MICHIGAN BOARD OF PHARMACY
RULES COMMITTEE WORK GROUP
MEETING

MINUTES
JUNE 7, 2023

The Michigan Board of Pharmacy Rules Committee Work Group met on June 7, 2023. The meeting was held via Zoom.

CALL TO ORDER

Andria Ditschman, Departmental Specialist, called the meeting to order at 1:02 p.m.

ATTENDANCE

Members Present: Pierre Boutros, R.Ph.
Grace Sesi, PharmD
Michael Sleiman, PharmD
Sandra Taylor, R.Ph.

Members Absent: None

Staff Present: Andria Ditschman, JD, Departmental Specialist,
Boards and Committees Section
Jacob Poynter, Manager, Licensing Division
Stephanie Wysack, Board Support Technician,
Boards and Committees Section

Public Present: Jamie Tharp – Pharmacy-Compliance, University of Michigan Health

RULES DISCUSSION

Pharmacy – General Rules– Public Comment Summary (A copy of the draft, pursuant to today's discussion, is attached)

Ditschman stated that the purpose of today's meeting was to review public comments received during the open comment period for the public hearing held on June 5, 2023.

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

Section (d):

Baran comment: The commenter requested that 338.588c be modified to 338.588b.

The committee agreed with the comment.

R 338.501 Definitions.

Section (1)(q):

Morris comment: The commenter asked that the definition of MPJE be removed from the rules.

The committee accepted the comment. The committee is removing the requirement to take the MPJE throughout the draft rules, therefore the definition is not necessary.

Section (1)(x):

Baran comment: The comment requested that "individual" be changed to "person."

The committee agreed with the comment as a virtual manufacturer could be a company which is a "person."

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

Baran comment: The commenter suggested adding a limit on how long proof of training should be retained.

Ditschman asked the committee if a timeline was needed.

Poynter stated that the language should be consistent with other rule sets.

The committee did not agree with the comment but asked that the department put out some form of statement regarding retention for audit purposes.

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

Section (1):

Roath comment: The commenter stated that the language "or is within 180 days of completing" appeared to be redundant and provided suggested language for clarification.

Discussion was held.

The committee rejected the comment as the language was clear as written.

Section (6):

Baran comment: The commenter suggested adding "and rule 338.7004" to the end of the rule to add clarification.

Discussion was held.

The committee agreed with the suggested addition.

R 338.517 Preceptor license and responsibilities.

Section (3)(b):

Baran and Young comments: The commenters requested that the reference to R 338.501(1)(u) be corrected to R 338.501(1)(v).

The committee agreed with the comment as it is the correct reference.

R 338.519 Examinations adoption; passing scores; reexamination.
R 338.521 Pharmacist licensure by examination.
R 338.523 Pharmacist license by endorsement; requirements.
R 338.525 Relicensure of a pharmacist license; requirements.

Multiple commenters requested that the MPJE be removed. There were also comments to retain the MPJE for endorsement, which is proposed to be modified to only an attestation.

Sleiman stated that the trend in other states is to remove the MPJE, so Michigan should do that too.

Taylor suggested leaving the MPJE as a requirement for examination and only require an attestation for endorsement.

Discussion held on the comments and rationale for removing the MPJE and only having an attestation for endorsement.

The committee agreed to remove the requirement for the MPJE throughout the rules but require an attestation of familiarity with Michigan law and rules for endorsement.

R 338.521 Pharmacist licensure by examination.

Ryan comment: The commenter requested a new provision to be added to allow for new graduates to apply by examination by submitting a score transfer.

Poynter stated that this would open up licensure for applicants as score transfer can cause an applicant to be stuck when applying to multiple states at one time. He suggested accepting this option and allowing it for applicants who have been licensed for less than one year in another state but used score transfer through NABP.

The committee agreed with the comment for applicants licensed less than one year in another state to be able to be licensed by examination with a score transfer.

R 338.525 Relicensure of a pharmacist license; requirements.

Section (1)(f) and (4)(g):

Young comment: The commenter suggested that the English proficiency requirement be removed as this should only be required for initial licensure, not relicensure.

Ditschman stated that the general rules state initial licensure so this should be removed.

