and (iii): The Rules Committee recommends adding the specific language for clarity, and also reference R 338.582 for patient specific drugs. (7)(a): The Rules Committee does not agree with changing supervision to personal charge. The pharmacist must be on site. The Rules Committee does not agree with modifying the rules to clarify that USP applies to entities other than	

	pharmacies, including private physician offices, dental offices, podiatric offices, veterinarian offices, infusion centers, surgical outpatient facilities, hospitals, and health facilities.

R 338.533 ~~Sterile~~ ~~compounding~~ Compounding standards and requirements; outsourcing facilities; requirements.

Rule 33. (1) The board approves and adopts by reference the compounding standards of the United States Pharmacopeia (USP), published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, MD 20852-1790. This includes, but is not limited to, USP Chapters 795, 797, and 800.

(2) The standards adopted by reference in subrule (1) of this rule are available at cost at http://www.usp.org/compounding, or at cost **from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, MI 48909.**

(3) A pharmacy that provides ~~sterile~~ compounding services shall comply with all current standards adopted in subrule (1) of this rule.

(4) An outsourcing facility located in this state or that dispenses, provides, distributes, or otherwise furnishes ~~sterile~~ compounded pharmaceuticals in this state shall be inspected and registered as an outsourcing facility by the United States Food and Drug Administration (FDA) prior to applying for a pharmacy license in this state.

~~(5) An outsourcing facility must undergo an inspection by the board or a third party recognized by the board if the outsourcing facility is registered with the FDA but has not received an FDA inspection as an outsourcing facility. Third party inspection providers approved by the board must be posted on the department's website.~~

(6) A licensed outsourcing facility shall submit to the board a copy of the biannual report it provided to the FDA that identifies the drugs compounded in the previous 6-month period, including a drug's active ingredients, strength, and dosage form.

(7) An outsourcing facility shall do all of the following:

(a) Compound drugs by or under the supervision of a licensed pharmacist.

(b) Compound drugs pursuant to current good manufacturing practices for finished pharmaceuticals set forth in 21 C.F.R. sections 211.1 to 211.208 (1978).

(c) Ensure that a pharmacist or pharmacists who conducts or oversees ~~sterile~~ compounding at an outsourcing facility is proficient in the practice of ~~sterile~~ compounding and has acquired the education, training, and experience to maintain that proficiency by doing any of the following:

(i) Participating in seminars.

(ii) Studying appropriate literature.

(iii) Consulting with colleagues.

(iv) Being certified by a compounding certification program approved by the board.
(d) Label compounded drugs with all of the following and label compounded drugs that are patient specific with all of the following and consistent with the requirements in R 338.582:
(i) Required drug and ingredient information.
(ii) Facility identification.
(iii) The following or similar statement: "This is a compounded drug. For office use only" or "Not for resale."
(e) Ensure that bulk drug substances used for ~~sterile~~ compounding meet specified FDA criteria.
(8) An outsourcing facility may compound drugs that appear on an FDA shortage list, if the bulk drug substances used to compound the drugs comply with the criteria specified in this rule.

Board Response	The Board

Rule 338.534 Inspections.

Rule Numbers	Commenter	Comment
	Carlson/MHA	Under the "Inspections of applicants and licensees" section, the MHA feels the inspection should also exclude data gathered by the licensed health facility for quality improvement or professional practice review purposes. The collection of quality improvement data enables providers to work to improve patient safety and reduce the incidence of adverse events. This data could be incorrectly interpreted, which may deter providers from collecting data for quality improvement purposes. Professional practice evaluation is the process by which a health facility, using its own medical staff, performs a peer review of a privileged practitioner's professional practice for performance improvement and to ensure safe and high-quality patient care. The data should be left out of the inspection to ensure honest research and responses, which will ultimately lead to improved patient safety and quality. Michigan hospitals are committed to transparency and share quality of care data to state residents at verifymicare.org. Also, add the Joint Commission to (4).
Section (4)	Sapita/MPA	Remove "the NABP-VPP" replace with "a board approved accrediting organization."
Rules Committee Response	The Rules Committee agrees with Carlson/MHA's comments and recommends the language used in R 338.505. (4): The Rules Committee agrees with the comment.	

R 338.534 Inspections.

Rule 34. (1) A pharmacy located outside of this state that applies for licensure in this state as a pharmacy that will not ship compounded sterile pharmaceutical products into this state, shall submit to the department a copy of its most recent pharmacy inspection that was performed within the last 2 years.

(2) An applicant for a new pharmacy located in this state shall have an inspection conducted by the department or its designee prior to licensure.

(3) An applicant for licensure of a pharmacy that will provide sterile compounded pharmaceuticals shall have all of the following:

(a) An onsite physical inspection conducted by any of the following:

(i) The department.

(ii) The national association of boards of pharmacy verified pharmacy program (NABP-VPP).

(iii) An accrediting organization according to R 338.532.

(iv) A state licensing agency of the state in which the applicant is a resident and in accordance with the NABP's multistate pharmacy inspection blueprint program.

(b) A physical inspection and corresponding report completed within 18 months of application.

(c) A physical inspection and corresponding report that demonstrates compliance with all applicable standards that are adopted by reference in R 338.533.

(4) An out-of-state pharmacy that intends to ship sterile compounded pharmaceutical products into this state shall obtain an inspection from a board approved accrediting organization ~~the NABP-VPP~~ every 18 months.

(5) The inspection must not extend to information gathered by a licensed health facility for quality improvement or professional practice review.

Board Response	The Board

Rule 338.535 Discontinuing sterile compounding services; requirements to resume sterile compounding services.

Rule Numbers	Commenter	Comment
Section (1)	Kuhns/Portage Pharmacy	Add "or outsourcing facility" to (1): A sterile compounding pharmacy or outsourcing facility.
Section (3)		Add the following:

		(3) An outsourcing facility shall not resume providing sterile compounding services in this state until the outsourcing facility is approved by the department and verifies that it is compliant by an organization satisfying the requirements of R 338.533(4-10).
Rules Committee Response	(1) and (3): The Rules Committee agrees with both comments.	

R 338.535 Discontinuing sterile compounding services; requirements to resume sterile compounding services.

Rule 35. (1) A sterile compounding pharmacy or outsourcing facility that ceases to provide sterile compounding services in this state shall notify the department within 30 days of ceasing to provide sterile compounding services.

(2) A pharmacy shall not resume providing sterile compounding services in this state until the pharmacy is approved by the department and is accredited or verifies that it is USP compliant by an organization satisfying the requirements of R 338.532(1).

(3) A pharmacy shall apply for approval to resume sterile compounding services by submitting to the department an application on a form provided by the department together with the requisite fee.

(4) An outsourcing facility shall not resume providing sterile compounding services in this state until the outsourcing facility is approved by the department and verifies that it is compliant by an organization satisfying the requirements of R 338.533(4-10).

Board Response	The Board

Rule 338.536 Housing of a pharmacy.

Rule Numbers	Commenter	Comment
Section (2)	Baran/Ferris	The 150 square feet requirement has been in the rule for over 30 years. Given the increase in technology and the number of drugs requiring an increase in space this minimum should be at least 250 square feet for any new licenses issued. 250 square feet is used by a couple of the great lake states.
	Baskerville	This rule states that there should be not less than 10 feet of free counterspace, but it does not consider the amount of technology that a pharmacy utilizes or the technicians. A minimum of 10 feet is too small when you account for computers, printers, fax machines, and separate workspaces for the technicians. Add: not less than 16 feet of free workspace.

Section (3)	Baran	Add exception here for restroom breaks and assisting patients in the over the counter purchases.
Rules Committee Response	(2) and (3): The Rules Committee does not agree with either comment as the current space requirement is appropriate and the pharmacist is still on the premises while in the restroom.	

R 338.536 Housing of a pharmacy.

Rule 36. (1) All professional and technical equipment and supplies and prescription drugs must be housed in a suitable, well-lighted, and well-ventilated room or department with clean and sanitary surroundings.

(2) All pharmacies shall have a prescription department that is devoted primarily to the practice of pharmacy that occupies not less than 150 square feet of space, and that includes a prescription counter that provides not less than 10 square feet of free working surface. For each additional pharmacist who is on duty at any 1 time, the free working space must be increased by not less than 4 square feet. The prescription counter must be kept orderly and clean. The space behind the prescription counter must be sufficient to allow free movement within the area and must be free of obstacles.

(3) All pharmacies that occupy less than the entire area of the premises owned, leased, used, or controlled by the licensee must be permanently enclosed by partitions from the floor to the ceiling. All partitions must be of substantial construction and must be securely lockable so that drugs and devices that can be sold only by a pharmacist will be unobtainable during the absence of the pharmacist. Only the area of the premises owned, leased, used, or controlled by the licensee may be identified by the terms "drugstore," "apothecary," or "pharmacy," or by use of a similar term or combination of terms as listed in section 17711(2) of the code, MCL 333.17711(2). A pharmacy department must be locked when the pharmacist is not on the premises.

Board Response	The Board

Rule 338.537 Professional and technical equipment and supplies.

Rule Numbers	Commenter	Comment
Section (2)	Baskerville	This rule does not give any guidelines about the refrigerator and it does not give any requirements on a freezer. Add: a refrigerator that has a maximum temperature of 35 degrees Fahrenheit and a freezer that has a maximum temperature of 0 degrees Fahrenheit if necessary, of reasonable capacity located in the pharmacy department.
Rules Committee Response	(2): The Rules Committee does not agree with the comment to add requirements on a freezer as the pharmacist must use their professional judgment and this is part of professional responsibility.	

R 338.537 Professional and technical equipment and supplies.

Rule 37. A pharmacy must be equipped with all of the following:

(a) Drawers, shelves, and storage cabinets.

(b) A sink that has hot and cold running water.

(c) A refrigerator of reasonable capacity located in the pharmacy department.

(d) Current editions or revisions of the Michigan pharmacy laws and rules, and not less than 2 current or revised pharmacy reference texts that pertain to pharmacology, drug interactions, or drug composition. A current electronic version of pharmacy laws, rules, and pharmacy reference texts, including accessible internet versions, meets the requirements of this subrule.

Board Response	The Board

Rule 338.538 Closing pharmacy.

Rule Numbers	Commenter	Comment
Section (d)	Baran/Ferris	Change this to 14 days to coincide with federal requirements.
Rules Committee Response	(1)(d): The Rules Committee does not agree with changing 15 days to 14 days as this requirement is necessary when the pharmacy is registered with the DEA. One day does not have any affect on the public's safety.	

R 338.538 Closing pharmacy.

Rule 38. (1) A pharmacy that is ceasing operations shall return to the department the pharmacy license and the controlled substance license, if applicable, and shall provide the department with written notification of all of the following at least 15 days prior to closing:

(a) The effective date of closing.

(b) The disposition of controlled substances.

(c) The disposition of non-controlled substances.

(d) The disposition of records and prescription files.

(2) A pharmacy shall comply with all applicable federal requirements for discontinuing operation as a pharmacy that dispenses controlled substances.

Board Response	The Board

Rule 338.551 Manufacturer license; application.

Rule Numbers	Commenter	Comment
	Sapita/MPA	MPA believes that R 338.493a(3) should not be deleted and should read " If the total number of dosage units of all prescription drugs that are prepared or compounded by a pharmacy for resale, compounding, or dispensing by another person, as defined in section 1106 of the code, during any consecutive 12-month period is more than 5% of the total number of dosage units of prescription drugs prepared by the pharmacy during the 12-month period, then the pharmacy is a manufacturer as defined in section 17706(1) of the code."
Rules Committee Response	The Rules Committee agrees with the comment to clarify when a pharmacy must be treated as a manufacturer.	

R 338.551 Manufacturer license; application.

Rule 51. (1) An applicant for a manufacturer license shall submit to the department a completed application on a form provided by the department with the requisite fee.

(2) An applicant shall provide all of the following information:

(a) A criminal history background check required pursuant to section 17748(6) of the code, MCL 333.17748(6).

(b) Verification or certification from every state or province where the applicant is currently licensed or has ever held a license.

(c) Certified copies of articles of incorporation or certificates of partnership and assumed name certificates, if applicable.

(d) The identity and address of each partner, officer, or owner, as applicable.

(e) A completed compliance checklist for manufacturers.

(f) A list or a catalog of all drug products or devices to be manufactured by the facility.

(g) Unless exempt under section 17748(2) of the code, MCL 333.17748(2), the name and license number of the pharmacist designated as the pharmacist in charge (PIC).

(h) A copy of the FDA certification for the site to be licensed, if an applicant is a manufacturer of biologicals.

(i) An inspection from the manufacturer's resident state board of pharmacy or verified-accredited wholesale distributors (VAWD) accreditation dated not more than 2 years prior to the application.

(3) A separate license is required for each location where prescription drugs or devices are manufactured.

(4) A pharmacy is a manufacturer and shall obtain a manufacturer license if it prepares or compounds prescription drugs for resale, compounding, or dispensing by another person in an amount that exceeds 5% of the total number of dosage units of prescription drugs prepared by the pharmacy during a consecutive 12-month period.

Board Response	The Board

Rule 338.561 Pharmacy as wholesale distributor; licensure.

Rule Numbers	Commenter	Comment
Section (b)	Baran/Ferris	Need to delete (b) entirely as (b) is in violation of 333.17748a(7) and the Drug Quality and Security Act section 503A, a pharmacy may only compound a drug for an identified individual patient based on the receipt of a valid prescription order, or a notation, approved by the prescribing practitioner. A pharmacy may not compound drugs for resale.
	Baskerville	This draft rule does not consider the federal law that states that a pharmacy cannot sell another pharmacy a compounded product. Delete (b).
Rules Committee Response	The Rules Committee agrees with the comment to delete (b).	

R 338.561 Pharmacy as wholesale distributor; licensure.

Rule 61. A pharmacy that transfers prescription drugs or devices shall obtain a wholesale distributor license if it satisfies either of the following:

(a) Distributes more than 5% of the total dosage units of prescription drugs dispensed during any consecutive 12-month period.

~~**(b) Prepares or compounds prescription drugs for resale, compounding or dispensing by another person in an amount that exceeds 5% of the total number of dosage units prepared and compounded for dispensing by the pharmacy during a consecutive 12-month period.**~~

Board Response	The Board

Rule 338.563 Wholesale distributor; application for licensure; requirements.

Rule Numbers	Commenter	Comment
Section (2)(i)(B)	Roath/SpartanNash	While the training requirements under Rule 63, Subrule (2)(i)(B)are advisable to a person in the facility manager position, a lack of accredited or universally recognized training program makes the path to compliance with this rule unclear. Given that no accredited program exists, employers should have the discretion as to exactly what kind of training they require of an individual in this position absent a regulatory requirement. Additionally, Subrule (2)(i)(C) establishes experience requirements that should address any concerns as to whether a facility manager is qualified to fill their position. As such, we recommend that Subrule (2)(i)(C) and all requirements under this subrule be removed from the rules as proposed.
	Sapita/MPA	MPA is not aware of any specific training programs that cover all listed topics and believes this responsibility should lie with the wholesaler rather than the board.
Rules Committee Response	The Rules Committee members are split on whether the term "training program" should be modified. The comment requires further discussion.	

R 338.563 Wholesale distributor; application for licensure; requirements.

Rule 63. (1) An applicant for a wholesale distributor license shall submit to the department a completed application on a form provided by the department with the requisite fee. A wholesale distributor includes virtual manufacturers.

(2) An applicant shall provide all of the following information:

(a) A criminal history background check required pursuant to section 17748(6) of the code, MCL 333.17748(6).

(b) Proof of registration or licensure from every state where the applicant currently holds or has ever held a license or registration.

(c) Certified copies of articles of incorporation or certificates of partnership and assumed names if applicable.

(d) The identity and address of each partner, officer, or owner as applicable.

(e) A completed compliance checklist.

(f) A list or catalog of all drug products and devices to be distributed.

(g) A copy of the FDA certification for the site to be licensed, if the applicant is distributing biologicals.