The committee agreed with the comment to remove the English proficiency requirement.

R 338.531 Pharmacy license; remote pharmacy license; applications; requirements.

Section (1)(d):

Foumia comment: The commenter asked at what point in an extended absence from work is the 8 hours per week requirement forgone. Should clarification be added to the rule?

Sesi and Sleiman both stated that the 8 hour per week requirement is an average and would not be affected by an absence.

The rules committee rejected the comment because 8 hours per week is an average and any change would possibly penalize the licensee on leave or the pharmacy.

R 338.532 Sterile compounding accrediting organizations; board.

Section (5):

Baran comment: The comment provided proposed language for (a) and (b) as to when the department should provide notification of rescinded approvals and how a pharmacy would receive this information from accrediting organizations.

Discussion held.

The committee rejected the comments, stating that removal from the posted list is sufficient.

R 338.533 Compounding standards and requirements; outsourcing facilities; requirements.

Section (1): Multiple commenters asked for the removal of the specific dates in the rule, only including the 2023 version of the USP, to include a reference to adopting USP 800, and to include a statement that all future versions would be adopted.

Ditschman read the requirement from the code.

Discussion was held as to the fact that parts of USP 800 are referenced under USP 795 and 797, therefore portions of USP 800 will be included when UPS 795 and 797 are adopted.

The committee rejected the comment to delete all dates in the rule or to adopt all future versions of USP, as there is a process in the code to adopt changes to the USP that occur in the future. The rejected the comment to adopt all of USP 800, as it is not yet being adopted in its entirety and recognizing that once it is, the department will address that with the board.

Section (1):

Young comment: The commenter asked that “except for flavoring” be adopted and that the range for relative humidity be addressed.

The committee agreed with the “exception of flavoring.”

Discussion held about a level for monitoring relative humidity. Ditschman stated that NABP currently uses a range of 35-60%. Ditschman will obtain further information and the issue will be open for discussion with the board.

Section (2): Multiple commenters asked that the rule be clarified to state that there was a charge for obtaining copies of USP chapters.

The committee agreed with the comment as well as to indicate that the department cannot provide that information.

Section (4):

Herz/Tharp comment: Tharp clarified her comment regarding the date for cGMP.

Ditschman clarified that the rules for writing rules required a date or version, however, as this is a federal law and should be followed. The language “or as amended” will be added.

The committee agreed with the comment and the suggested language to accommodate for changes in the date.

Tharp clarified the suggested language that requested modifying the rule to a 2-step inspection process, similar to the proposed language for in-state initial pharmacy license inspections.

Poynter stated that the change would be beneficial to obtaining licensure.

The committee agreed with the comment and to add the suggested language for a 2-step inspection process.

R 338.534a In-state initial pharmacy license inspections.

King/Belding comment: The commenters asked that the 2-step inspection process be removed as a second inspection is redundant and burdensome on the facility.

Poynter explained that the 2-step process was added in order to allow for preliminary licensure to be granted as it was difficult for facilities to meet the requirements of an inspection to show USP compliance without licensure that allowed them to have inventory, etc.

Discussion was held.

The committee rejected the comment, stating that the 2-step process was beneficial to the facility seeking licensure.

R 338.537 Professional and technical equipment and supplies.

Section (1)(b):

Young comment: The commenter provided updated language to incorporate technology and allow for electronic copies.

Discussion was held.

The committee agreed with the suggested language as hard copies are rarely used and can be outdated.

Section (2):

Baran comment: The comment provided suggested language to clarify equipment and supplies required in a pharmacy.

Discussion was held.

The committee rejected the language as it would cause the rule to be too restrictive.

R 338.538 Closing pharmacy.

Section (1):

Foumia comment: The commenter suggested removing language requiring the return of the license to the department as licenses are now provided as a printable PDF and not mailed out by the department.

The committee agreed with the comment and to remove the language requiring the return of a license.

R 338.555 Federal regulation on good manufacturing practice for finished pharmaceuticals; adoption by reference; compliance.

Multiple commenters suggested removing the date for cGMP.

Ditschman stated that the same change could be made as agreed to for R 338.533, Section (4).

The committee agreed with the comment and the suggested language change.