(h) Unless exempt under section 17748(2) of the code, MCL 333.17748(2), the name and the license number of the pharmacist designated as the pharmacist in charge (PIC) or the name of the facility manager. For individuals designated as a facility manager, the applicant shall provide the following:

(i) Proof, in the form of an affidavit, that the facility manager has achieved the following:

(A) A high school equivalency education, or higher, defined as 1 of the following:

(1) A high school diploma.

(2) A general education development certificate (GED).

(3) A parent-issued diploma for home schooled individuals.

(4) Completion of post-secondary education, including an associate's, bachelor's, or master's degree.

(B) Completion of a training program that includes, but is not limited to, all of the following subjects:

(1) Knowledge and understanding of laws in this state and federal laws relating to the distribution of drugs and devices.

(2) Knowledge and understanding of laws in this state and federal laws relating to the distribution of controlled substances.

(3) Knowledge and understanding of quality control systems.

(4) Knowledge and understanding of the USP standards relating to the safe storage and handling of prescription drugs.

(5) Knowledge and understanding of pharmaceutical terminology, abbreviations, dosages, and format.

(C) Experience equal to either of the following:

(1) A minimum of 1 year of work experience related to the distribution or dispensing of prescription drugs or devices where the responsibilities included, but were not limited to, recordkeeping.

(2) Previous or current employment as a designated representative of a wholesale distributor certified by the VAWD of NABP.

Board Response	The Board

Rule 338.582 Prescription drug labeling and dispensing.

Rule Numbers	Commenter	Comment
Section (3)	Baran/Ferris	Need to delete "**or the reference "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products**" from the rule. The rule was created before computer software was standard practice in pharmacy over 30 years ago. This terminology is no longer used on prescription labels because computers made it obsolete.
Section (3)	Kurzman/NACDS	Delete (3) for the following reasons:

		Under R 338.582 (2) and (3), the Board proposed rule changes that address labeling requirements when a brand vs. generic drug is dispensed. Language under subrule (2)(g) and (i) specifies that prescription labels must include the medication name and the manufacturer or supplier of the drug if the drug has no brand name, unless the prescriber indicates “do not label”. Notably, the proposed language further specifies under subrule (3) that when “a drug is dispensed that is not the brand prescribed… the prescription label must indicate both the name of the brand prescribed and the name of the brand dispensed. If the dispensed drug does not have a brand name, the prescription label must indicate the name of the brand prescribed followed by the generic name of the drug dispensed or the reference "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products.” However, if the if the prescriber indicates "do not label”… [the] subrule does not apply…" We are concerned that altogether, the language in subrule (2)(g) and (i) and in subrule (3) is duplicative and may lead to confusion. To simplify and clarify this issue, we recommend that subrule (3) be stricken entirely as that provision is redundant to the requirements outlined in subrule (2)(g) and (i).
Section	Eid/Ferris	Although being worked on within the Pharmacy Technician specific rules, consider the following for both this section and the Pharmacy Technician rule set. Tech-check-tech, or as some states are now calling it "accuracy checking" or “technician product verifiction” has been successfully and safely practiced in some states for decades. There are approximately 20 studies to date on the topic in various settings including community based and health systems. **Adams et al** reviewed and demonstrated safety data, including that results of 11 studies published since 1978 indicate that technicians’ accuracy in performing final dispensing checks is very comparable to pharmacists’ accuracy (mean ± S.D., **99.6%** ± 0.55% versus **99.3%** ± 0.68%, respectively. **Frost et al** also reviews data in the community setting and also showed that in 2 studies that reported accuracy rates, pharmacy technicians performed at least as accurately as pharmacists (**99.445** vs **99.73%,** P = .484; **99.95** vs **99.74**, P < .05). In addition, there are multiple pilot and research programs in states such as Wisconsin, Tennessee, Iowa, South Dakota, and more which have been studying the workflow and outcomes of implementing these models. I encourage the board and other stakeholders to move forward on this as it will only help to improve patient care initiatives and allow for pharmacists to spend more time with patients as demonstrated by **Andreski et al.** I'd also encourage the board to

		refer to **Adams** for deliberations of the Idaho regulatory board on advancing technician practice, which an example from.
Rules Committee Response	(3): The Rules Committee agrees with the comment to delete "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products" from the rule but does not agree with deleting the rule in its entirety as the use of generic needs to be disclosed if being used.	

R 338.582 Prescription drug labeling and dispensing.

Rule 82. (1) All labeling of prescription drugs must comply with the requirements of the code and the federal food, drug, and cosmetic act of 2016, 21 U.S.C. sections 351 to 399f.

(2) All containers in which prescription medication is dispensed must bear a label that contains, at a minimum, all of the following information:

(a) Pharmacy name and address.

(b) Prescription number.

(c) Patient's name.

(d) Date the prescription was most recently dispensed.

(e) Prescriber's name.

(f) Directions for use.

(g) The name of the medication and the strength, unless the prescriber indicates "do not label."

(h) The quantity dispensed, if applicable.

(i) The name of the manufacturer or supplier of the drug if the drug has no brand name, unless the prescriber indicates "do not label."

(3) If a drug is dispensed that is not the brand prescribed, the pharmacy shall notify the purchaser and the prescription label must indicate both the name of the brand prescribed and the name of the brand dispensed. If the dispensed drug does not have a brand name, the prescription label must indicate the name of the brand prescribed followed by the generic name of the drug dispensed ~~or the reference "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products~~. This subrule does not apply if the prescriber indicates "do not label."

(4) If drug product selection takes place, the brand name or the name of the manufacturer or supplier of the drug dispensed must be noted on the prescription.

(5) This rule does not apply to pharmacy services provided in a medical institution.

Board Response	The Board

Rule 338.584 Noncontrolled prescriptions.

Rule Numbers	Commenter	Comment
Section (4)	Baran/Ferris	Modify to: (4) A noncontrolled prescription is valid for 1 year from the date the prescription was issued. This makes it clear this only applies to noncontrolled prescriptions.
Rules Committee Response	The Rules Committee does not agree with the comment as "noncontrolled" is used in the heading and adding "noncontrolled" would therefore be redundant.	

R 338.584 Noncontrolled prescriptions.

Rule 84. (1) A prescriber who issues a prescription for a noncontrolled prescription drug shall date the prescription; provide a manual signature on the prescription, as defined in R 338.501(1)(h) of these rules; and ensure that the prescription contains all of the following information:

(a) The full name of the patient for whom the drug is being prescribed.

(b) The prescriber's printed name and address.

(c) The drug name and strength.

(d) The quantity prescribed.

(e) The directions for use.

(f) The number of refills authorized.

(2) A prescriber shall ensure that a prescription is legible and that the information specified in subrule (1)(c) to (f) of this rule is clearly separated.

(3) A prescriber shall not prescribe more than either of the following on a single prescription form as applicable:

(a) For a prescription prescribed in handwritten form, up to 4 prescription drug orders.

(b) For a prescription prescribed on a computer-generated form or a preprinted list or produced on a personal computer or typewriter, up to 6 prescription drug orders.

(4) A prescription is valid for 1 year from the date the prescription was issued.

(5) A prescriber may electronically transmit a noncontrolled substance prescription to the pharmacy of the patient's choice by utilizing a system that includes all of the following:

(a) A combination of technical security measures such as, but not limited to, those listed in security standards for the protection of electronic protected health information set forth in 45 C.F.R. section 164.312 (2013) that implements the federal health insurance portability and accountability act of 1996 (HIPAA), to ensure all of the following:

(i) Authentication of an individual who prescribes or dispenses.

(ii) Technical non-repudiation.

(iii) Content integrity.

(iv) Confidentiality.

(b) An electronic signature as defined in R 338.501(1)(g). An electronic signature is valid when it is used to sign a noncontrolled prescription.

(c) Appropriate security measures to invalidate a prescription if either the electronic signature or prescription record to which it is attached or logically associated is altered or compromised following transmission by the prescriber. The electronic prescription may be reformatted to comply with industry standards provided that no data is added, deleted, or changed.

(6) The electronic prescription must meet all requirements of the HIPAA.

(7) The electronic prescription must permit the prescriber to instruct the pharmacist to dispense a brand name drug product provided that the prescription includes both of the following:

(i) The indication that no substitute is allowed, such as "dispense as written" or "DAW."

(ii) The indication that no substitute is allowed and that it is a unique element in the prescription.

(8) If the prescription is transmitted electronically, the prescriber shall generate and transmit the prescription in a format that can be read and stored by a pharmacy in a retrievable and readable form. The electronic prescription must identify the name of the pharmacy intended to receive the transmission, and must include the information identified in subrule (1) of this rule.

(9) The electronic prescription must be preserved by a licensee or dispensing prescriber for not less than 5 years. A paper version of the electronic prescription must be made available to an authorized agent of the board upon request. A secured copy must be retained for a minimum of 1 year by the transaction service vendor for record-keeping purposes and must be shared only with the parties involved in the transaction except as otherwise permitted by state or federal law.

(10) An electronic signature that meets the requirements of this rule has the full force and effect of a handwritten signature on a paper-based written prescription.

(11) A pharmacy shall keep the original prescription record for 5 years. After 3 years, a pharmacy may make an electronic duplicate of the original paper prescription, which will become the original prescription. A pharmacy shall present a paper copy of the electronic duplicate of the prescription to an authorized agent of the board upon request.

(12) This rule does not apply to pharmacy services provided in a medical institution.

Board Response	The Board

Rule 338.585 Customized patient medication package.

Rule Numbers	Commenter	Comment
Section (b)	Baran/Ferris	Change this first sentence to: "A CPMP must be accompanied by any mandated patient information required under federal law." This would cover any medication guides required.
Rules Committee Response	The Rules Committee agrees with the comment.	

R 338.585 Customized patient medication package.

Rule 85. (1) A pharmacist may, with the consent of the patient, or the patient's caregiver, or a prescriber, provide a customized patient medication package (CPMP). A CPMP is a package that is prepared by a pharmacist for a specific patient and that contains 2 or more prescribed solid oral dosage forms. The CPMP is designed and labeled to indicate the day and time or period of time that the contents within each CPMP are to be taken. The person who dispenses the medication shall instruct the patient or caregiver on the use of the CPMP.

(2) If medication is dispensed in a CPMP, all of the following conditions must be met:

(a) Each CPMP must bear a readable label that states all of the following information:

(i) A serial number for the CPMP and a separate identifying serial number for each of the prescription orders for each of the drug products contained in the CPMP.

(ii) The name, strength, physical description, and total quantity of each drug product contained in the CPMP.

(iii) The name of the prescriber for each drug product.

(iv) The directions for use and cautionary statements, if any, contained in the prescription order for each drug product in the CPMP.

(v) The date of the preparation of the CPMP.

(vi) An expiration date for the CPMP. The date must not be later than the earliest manufacturer's expiration date for any medication included in the CPMP or 60 days after the date of dispensing.

(vii) The name, address, and telephone number of the dispenser.

(viii) Any other information, statements, or warnings required for any of the drug products contained in the CPMP.

(b) A CPMP must be accompanied by any mandated patient information required under federal law. Alternatively, required medication information may be incorporated by the pharmacist into a single educational insert that includes information regarding all of the medications in the CPMP.

(c) At a minimum, each CPMP must be in compliance with the United States Pharmacopeia (USP) and national formulary, as defined in section 17706(2) of the code, MCL 333.17706(2), for moisture permeation requirements for a class b single-unit or unit-dose container. Each container must be either non-reclosable or so designed as to show evidence of having been opened. Each CPMP must comply with all of the provisions of the poison prevention packaging act of 2016, 15 U.S.C. sections 1471 to 1477.

(d) When preparing a CPMP, the dispenser shall take into account any applicable compendial requirements or guidelines, the physical and chemical compatibility of the dosage forms placed within each container, and any therapeutic incompatibilities that may attend the simultaneous administration of the medications. Medications must not be dispensed in CPMP packaging in any of the following situations:

(i) The USP monograph or official labeling requires dispensing in the original container.

(ii) The drugs or dosage forms are incompatible with packaging components or each other.

(iii) The drugs are therapeutically incompatible when administered simultaneously.

(iv) The drug products require special packaging.

(e) If 2 medications have physical characteristics that make them indistinguishable from each other, then the medication must not be packaged together in the same CPMP.

(f) Medications that have been dispensed in CPMP packaging shall not be returned to stock or dispensed to another patient when returned to the pharmacy for any reason. If a prescription for any drug contained in the CPMP is changed, then a new appropriately labeled CPMP must be prepared for the patient.

(g) In addition to all individual prescription filing requirements, a record of each CPMP dispensed must be made and filed. At a minimum, each record must contain all of the following information:

(i) The name and address of the patient.

(ii) The serial number of the prescription order for each drug product contained in the CPMP.

(iii) Information identifying or describing the design, characteristics, or specifications of the CPMP sufficient to allow subsequent preparation of an identical CPMP for the patient.

(iv) The date of preparation of the CPMP and the expiration date assigned.

(v) Any special labeling instructions.

(vi) The name or initials of the pharmacist who prepared the CPMP.

Board Response	The Board

Rule 338.587 **Prescription refill records; manual systems; profile systems; automated pharmacy data systems; nonapplicability to medical institution service; record confidentiality; and access.**

Rule Numbers	Commenter	Comment
Section (2)	Baran/Ferris	Delete (2) entirely as this method is outdated by the use of computers. This part is more than 40 years old with no one using this process today.
Section (3)(vii) and (4)(vii)	Sapita/MPA	Remove "name of the manufacturer."
Section (6)	Sapita/MPA	Subrule (2) should be included in this section.
Rules Committee Response	(2): The Rules Committee does not agree with the comment as the manual method may be used in a natural disaster. (3)(viii) and (4)(viii): The comment was withdrawn. (6): Subrule will be added back in as its deletion was a typographical error.	

R 338.587 Prescription refill records; manual systems; profile systems; automated pharmacy data systems; nonapplicability to medical institution service; record confidentiality; and access.

Rule 87. (1) A pharmacist shall record prescription refills using only 1 of the systems described in subrule (2), (3), or (4) of this rule and in compliance with the provisions of subrule (2), (3), or (4) of this rule, as applicable.

(2) A pharmacy may utilize a manual system of recording refills if the system is in compliance with both of the following criteria:

(a) The amount and date dispensed must be entered on the prescription in an orderly fashion and the dispensing pharmacist initials the entry. If the pharmacist only initials and dates the prescription, then the full face amount of the prescription must be deemed dispensed.

(b) If the drug that is dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed must be indicated on the prescription.

(3) A pharmacy may utilize a uniform system of recording refills if the system is in compliance with all of the following criteria:

(a) Records must be created and maintained in written form. All original and refill prescription information for a particular prescription appears on single documents in an organized format. The pharmacy shall preserve the records for 5 years. The records are subject to inspection by the board or its agents.

(b) The following information for each prescription must be entered on the record:

(i) The prescription number.
(ii) The patient's name and address.
(iii) The prescriber's name.
(iv) The prescriber's federal drug enforcement administration (DEA) number, if appropriate.
(v) The number of refills authorized.
(vi) The "dispense as written" instructions, if indicated.
(vii) The name, strength, dosage form, quantity, and name of the manufacturer of the drug prescribed, and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed must be indicated.
(viii) The date of issuance of the prescription.
(ix) The date and identifying designation of the dispensing pharmacist for the original filling and for each refill.
(c) Prescription entries must be made on the record at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized so that information already entered on the record may appear for a prescription or refill without reentering the information. The dispensing pharmacist is responsible for the completeness and accuracy of the entries and must initial the record each time a prescription is filled or refilled.
(d) The information required by subdivision (b) of this subrule must be entered on the record for all prescriptions filled at a pharmacy, including nonrefillable prescriptions. This requirement is in addition to the requirements set forth in R 338.586.
(4) A pharmacy may utilize a uniform automated data processing system of recording refills if the system is in compliance with all of the following criteria:
(a) All information that is pertinent to a prescription must be entered on the record, including all of the following information:
(i) The prescription number.
(ii) The patient's name and address.
(iii) The prescriber's name.
(iv) The prescriber's federal DEA number, if appropriate.
(v) The number of refills authorized.
(vi) Whether the drug must be dispensed as written.
(vii) The name, strength, dosage form, quantity, and name of the manufacturer of the drug prescribed and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed must be indicated.
(viii) The date of issuance of the prescription.