R 338.569 Wholesale distributor and wholesale distributor-broker recordkeeping and policy requirements.

Section (1)(d):

Baran comment: The commenter provided language to clarify the rule to include the drug supply chain security act.

Sesi stated that federal regulation was being followed, so additional clarification in the rule was not need.

The committee rejected the comment stating that no further clarification was needed as federal regulation was being followed.

R 338.583a Pharmacy acquisition and distribution records.

Section (1):

Baran comment: The comment requested that "and non-prescription" be deleted as it was burdensome for the pharmacies.

Discussion was held.

The committee agreed with the comment to delete "and non-prescription."

The commenter additionally requested that the rule be written to be consistent with the controlled substance rules to maintain "records for 2 years."

Ditschman stated that the controlled substance rules had been modified to be "5 years with ability to make electronic after 2 years."

Since the controlled substance rules had already been modified to "5 years with ability to make electronic after 2 years," no change was needed.

R 338.588 Automated devices.

Baran comment: The commenter stated that the timeframe in this rule is inconsistent with the controlled substance rules.

Discussion was held.

The committee agreed with the comment, except that the change needed to be made in the controlled substance rules.

R 338.588a Automated devices in non-inpatient settings.

Section (1)(a): Multiple commenters requested that the rule be modified to allow for controlled substances.

Poynter clarified that the DEA does not allow for controlled substances except for limited circumstances to be dispensed from automated devices.

The committee rejected the comment as the DEA will only allow in limited circumstances for controlled substances to be dispensed from an automated device.

ADJOURNMENT

Ditschman stated that another Rules Committee Work Group meeting would be needed to complete the review of the public comments.

Ditschman adjourned the meeting at 3:00 p.m.

Prepared by:
Stephanie Wysack, Board Support Technician June 20, 2023
Bureau of Professional Licensing

Pharmacy – General Rules - ORR 2022-08 LR
Public Comment Summary
Rules Committee's Recommendations and Board Decisions regarding June 2, 2023, Public Comments

Testimony/Comments Received:

Douglas Apple, Ascension Michigan
Rose Baran
Todd Belding, Sparrow
Ryan Bickel, Ascension Borgess
Gary Blake
Randy Burke
Alisha Cottrell, Ascension Michigan
Michelle Dehoorne
Deeb Eid, CVS Health
Rony Foumia
Denise Frank, Gates Healthcare Associates, Inc.
Mark Guzzardo
Lisa Herz
Lee King, Sparrow Health System
Bradley McCloskey, University Compounding Pharmacy
David Medina
Jasmine Mehta
David Miller, Keystone Pharmacy
Jessica Morris
Eric Roath, Michigan Pharmacists Association
Colleen Ryan
Renee Smiddy, Michigan Health & Hospital Association
Jamie Tharp, Pharmacy-Compounding Compliance, University of Michigan Health
Jeffrey Thomas, Ascension Rx

Chad Whitefield, University Compounding Pharmacy
Maria Young, University Pharmacy

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

Rule Numbers	Commenter	Comment
Section (d)	Baran	Delete 338.588c as there is no rule 338.588c in this rule set or the current rule set.
Rules Committee Response	The Rules Committee agrees that 338.588c should be modified to 338.588b.	

Board Response	

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 that is licensed or approved by the state, which directly or indirectly provides or includes pharmacy services.

(b) "Pharmacy services" means the direct and indirect patient care services **for patients in a medical institution,** associated with the practice of pharmacy.

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

(3) Pharmacy personnel who assist the pharmacist by performing delegated functions in the care of patients of a medical institution ~~shall be~~**are** 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 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 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 prescriber before **the** administration of first doses. If the interpretation and review will cause a ~~medically unacceptable~~ delay **that would adversely affect a patient's medical condition,** ~~then~~ a limited number of medications may be stocked at the patient care areas for the

administration of first doses. Medications must be provided in a manner that ensures security and immediate availability, ~~such as~~**including** 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) **Furnishing medications for administration to registered patients under R 338.588 and 338.588~~c~~b.** ~~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.

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

(g) 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.

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

(i) Providing educational programs ~~regarding~~ **that include, but are not limited to,** medications **used by the medical institution** and their safe use.

(j) Providing a ~~method~~**process** 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 process must comply with all of the following:**

(i) ~~The method shall minimize~~**Minimize** the potential for medication error.

(ii) During the absence of a pharmacist, the services of a pharmacist must be available on an on-call basis.

(iii) Only a limited number of medications that are packaged in units of use must be available.

(iv) The medications must be approved and reviewed periodically as **determined** ~~deemed~~ necessary, but not less than once a year, by an appropriate interdisciplinary practitioner committee of the medical institution.

(v) The medication must be ~~kept~~ **maintained** in a securely locked, substantially constructed cabinet or its equivalent in an area of limited access in a centralized area outside the pharmacy.

(vi) Each medication must be labeled to include the name of the medication~~,~~**;** the strength~~,~~**;** the expiration date, if dated~~,~~**;** and the lot number.

(vii) A written order and a proof of removal and use document ~~must be~~**are** obtained for each medication unit removed **and** ~~The order and document shall be~~ reviewed by the pharmacist within 48 hours of removing medication from the cabinet or its equivalent.

(viii) The pharmacist who directs pharmacy services in the medical institution shall designate the practitioners who are ~~permitted~~ **allowed** to remove the medication.

(ix) A pharmacist shall audit the storage locations as often as needed to guarantee control, but not less than once every 30 days.

(5) ~~Upon~~ **On the** recommendation of an interdisciplinary 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~~**not less than** 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, must be labeled on the medication container. The container may be the individual patient's assigned medication drawer. The directions for use 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 must be on the container. The provisions of this subrule are minimum labeling standards only and do not supersede other applicable laws or rules.

(7) A pharmacist shall supervise the destruction of unused portions of prescription medication, other than controlled substances under part 71 of the code, MCL 333.7101 to 333.7125, dispensed to patients. However, medications in single-unit packages and intravenous solutions ~~which~~**that** 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~~ **must** not be returned to stock for dispensing.

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

Rule 338.501 Definitions.

Rule Numbers	Commenter	Comment
Section (1)(q)	Morris	Delete MPJE definition.
Section (1)(x)	Baran	Individual in this section (**x**) should be changed to "person".
Rules Committee Response	(1)(q): As the Rules Committee agrees that with the comments to delete the requirement for licensing to take the MPJE, the reference to the MPJE in the definitions should be deleted. (1)(x): The Rules Committee agrees with the comment that "individual" should be changed to "person" as a virtual manufacturer may be a company.	

Board Response	

(q) ~~"MPJE" means the Michigan multistate pharmacy jurisprudence examination.~~

(x)(~~k~~) "Virtual manufacturer" means ~~**an individual**~~ 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 ~~**individuals**~~ persons, for resale, compounding, or dispensing of, drugs or devices, salable on prescription only.

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

Rule Numbers	Commenter	Comment
New provision	Baran	The rule lacks a time period the licensee needs to hold the documentation of completing the training for identifying the victims of human trafficking. The current status of this rule would mean the licensee would have to retain documentation for as long as they are licensed in Michigan. Add: (3) *A licensee or registrant shall retain documentation of meeting the requirements of this rule for a period of 6 years after the date of applying for licensure, registration, or renewal.*
Rules Committee Response	The Rules Committee does not agree to add a time limit for maintaining proof of attendance as this rule is the same in all health professions. However, the Rules Committee has asked the Department to address the concern.	

Board Response	

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

Rule 11. (1) ~~Pursuant to~~**Under** section 16148 of the code, MCL 333.16148, ~~an~~ **the** individual seeking licensure or **who** is licensed shall **have** complete**d** 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~~**healthcare** settings.

(iii) Identifying the warning signs of human trafficking in ~~health care~~**healthcare** settings for adults and minors.

(iv) **Identifying** ~~Resources~~ **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~~ **peer-review** journal, ~~health care~~**healthcare** 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 **an individual** ~~a sample of individuals~~ and request documentation of proof of completion of training. If audited by the department, ~~an~~ **the** 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~~ **the** individual. The certification statement must include the individual's name and ~~either~~ **1** of the following:

(i) For training completed ~~pursuant to~~**under** subrule (1)(b)(i) to (iii) of this rule, the date, training provider name, and name of training.