(ix) The date and identifying designation of the dispensing pharmacist for the original filling and for each refill.

(b) Prescription entries must be made on the record at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized so that information already entered on the record may appear for a prescription or refill without reentering the information. The dispensing pharmacist is responsible for the completeness and accuracy of the entries. The pharmacy shall preserve the records on-site for 5 years. The records are subject to inspection by the board or its agents. A procedure must be established to facilitate inspections.

(c) The required information must be entered on the record for all prescriptions filled at the pharmacy, including nonrefillable prescriptions. This requirement is in addition to the requirements set forth in R 338.586.

(d) The recording system must provide adequate safeguards against improper manipulation, the alteration of records, and the loss of records.

(e) The recording system must have the capability of producing a printout of all original and refilled prescription data, including a prescription-by-prescription and refill-by-refill audit trial for any specified strength and dosage form of a controlled substance by either brand or generic name or an audit trail of controlled substance prescriptions written for a particular patient or by a particular practitioner. A printout of an audit trail or other required information must be made available to an authorized agent of the board upon request. The prescription data must be maintained for 5 years. Data older than 16 months must be provided within 72 hours of the time the request is first made by the agent. Prescription data for the most current 16 months must be readily retrievable on site and available for immediate review.

(f) If the automated data processing system is inoperative for any reason, then the pharmacist shall ensure that all refills are authorized and that the maximum number of refills is not exceeded. When the automated data processing system is restored to operation, the pharmacist shall enter the information regarding prescriptions filled and refilled during the inoperative period into the automated data processing system within 48 hours.

(g) A pharmacy shall make arrangements with the supplier of data processing services or materials to ensure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with the supplier terminates for any reason. A pharmacy shall ensure continuity in the maintenance of records.

(h) The automated data processing system must be an integrated system that is capable of complying with all of the requirements of these rules.

(5) This rule does not apply to pharmacy services provided in a medical institution.

(6) Records that are created under subrule (2), (3), or (4) of this rule are subject to the same requirements regarding confidentiality and access that apply to original prescriptions.

Board Response	The Board

Rule 338.588 Automated devices.

Rule Numbers	Commenter	Comment
Section (1) (1)(h)	Sapita/MPA	Consider keeping the current rule, "An automated device means a device designed for the specific purpose of selling, dispensing, or otherwise disposing of any drug or device ordered by a prescription." MPA would like clarification if the location would need to be owned and operated by the pharmacy and who would be responsible for the device.
Section (2)	Roath/SpartanNash	Statutory changes that have occurred since the original rules regarding the use of automated devices in healthcare settings, as well as the addition of Subrule (2)(h) in these proposed rules, creates the potential for automated devices to be used in locations outside a pharmacy but at the same physical address of the pharmacy. However, this is currently limited only to hospital settings. Given that hospital pharmacies do not have any differentiation in license classification and, in some circumstances, have the ability to operate as outpatient facilities, this creates an environment where certain outpatient pharmacies are able to use these devices in capacities that are denied to pharmacies in the community practice setting. To address this discrepancy, we recommend that Rule 88, Subrule (2)(a) be modified to read "a pharmacy, or at the same physical address as the pharmacy provided that the location of the device is owned and operated by the same legal entity as the pharmacy."
Section (3)	Baran/Ferris Roath/SpartanNash	Add this language following the first sentence in (3) "*If the automated device contains controlled substances, the pharmacy must obtain an additional controlled substance license for the automated device as well as a DEA registration for the device.* The current definition "automated device" in the Michigan Public Health Code and in the rules as proposed encompasses several devices that may be used in workflow for tasks other than the delivery of a medication to patient or other healthcare provider (e.g., counting machines and packaging devices operated by pharmacy staff as part of the dispensing process). We feel that to register each of these devices with the department goes beyond the intent of the Board and the Department and will cause devices that do not require department oversight to be erroneously registered with the Department. To correct this, we recommend that Rule 88, Subrule (3) be

		modified to read: "A pharmacy that operates an automated device under this section to deliver a drug or device directly to a patient or other healthcare provider shall notify the department of the automated device's location on a form provided by the department …"
Section (4)	Sapita/MPA	Remove "unless the prescriber's office is affiliate with a hospital consisted with section 17760 of code, MCL 333.17760." This is not relevant to this section.
Section (5)	Baran/Ferris	Rule 338.3154 does not identify what is "board-approved error-prevention technology" and refers back to rule 338.490 which is being rescinded by the new draft rules. 338.3154 and 338.490 go around in a circle without ever defining "board-approved error-prevention technology". Will have to define "board-approved error-prevention technology" and list those that have been board approved.
	Sapita/MPA	After "licensed" add "and located."
Section (7)	Roath/SpartanNash	To provide consistency in the record keeping requirements for pharmacies and dispensing prescribers, we recommend that Rule 88, Subrule (7)(b) be modified to read: "Records must be maintained for 5 years by the pharmacy or dispensing prescriber and must be retrievable on demand for review by an agent of the board…"
(7)(a)	Sapita/MPA	After "pharmacy" add "or dispensing prescriber."
Rules Committee Response	(1): The Rules Committee does not agree with the comment to change the definition of "automated device" as the definition of automated device is from the Code. (2): The Rules Committee agrees with the comment to add the language "a pharmacy, or at the same physical address as the pharmacy provided that the location of the device is owned and operated by the same legal entity as the pharmacy." (3): The Rules Committee does not agree with the comment from Baran as this is already addressed in the controlled substances rules but does agree with the comment from Roath as this is current practice. (4): The Rules Committee does not agree with the comment as the purpose of the provision is to state when a pharmacy can own a device at a dispensing prescriber's office. A reference to (2)(h) should be added here. (5): The Rules Committee agrees with the comment and recommends deleting the reference to R 338.3154. (7): The Rules Committee agrees with the comments.	

R 338.588 Automated devices.

Rule 88. (1) "Automated device" means a mechanical system that performs an operation or activity, other than compounding or administration, relating to the storage, packaging, dispensing, or delivery of a drug and that collects, controls, and maintains transaction information.

(2) An automated device may be used only in the following locations:

(a) A pharmacy, or at the same physical address as the pharmacy provided that the location of the automated device is owned and operated by the same legal entity as the pharmacy.

(b) A hospital.

(c) A county medical care facility.

(d) A hospice.

(e) A nursing home.

(f) Other skilled nursing facility as defined in section 20109(4) of the code, MCL 333.20109(4).

(g) An office of a dispensing prescriber.

(h) A location affiliated with a hospital, but not at the same physical address as the pharmacy, that is owned and operated by the hospital, consistent with section 17760 of the code, MCL 333.17760.

(3) A pharmacy that operates an automated device under this section to deliver a drug or device directly to an ultimate user or other health care provider shall notify the department of the automated device's location on a form provided by the department. An automated device located within a licensed pharmacy must be used only by a pharmacist or his or her pharmacy personnel under the personal charge of a pharmacist.

(4) If an automated device is used in a dispensing prescriber's office, the device must be used only to dispense medications to the dispensing prescriber's patients and only under the control of the dispensing prescriber. A pharmacy shall not own, control, or operate an automatic dispensing device in a dispensing prescriber's office, unless the prescriber's office is affiliated with a hospital consistent with section 17760 of the code, MCL 333.17760 and subrule (2)(h) of this rule.

(a) If a dispensing prescriber delegates the stocking of the automated device, then technologies must be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing a board-approved error prevention technology that complies with R 338.3154.

(b) A dispensing prescriber operating an automated device is responsible for all medications that are stocked and stored in that device as well as removed from that device.

(c) If any medication or device is dispensed from an automated device in a dispensing prescriber's office, then documentation as to the type of equipment, serial numbers, content, policies, procedures, and location within the facility must be maintained

by the dispensing prescriber for review by an agent of the board. This documentation must include at least all of the following information:

(i) Manufacturer name and model.

(ii) Quality assurance policy and procedure to determine continued appropriate use and performance of the automated device.

(iii) Policy and procedures for system operation that addresses at a minimum all of the following:

(A) Accuracy.

(B) Patient confidentiality.