(ii) For training completed ~~pursuant to~~**under** subrule (1)(b)(iv) of this rule, the title of article, author, publication name of ~~peer review~~ **the peer-review** journal, ~~health care~~**healthcare** journal**,** or professional or scientific journal, and **the** 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 January 1, 2020 and for initial licenses issued after November 13, 2022.~~

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

Rule Numbers	Commenter	Comment
Section (1)	Roath	The phrase "or is within 180 days of completing" seems redundant. If an individual is within 180

		days of completing a program, it would stand to reason they are actively enrolled in the program. We believe that this phrasing may have been an oversight, and that the original intent of the rule was to allow individuals who had recently completed an education program to secure an educational limited license. This grace period is important for allowing new graduates from out of state to work in the pharmacy while their full license is pending. Suggested revision: "(1)(a) That the applicant is actively enrolled in an approved educational program *or has completed an approved educational program within the past 180 days.*" "(2)(a) At the time of renewal, the applicant shall submit verification to the department that the applicant is actively enrolled in an approved educational program, *or has completed an approved educational program within the past 180 days*."
Section (6)	Baran	Rule 338.7004 requires an individual applying for licensure or registration under article 15 of the code, MCL 333.16101 to 333.18838, except those seeking to be licensed under part 188 of the code to obtain Implicit Bias Training. Add at the end of (6): *and rule 338.7004.*
Rules Committee Response	(1): The Rules Committee does not agree to change the language as it feels that the current language is clear. (6): The Rules Committee agrees that "and rule 338.7004" to clarify for applicants that they must attend the implicit bias training to receive an educational limited license.	

Board Response	

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~~ **1** of the following:

(a) That the applicant is actively enrolled in, or is within 180 days of completing, an approved educational program.

(b) That the applicant has received a ~~Foreign Pharmacy Graduate Examination Committee (~~FPGEC~~)~~ certification from the ~~National Association of Boards of Pharmacy (~~NABP~~)~~ Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr**ive.**~~.~~, Mount Prospect, Illinois, 60056, https://nabp.pharmacy/programs/fpgec/.~~)~~

(2) The educational limited license must be renewed annually as follows:

(a) At the time of renewal, the applicant shall submit verification to the department that ~~he or she~~ **the applicant** is actively enrolled in, or is within 180 days of completing, 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~~ **the licensee's** pharmacy preceptor holds a valid preceptor license ~~prior to~~ **before** 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~~ **the licensee** 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 **and R 338.7004**.

Rule 338.517 Preceptor license and responsibilities.

Rule Numbers	Commenter	Comment
Section (3)(b)	Baran, Young	R 338.501(1)(u) should be modified to R 338.501(1)(v), as (u) is not the correct definition.
Rules Committee Response	The Rules Committee agrees that the reference to (u) should be modified to (v).	

Board Response	

R 338.517 Preceptor license and responsibilities.

Rule 17. (1) An applicant for licensure as a pharmacist preceptor shall submit to the department a completed application on a form provided by the department.

(2) The applicant shall satisfy both of the following:

(a) Have an unrestricted pharmacist license from this state that is in good standing for the past year.

(b) Have been engaged in the practice of pharmacy in this state for at least 1 year.

(3) A preceptor shall do all of the following:

(a) Ensure that the pharmacist on duty is supervising not more than 2 pharmacist interns at the same time. The approved preceptor is responsible for the overall internship program at the pharmacy.

(b) Determine the degree of the intern's professional skill on the topics listed in R 338.501(1)(~~j~~**u**) and develop a training program where~~by~~ the intern can improve ~~his or her~~ **the intern's** skill in these areas.

(c) Ensure sufficient time to instruct the intern on the topics in R 338.501(1)(~~j~~**u**) and review and discuss the intern's progress on the topics in R 338.501(1)(~~j~~**uv**).

(4) ~~(d) Annually submit to the department training affidavits that include the number of internship hours completed by the intern in the practice of pharmacy.~~

Unless the hours are completed in an educational program, the preceptor shall submit to the department a training affidavit that includes the number of internship hours completed by the intern in the practice of pharmacy.

Rule 338.519 Examinations adoption; passing scores; reexamination.