(C) Access.

(D) Data retention or archival records.

(E) Downtime procedures.

(F) Emergency procedures.

(G) Medication security.

(H) Quality assurance.

(5) An automated device that is to be used for furnishing medications for administration to registered patients in any hospital, county medical care facility, nursing home, hospice, or any other skilled nursing facility, as defined in section 20109(4) of the code, MCL 333.20109(4), must be supplied and controlled by a pharmacy that is licensed in this state. The use of an automated device in these locations is not limited to the provisions of subrule (3) of this rule. If a pharmacist delegates the stocking of the device, then technologies must be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing bar-coding or another board-approved error-prevention technology ~~that complies with R 338.3154~~. Each automated device must comply with all of the following provisions:

(a) A pharmacy operating an automated device is responsible for all medications that are stocked and stored in that device as well as removed from that device.

(b) If any medication or device is dispensed from an automated device, then documentation as to the type of equipment, serial numbers, content, policies, procedures, and location within the facility must be maintained by the pharmacy for review by an agent of the board. The documentation must include at least all of the following information:

(i) Name and address of the pharmacy responsible for the operation of the automated device.

(ii) Name and address of the facility where the automated device is located.

(iii) Manufacturer name and model number.

(iv) Quality assurance policy and procedure to determine continued appropriate use and performance of the automated device.

(v) Policy and procedures for system operation that address at a minimum all of the following:
(A) Accuracy.
(B) Patient confidentiality.
(C) Access.
(D) Data retention or archival records.
(E) Downtime procedures.
(F) Emergency procedures.
(G) Medication security.
(H) Quality assurance.
(I) Ability to provide on demand to an agent of the board a list of medications qualifying for emergency dose removal without pharmacist prior review of the prescription or medication order.
(6) An automated device that is operated at a location affiliated with a hospital, but not at the same physical address as the pharmacy, that is owned and operated by the hospital, must comply with section 17760 of the code, MCL 333.17760.
(7) Records and electronic data kept by automated devices must meet all of the following requirements:
(a) All events involving access to the contents of the automated devices must be recorded electronically.
(b) Records must be maintained for 5 years by the pharmacy or dispensing prescriber and must be retrievable on demand for review by an agent of the board. The records must include all of the following information:
(i) The unique identifier of the automated device accessed.
(ii) Identification of the individual accessing the automated device.
(iii) The type of transaction.
(iv) The name, strength, dosage form, quantity, and name of the manufacturer of the drug accessed.
(v) The name of the patient for whom the drug was ordered.
(vi) Identification of the pharmacist responsible for the accuracy of the medications to be stocked or restocked in the automated device.
(8) Policy and procedures for the use of the automated device must include a requirement for pharmacist review of the prescription or medication order before system profiling or removal of any medication from the system for immediate patient administration. This subrule does not apply to the following situations:
(a) The system is being used as an after-hours cabinet for medication dispensing in the absence of a pharmacist as provided in R 338.486(4)(j).
(b) The system is being used in place of an emergency kit as provided in R 338.486(4)(c).

(c) The system is being accessed to remove medication required to treat the emergent needs of a patient as provided in R 338.486(4)(c). A sufficient quantity to meet the emergent needs of the patient may be removed until a pharmacist is available to review the medication order.

(d) In each of the situations specified in subdivisions (a) to (c) of this subrule, a pharmacist shall review the orders and authorize any further dispensing within 48 hours

(e) The automated device is located in a dispensing prescriber's office.

(9) A copy of all policies and procedures related to the use of an automated device must be maintained at the pharmacy responsible for the device's specific location or at the dispensing prescriber's office and be available for review by an agent of the board.

Board Response	The Board

Rule 338.589 Professional responsibility; "caregiver" defined.

Rule Numbers	Commenter	Comment
Section (4)(d)	Carlson/MHA	A requirement to document the consultation (or the reason why consultation was not completed) should be included. There are a number of reasons for this … not the least of which is to protect the pharmacist from liability should a patient claim he/she was not warned as required by this rule.
Section (5)	Baran/Ferris	There is no longer an exception in R 338.486(3).
Rules Committee Response	(4)(d): The Rules Committee does not agree with the comment because add a requirement not currently required by the Code. (5): The Rules Committee does not agree with the comment that there is no longer an exception in R 338.486. However, as there are multiple exceptions in this rule the reference to subsection (3) will be deleted.	

R 338.589 Professional responsibility; "caregiver" defined.

Rule 89. (1) A pharmacist has a professional responsibility for the strength, quality, purity, and the labeling of all drugs and devices dispensed under a prescription. In discharging this responsibility, a pharmacist shall utilize only those drugs and devices that are obtained from manufacturers and wholesale distributors licensed under section 17748 of the code, MCL 333.17748, or from other lawful channels of distribution.

(2) A pharmacist shall not fill a prescription order if, in the pharmacist's professional judgment, any of the following provisions apply:

(a) The prescription appears to be improperly written.

(b) The prescription is susceptible to more than 1 interpretation.

(c) The pharmacist has reason to believe that the prescription could cause harm to the patient.

(d) The pharmacist has reason to believe that the prescription will be used for other than legitimate medical purposes.

(3) A prescription drug must be dispensed only when the pharmacy is open and under the personal charge of a pharmacist.

(4) To encourage intended, positive patient outcomes, a pharmacist shall communicate to the patient, or the patient's caregiver, necessary and appropriate information regarding safe and effective medication use at the time a prescription is dispensed. As used in this subrule, "caregiver" means the parent, guardian, or other individual who has assumed responsibility for providing a patient's care. All of the following provisions apply to communicating medication safety and effectiveness information:

(a) The information must be communicated orally and in person, except when the patient or patient's caregiver is not at the pharmacy or when a specific communication barrier prohibits oral communication. In either situation, providing printed or electronic/digital material designed to help the patient use the medication safely and effectively satisfies the requirements of this subrule.

(b) The information must be provided with each prescription for a drug not previously prescribed for the patient.

(c) If the pharmacist deems it appropriate, the information must be provided with prescription refills.

(d) The information must be provided if requested by the patient or patient's caregiver or agent for any prescription dispensed by the pharmacy. This subrule does not require that a pharmacist provide consultation if a patient or a patient's caregiver refuses consultation.

This subrule does not apply to prescriptions dispensed for administration to a patient while the patient is in a medical institution.

(5) Pharmacist delegation of acts, tasks, or functions shall be in compliance with section 16215 of the code, MCL 333.16215, and under the personal charge of the delegating pharmacist, except as provided in R 338.486~~(3)~~. A pharmacist who delegates acts, tasks, or functions to a licensed or unlicensed person shall do all of the following:

(a) Determine the knowledge and skill required to safely and competently complete the specific act, task, or function to be delegated.

(b) Before delegating an act, task, or function, make a determination that the delegate has the necessary knowledge and skills to safely and competently complete the act, task, or function.

(c) Provide written procedures or protocols, or both, to be followed by the delegatee in the performance of the delegated act, task, or function.

(d) Supervise and evaluate the performance of the delegatee.

(e) Provide remediation of the performance of the delegatee if indicated.

(6) A delegating pharmacist shall bear the ultimate responsibility for the performance of delegated acts, tasks, and functions performed by the delegatee within the scope of the delegation.

Board Response	The Board

Rule 338.590 Hospice emergency drug box.

Rule Numbers	Commenter	Comment
Section (11)	Sapita/MPA	After "prescriptions" add issued by an appropriate prescriber" and remove "of the attending physician.
Rules Committee Response	(11): The Rules Committee agrees with the comment to update the language.	

R 338.590 Hospice emergency drug box.

Rule 90. (1) A pharmacy that establishes a medication box exchange program for hospice emergency care services rendered in patients' homes pursuant to the provisions of section 17746 of the code, MCL 333.17746, shall establish drug boxes that are in compliance with this rule. Before providing drug boxes for a hospice emergency care system, the pharmacist in charge shall ensure that the hospice has developed policies and procedures that require all of the following:

(a) Maintenance by the hospice of a drug box exchange log that accounts for the hospice's receipt of the boxes from the pharmacy, assignment of the boxes to registered nurses or physicians' assistants, and return of the boxes to the pharmacy for restocking.