Rule Numbers	Commenter	Comment
Section (2), (3), (5), (8)	Morris	Remove adoption of MPJE.
	Burke	Consider removing the MPJE requirement.
	Mehta	Remove the MPJE requirement.
Rules Committee Response	The Rules Committee agrees with the comments to remove the MPJE requirement for the following reasons: • There is no evidence that passing the examination increases a comprehensive knowledge of the law and therefore protects the public. • The ACPE requires law to be taught in a pharmacy program. • There is no evidence that the safety of the public is decreased if a licensee does not take the MPJE. • Taking and passing the examination does not result in a pharmacist applying the law correctly. • Technological advancements and electronic pharmacy dispensing systems have greatly facilitated adherence to professional practice standards. Many of the specific details, such as information on prescription labels or permissible refills, are now automatically checked and enforced by these systems, alleviating the burden on pharmacists to memorize every minute aspect of the laws.	

Board Response	

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~~**2**) The passing score for the NAPLEX ~~or the MPJE~~ accepted for licensure **is** ~~will be~~ the passing score established by the NABP.

(~~4~~**3**) An applicant **that** ~~who~~ fails to pass the NAPLEX shall wait ~~at least~~**not less than** 45 days to retest or comply with the current waiting period established by NABP, whichever is longer. An applicant **that** ~~who~~ has not achieved a passing score on the NAPLEX may not take the NAPLEX more than 3 times in a 12-month period.

~~(5) An applicant **that** who fails to pass the MPJE shall wait at least **not less than** 30 days to retest or comply with the current waiting period established by NABP, whichever is longer.~~

(~~6~~**4**) If an applicant for licensure fails to pass ~~either of these examinations,~~**the NAPLEX** within 3 attempts, the applicant shall request preapproval from the department, after consultation with a board member, if necessary, of a live or interactive examination preparation course, or instruction with an instructor with expertise on the subject matter, for the examination that ~~he or she~~ **the applicant** failed. After participating in the course or instruction the applicant shall provide the department with proof that ~~he or she~~ **the applicant** completed the course or instruction.

(~~7~~**5**) An applicant may not sit for the NAPLEX specified in subrule (4) of this rule more than 5 times, unless ~~he or she~~ **the applicant** successfully repeats an approved education program, as specified in R 338.521(2)(a)(i) and provides proof of completion to the department.

~~(8) An applicant may not sit for the MPJE specified in subrule (5) of this rule more than 5 times, unless he or she **the applicant** 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 department.~~

Rule 338.521 Pharmacist licensure by examination.

Rule Numbers	Commenter	Comment
Section (2)(b)	Morris	Remove the MPJE requirement. Pharmacy is among a minority of health professions that impose a jurisprudence exam as a prerequisite for licensure. It is worth considering which other health professions require a similar

		exam and if it is truly necessary for ensuring public safety. What evidence or published literature shows that an individual passing this exam one time improves patient safety or outcomes? There are none to my knowledge. When asked, even NABP can not produce an answer to this day-old question. Some arguments in favor of a law exam may stem from conflicts of interest, such as individuals or entities that benefit financially from creating study materials (such as state associations or colleges), generating exam questions, or providing educational content related to the exam. It is important to question the motivations behind such arguments and consider whether they truly contribute to public safety or simply serve vested interests. In addition, NABP has a vested financial interest in making this exam a requirement to ensure they are receiving revenue each year from students and licensees who are taking the test in multiple states. The historical belief that a law exam is required due to the complexity of pharmacy laws may not be entirely applicable today. Technological advancements and electronic pharmacy dispensing systems have greatly facilitated adherence to professional practice standards. Many of the specific details, such as information on prescription labels or permissible refills, are now automatically checked and enforced by these systems, alleviating the burden on pharmacists to memorize every minute aspect of the laws. It is worth noting that there are currently no published articles demonstrating a direct correlation between jurisprudence competence exams and patient safety. Without concrete evidence that passing such an exam leads to safer care provided by pharmacists, the burden of cost and time associated with the MPJE becomes difficult to justify. The COVID-19 pandemic serves as a poignant example of how additional examinations can exacerbate delays in equipping the pharmacy workforce and addressing staffing shortages. Executive orders were required to waive regulations and increase access to pharmacists during this critical time. By removing the MPJE requirement, Michigan can ensure a more efficient and timely

		process for licensing pharmacists. To address potential counterarguments, I offer the following responses: The argument that pharmacists need to know the law when other healthcare professionals may not overlooks the fact that each profession has its own set of laws and rules that its members must adhere to. If passing an exam directly equates to comprehensive knowledge of the laws and rules, then why don't other health professions impose a similar requirement? Technological advancements have significantly improved compliance with laws and regulations. Many aspects of pharmacy practice that previously required manual vigilance are now automated and integrated into computer software and systems. This reduces the reliance on individual pharmacists to memorize every detail, as the technology itself enforces compliance. Removing the MPJE requirement does not necessarily lower the bar for licensure or allow anyone to become a pharmacist. On the contrary, it could attract highly qualified candidates who are seeking a more efficient pathway to licensure and practice. Incompetence exists in every profession, and passing an exam does not guarantee competence. A comprehensive evaluation of candidates' qualifications, including their educational background and performance in pharmacy school, remains critical in ensuring the competency of licensed pharmacists. Concerns about NABP's opinion and potential loss of support should not overshadow the primary objective of protecting public safety. While NABP may experience financial losses due to the removal of the exam, it is the responsibility of the Board of Pharmacy to prioritize patient safety and outcomes over financial considerations. If patient safety remains unaffected by the removal of this administrative requirement, then it should not hinder progress. The responsibility of ensuring pharmacy graduates' competence in state and federal laws lies with the colleges and schools of pharmacy. Accreditation standards set by the Accreditation Council for Pharmacy Education (ACPE) require

		educational institutions to adequately prepare graduates in this regard. The role of the Board of Pharmacy is to evaluate whether passing one exam equates to sufficient competence in all state laws and rules, thus protecting public safety. Last July, the American Association of Colleges of Pharmacy (AACP) which is the association that houses all colleges of pharmacy and faculty as members passed a national emerging resolution in which the academy supports removal of a stand alone examination of federal and/or state pharmacy laws as a requirement for licensure. This was endorsed by members from neighboring states such as WI, OH, IL, and IA. It is also worth considering the examples set by other states that have revised their requirements: Idaho (ID): Since 2018, Idaho has operated without an MPJE requirement and has transitioned to an enforcement approach based on the standard of care. They have reported no increase in complaints to the board and no known patient safety issues resulting from the removal of the exam. Vermont (VT): Vermont recently voted to remove the MPJE requirement, aligning itself with the evolving trends in pharmacy licensure. Ohio (OH): Ohio does not require license transfer applicants to maintain their license by original examination. However, license transfer applicants must have a license in good standing from a member board and transfer their license through the NABP clearinghouse. This approach prioritizes evaluating the equivalence and thoroughness of the examination taken in another state. Wisconsin (WI): Wisconsin currently has a bill being heard by the legislature that would remove unnecessary and unproven licensure requirements for healthcare professionals. The MPJE is amongst those exams/requirements. The state association in WI has publically supported this bill and removal of the MPJE. In conclusion, I urge the Michigan Board of Pharmacy to carefully consider the arguments presented in favor of removing the MPJE requirement. Doing so would represent a progressive and

		forward-thinking approach to pharmacy licensure without compromising patient safety. By streamlining the licensing process, Michigan has the opportunity to attract highly qualified candidates and ensure a competent pharmacy workforce that can meet the evolving healthcare needs of the state. This move also ensures that the Board and staff are utilizing evidence and logical thinking to remove undue barriers while protecting the public.
	Burke	Consider removing the MPJE requirement. Schools of pharmacy are required to have a law course and students are required to memorize, practice, and pass multiple assessments. This has been required for some time now in all states, including Michigan. Our technology has become so advanced and will continue to advance. Even programs such as ChatGPT have shown the ability to pass standardized tests. Pharmacies have technology in place these days that help with ensuring laws/rules are generally followed and pharmacists are healthcare professionals who are held to a high standard. They can look things up in a split second as needed these days. The exam is expensive and costs students who take on an average of $170,000 of debt for pharmacy school yet another expense. NABP is really who profits and gets the financial gain from making students take this meaningless test. If NABP submits comments, there is a direct conflict of interest as they have financial gains from keeping the test as a state requirement (so those should not be considered by the board to be fair). Doctors, nurses, PAs, and almost all other healthcare professionals do not require a law exam to become licensed. Why are they not held to the same "standard" if the exam is so important for patient safety and to truly protect patients? Even Colleges of Pharmacy are calling for removal of the law exam at the national conferences. The article "The Impact of Jurisprudence Exams on Pharmacy Licensure and Patient Safety"