(b) A procedure to ensure that the drug boxes are inspected at least weekly to determine if they have expired or have been opened.

(c) Procedures for the storage and control of a drug box while it is assigned to, and being used by, the prescriber, a registered nurse, or a physician's assistant.

(d) A procedure for implementing the hospice medical director's responsibility for ensuring that prescriptions for drugs removed from the drug boxes are obtained from an appropriate prescriber.

(2) A pharmacy shall stock drug boxes for a hospice emergency care system in accordance with the policies and procedures developed by the hospice and approved by the hospice medical director.

(3) The drugs contained in each drug box must be listed inside the front cover of the box. Each box must be equipped with only 1 nonreusable, tamper-evident seal or sealing system which is a color that designates that the box has not been opened

and several nonreusable, tamper-evident seals or sealing systems which are a different color that designates that the box has been opened.

(4) A drug box must be numbered. A permanent record of all drug boxes must be maintained at the pharmacy.

(5) A label that contains all of the following information must be attached to the drug box so that it is visible from the outside of the box:

(a) The name and address of the pharmacy.

(b) The name and address of the hospice.

(c) The name of the pharmacist who last inspected and restocked the drug box.

(d) The date the drug box was last restocked.

(e) The date on which the drug box must be returned to the pharmacy for the replacement of expired drugs.

(f) The number of the drug box.

(6) After the drug box has been stocked and labeled, the pharmacist shall seal it with the nonreusable, tamper-evident seal or sealing system which is the color that designates that the box has not been opened.

(7) A drug box must be kept in a substantially constructed, securely locked storage compartment when not under the direct control of the pharmacist, prescriber, registered nurse, or physician's assistant. The box must be stored under conditions that will maintain the stability, integrity, and effectiveness of the drugs. Access to the storage compartment and to the drug box must be limited to individuals who are authorized to stock the drug box or to dispense drugs from the drug box on the order of an appropriate prescriber.

(8) The drug box must remain sealed at all times, except when in use. All drugs removed from the box must be recorded on a medication use form. After completing the form, the physician, registered nurse or physician's assistant who removed the drug must place the form in the drug box and seal the box with a nonreusable, tamper-evident seal or sealing system which is a color that designates that the box has been opened.

(9) Each drug box under the control of the pharmacy must be examined at least weekly to ensure that the seal which designates that the box has not been opened is still intact and the expiration date has not been exceeded. If the expiration date has been exceeded or the box has been opened, the box must be returned to the pharmacy. The written prescription for all drugs that have been administered from the drug box must accompany the drug box when it is returned to the pharmacy after opening.

(10) The pharmacy shall maintain a permanent record of drug box exchanges on a drug box exchange log. The record must contain all of the following information:

(a) The number of the box.

(b) The name of the hospice to which the box is released.

(c) The date the box is released to the hospice.
(d) The name and signature of the pharmacist who releases the box to the hospice.
(e) The expiration date assigned.
(f) The date the box is returned to the pharmacy for restocking.
(g) The name and signature of the pharmacist who received the box for restocking.
(11) Upon return of the drug box to the pharmacy, the pharmacist shall reconcile the drugs dispensed from the drug box with the prescriptions of the ~~attending physician~~ appropriate prescriber or medical director of the hospice. The pharmacist shall note that the prescriptions were dispensed issued from the hospice drug box on the back of the prescriptions. The prescriptions must be filed in the same manner as other prescriptions are maintained at the pharmacy.

Board Response	The Board

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~~ **secretary** of ~~State~~ **state** unless adopted under section 33, 44, 45a(6), **of the administrative procedures act** ~~or 48~~ 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~~ **secretary** of ~~State~~ **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, **and 17742a** of **the public health code,** 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 333.17742a** 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, and R 338.3662 are added as follows:

R 338.3651 Pharmacy technician licensure; eligibility; examination.

Rule 1. **Unless exempt pursuant to section 17739a(4) of the code, MCL 333.17739a, while a student enrolled in a pharmacy technician program approved by the board under R 338.3655, or a licensee who holds a temporary pharmacy technician license under R 338.3652 and section 17739b of the code, MCL 333.17739b, or holds 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~~ **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 (PTCB) or the National Healthcareer Association (NHA).**

(ii) A nationally recognized **and administered** pharmacy technician certification examination that ~~covers 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 338.3654**.

(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 meet the English proficiency requirement in R 338.7002b.~~

(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.

R 338.3652 Temporary License.

Rule 2. (1) Subject to the limitations in section 16181 of the code, MCL 333.16181, and under section 17739b, MCL 333.17739b, the department may issue a nonrenewable, temporary license to an applicant who is preparing for the proficiency examination and has completed all requirements for licensure as a pharmacy technician except passing the proficiency examination required under section 17739a(1)(d) of the code, MCL 333.17739a.

(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~~ **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 of 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 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 licensed 5 or more years in another state, the applicant is presumed to meet the requirements of section 17739a(1)(d) of the code, MCL 333.17739a(1)(d).~~

~~(c) Beginning March 16, 2021, meet the English proficiency requirement in R 338.7002b.~~

(e) 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) **and (2)** 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) Except for the Pharmacy Technician Certification Board examination and National Healthcareer Association examination, 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) Applications filed after the effective date of this rule for approval of an employer-based training program proficiency examination shall be offered in association with a specific employer-based training program and cover the topics specified in section 17739a(1)(d)(iv) of the code, MCL 333.17739a.

(4) Beginning July 1, 2022, all employer-based training program proficiency examinations must be offered in association with a specific employer-based training program, meet the accreditation standards of the accrediting body that accredited the program under R 338.3655, and cover the topics specified in section 17739a(1)(d)(iv) of the code, MCL 333.17739a.

(5) The applicant shall submit to the department a completed application on a form provided by the department and a copy of the examination with the correct answers clearly identified for each question.

(6) Board approval of a nationally recognized certification proficiency examination or an employer-based training program examination before the effective date of this rule expires on July 1, 2022. Board approvals after July 1, 2022, shall be made pursuant to all of the subrules, except subrule (3), in this rule, and the approval shall expire 5 years after the date of approval.

(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~~ **The** following pharmacy technician programs are considered board-approved ~~for this purpose~~:

(a) A pharmacy technician program that is accredited by the ~~accreditation council~~ **Accreditation Council** for ~~pharmacy education~~ **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**.

(2) An applicant for approval of a pharmacy technician program listed in this subrule shall submit an application to the department on a form provided by the department, along with an attestation form that verifies compliance with the information required by subrule (3) of this rule.

~~(c)~~ **(a)** A 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.

~~(d)~~ **(b)** A pharmacy technician training program utilized by a pharmacy or employer that includes training in the functions, specified in **section 17739(1) of the code,** MCL 333.17739~~(1)~~, **and R 338.3665,** required to assist the pharmacist in the technical functions associated with the practice of pharmacy.

~~(2)~~ **(3)** The contents of the training programs offered under ~~subdivisions (c) and (d) of~~ subrule ~~(1)~~ **(2)** of this rule **must** 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 application shall 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.~~

(4) Beginning July 1, 2022, applicants shall meet this subrule and subrules (5) to (9) of this rule. All board approved pharmacy technician ~~program~~**programs, including employer-based training programs, shall be** ~~that is~~ accredited by ~~the accreditation council for pharmacy education (acpe)~~**an accrediting body recognized by the U.S. Department of Education.**

(5) As of the effective date of this rule, a pharmacy technician program that is accredited by a body recognized by the U.S. Department of Education will be approved by the board after submittal of a complete application on a form provided by the department, to the department with proof of accreditation.

(6) ~~(4)~~ **The pharmacy technician program or employer shall maintain** ~~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~~ **for 3 years after a student completes or leaves the program, which shall include all of the following**:

(a) The full name and date of birth of the pharmacy technician student.

(b) The starting date of the pharmacy technician ~~education~~ program and date the student successfully completed the program.

(c) The program syllabus and activities performed in the program.

(7) A pharmacy technician program that was board approved before the effective date of these rules must meet the requirements in these rules beginning July 1, 2022 and may apply to maintain board approval by complying with subrule 4 of this rule after the effective date of these rules. Board approvals beginning July 1, 2022, shall be pursuant to the requirements of this rule and the approval expires 5 years after the date of approval. Upon review after 5 years, a pharmacy technician program may be reapproved if it has maintained its accreditation.

(8) A student shall complete a board approved pharmacy technician program within 2 years of beginning the program in order to maintain his or her exemption from licensure in subrule (9) of this rule, and R 338.3651.

(9) A student in a board approved pharmacy technician program under this rule is exempt from, and not eligible for, licensure while in the program.

R 338.3657 ~~Requirements for relicensure;~~ **Relicensure requirements for** pharmacy ~~technician~~ **technicians**.

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~~ **as applicable,** 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 pharmacy technician who has let his or her license lapse and who is not currently licensed in another state:**	Lapsed 0-3 ~~Years~~ **years**	Lapsed more than 3 years
(a) ~~Application and fee~~ **Application and fee**: Submit a completed application on a form provided by the department, together with the requisite fee**.**	√	√
(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 338.47.	√	√
(c) Submit fingerprints: Submit fingerprints as required under section 16174(3) of the code, MCL 333.16174.		√
(d) ~~Continuing education~~ **Continuing education**: Submit proof of having completed 20 hours of continuing education specified in R 338.3661(1)**(d)**~~(a)(i)~~ which was completed within the 2-year period ~~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 relicensure, pass 1 of the examinations specified in R 338.3651(b)(i**)** to **(**iii).		√
(f) 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.	√	√
(g) Verification: Submit verification from the licensing agency of all other states of the United 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.~~

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 338.3661 ~~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 preceding the end of the license cycle,** shall **during the 2 years immediately preceding the application for 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 March 16, 2021, meet the English proficiency requirement in R 338.7002b.**

~~(c) Comply with R 338.3659.~~ **(b) Complete the training in identifying victims of human trafficking as required in R 338.3659.**

~~(d)~~ **(c) If licensed for the entire 2-year period preceding the application for renewal,** Comply ~~**comply**~~ with 1 of the following:

(i) ~~Except as otherwise provided, complete at least~~ **Complete not less than** 20 hours of continuing education courses or programs **approved by the board, during the 2 years preceding the application for renewal,** as follows:

(A) No more than 12 hours of continuing education credit may be earned during a 24-hour period.

(B) ~~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 the same 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) ~~At least~~ **Not less than** 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) A continuing education course or program that is offered or approved by any of the following providers is approved by the board:

(1) A pharmacy technician educational program that has been approved by the board.

(2) A course or program approved by another state board of pharmacy.

(3) A program approved by the ACPE.

(4) A course or program approved by the board under R 338.3663.

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

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

(ii) Complete a proficiency examination as specified in R 338.3651(b)(i) to (iii).

~~(2)~~ **(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.

(4) Effective for applications for renewal that are filed for the renewal cycle that begins 1 year or more after the effective date of this subrule, the applicant shall meet the requirements of this subrule, and the requirements in subrules (1)(a), (1)(b), (2), and (3) of this rule. An applicant for a pharmacy technician license who has been licensed for the entire 2-year period preceding the end of the license cycle, shall during the 2 years immediately preceding the application for renewal complete not less than 20 hours of continuing education courses or programs approved by the board under R 338.3662 as follows:

(a) One hour shall be in pharmacy ethics and jurisprudence.

(b) 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, and clinical applications as they relate to professional practice.

(c) One hour shall be in patient safety.

(d) No more than 12 hours of continuing education credit may be earned during a 24-hour period.

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

(f) Not less than 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.

R 338.3662 Format of acceptable continuing education for licensees.

Rule 12. Effective for applications for renewal that are filed for the renewal cycle that begins 1 year or more after the effective date of this subrule, 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:**	**The number of hours earned is 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**

	• A pharmacy program accredited by the 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 program or activity for continuing education credit, and the date on which the program was held, or activity completed.	of participation may be earned. No limitation on the number of hours earned.
(b)	Completion of pharmacy practice or administration courses offered for credit in a pharmacy program accredited by the ACPE or the CCAPP. If audited, a licensee shall submit an official transcript that reflects completion of the postgraduate pharmacy practice or administration course and number of semester or quarter credit hours earned.	Twelve hours of continuing education are earned for each academic quarter credit earned and 18 hours are earned for each academic semester credit earned. No limitation on the number of 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. 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.	One hour is earned for each hour devoted to a home study program. A maximum of 20 hours per renewal period.
(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	Twenty hours are earned. A maximum of 20 hours may be earned in each renewal period.

	licensee resides and practices in another state. **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 as the author or a publication acceptance letter.**	**Ten hours are earned per publication.** **A maximum of 10 hours may be earned in each renewal period.**
(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 description.** **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.**	**Two hours for every 50 minutes devoted to presenting the program.** **A maximum of 10 hours may be earned in each renewal period.**
(g)	**Attendance at a pharmacy-related program, which is approved by the board pursuant to R 338.3663.** **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 education credit, and the date on which the program was held or the activity was completed.**	**The number of hours earned is 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.**

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 meets the requirements of R 338.3661(1):~~

~~(a) A pharmacy technician educational program that has been approved pursuant to R 338.3655.~~

~~(b) Another state board of pharmacy.~~

~~(c) A program approved by the Accreditation Council for Pharmacy Education (ACPE).~~

~~(2)~~ **(1)** A continuing education ~~provider~~ **course or program** that is not pre-approved under ~~subrule (1) of this rule~~ **R 338.3661(2)(a)(v) or 338.3662(a)** 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 **course or** program date**, and no later than 70 days before the next regularly scheduled board meeting**. **A continuing education course or program conducted before board consideration and approval shall 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.

(2) A continuing education course or program must meet the standards and criteria for an acceptable category of continuing education in effect at the time of application and must be relevant to health care and advancement of the licensee's pharmacy technician education.

(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~~ **contributes** 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~~ **enhances** 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 from the date of approval.

(5) An approved continuing education course or program must be reevaluated by the board before 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 not less than 70 days before the date the continuing education course or program is offered to participants and not less than 70 days before the next regularly scheduled board meeting to be considered for approval by the board. Changes to a submitted and previously approved continuing education course or program, other than those approved under subdivision (d) of this subrule, shall not be made to the course or program without prior approval.

(d) Emergency changes to instructors and speakers that are unable to be submitted to the board not less than 70 days before 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 is 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 non-sterile dosage forms consistent with approved labeling provided by the manufacturer of a commercially available product.

(b) Technology-assisted final product verification, which means a licensed pharmacy technician verifies the work of another licensed pharmacy technician, where the first licensed pharmacy technician processed a medication order or prescription, pursuant to pharmacist verification of that order; using bar-coding or another board-approved error prevention technology, subject to all of the following requirements:

(i) The licensed pharmacy technician holds a current full pharmacy technician license in this state, not a temporary or limited license.

(ii) The licensed pharmacy technician performing technology-assisted final product verification has completed a board approved pharmacy technician program under R 338.3655.

(iii) The licensed pharmacy technician performing technology-assisted final product verification has not less than 1000 hours of pharmacy technician work experience in the same kind of pharmacy practice site in which the technology-assisted final product verification is performed while holding a current full pharmacy technician license in this state, not a temporary or limited license.

(iv) The practice setting where a licensed pharmacy technician performs technology-assisted final product verification has in place policies and procedures including a quality assurance plan governing pharmacy technician technology-assisted final product verification.

(v) The licensed pharmacy technician uses a technology-enabled verification system to perform final product verification.

(vi) The technology used must document and electronically record each step of the prescription process including which individuals complete each step.

(vii) A licensed pharmacy technician shall not perform technology-assisted final product verification for sterile or nonsterile compounding.

(viii) Technology-assisted final product verification by a licensed pharmacy technician is not limited to a practice setting.

(ix) Except for a remote pharmacy that is regulated under sections 17742a and 17742b of the code, MCL 333.17742a and MCL 333.17742b, a pharmacy technician shall not participate in technology-assisted final product verification remotely. Technology-assisted product verification must be done on-site.

(ix) A pharmacist using their professional judgment may choose to delegate technology-assisted final product verification after ensuring licensed pharmacy technicians have completed and documented relevant training and education.