		underscores the need to reassess the role of law exams in pharmacy licensure, focusing on competency assessment and meaningful measures of patient care. It provides great examples of how a state like Idaho logically thought through the process and provides rationale and level headed insights as to why.
	Mehta	Remove the MPJE requirement.
New provision	Ryan	Allow licensure by examination by new grads with a score transfer even though they may be licensed in another state.
Rules Committee Response	(2)(b): The Rules Committee agrees with the comment to delete the MPJE requirement for the reasons stated in R 338.519. (2)(a)(iii): The Rules Committee agrees with the comment to allow initial licensure by score transfer if the applicant has been licensed in another state for 1 year or less.	

Board Response	

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~~,~~**; R 338.7001 to R 338.7005; and any other rules promulgated under the code,** an applicant for licensure shall satisfy all of the following requirements:

(a) ~~Have earned~~**EarnObtain** ~~either~~**one** of the following:

(i) A professional degree from a school of pharmacy accredited by the ACPE.

(ii) A FPGEC certification from the NABP. An applicant **that** ~~who~~ has an FPGEC certification from NABP has met the English proficiency requirement as the applicant's credentials and English proficiency have been evaluated and determined to be equivalent to the credentials required in this state.

(iii) A score transfer from NABP if the applicant has been licensed in another state for 1 day to 1 year.

(b) ~~Passed~~**Pass** the ~~MPJE and the~~ NAPLEX.

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

(d) ~~Completed~~**Complete** a 1-time training identifying victims of human trafficking as required in R 338.511 and section 16148 of the code, MCL 333.16148.

(e) ~~Completed~~**Complete** a 1-time training in opioids and other controlled substances awareness as required in R 338.3135.

(f) ~~Submitted proof to the department of meeting the English language requirement under R 338.7002b and the implicit bias training required in R 338.7004.~~ ~~An applicant who has an FPGEC certification from NABP has met the English proficiency requirement as the applicant's credentials and English proficiency have been evaluated and determined to be equivalent to the credentials required in this state.~~

(3) An applicant **that** ~~who~~ is or has ever been licensed, registered, or certified in a health profession or specialty by ~~any other~~**another** state, the United States military, the federal government, or another country, shall do both of the following:

(a) Disclose each license, registration, or certification on the application form.

(b) Satisfy the requirements of section 16174(2) of the code, MCL 333.16174, **including** ~~which includes~~ verification from the issuing entity showing that disciplinary proceedings are not pending against the applicant and sanctions are not in force at the time of application.

Rule 338.523 Pharmacist license by endorsement; requirements.

Rule Numbers	Commenter	Comment
Section (2)(b)	Morris	Delete MPJE requirement.
Section (2)(b)	Baran	Leave the language: *Pass the MPJE as required under R 338.519.* A pharmacist needs knowledge of both state and federal regulations to competently practice in this state as identified in the competency statements of the MPJE exam. This would allow an applicant who failed the Michigan MPJE to obtain a license in another state and then by endorsement get licensed in Michigan if they attest to the department that they have sufficient knowledge of the code and the board's rules even though they failed the MPJE. Also, there is no attestation here that the applicant is attesting to sufficient knowledge of the laws of the United States Code and Code of Federal Regulations relevant to the practice of pharmacy.
Section 2(b)	Roath	MPA is opposed to removing the requirement to pass the MPJE if seeking licensure via endorsement. We believe an applicant must demonstrate competency in pharmacy practice law in the State. Failure to demonstrate this competency increases the likelihood that pharmacists may inadvertently practice outside of Michigan's state-specific regulations. This represents not only a risk to patient safety but also increases liability exposure for the practitioner.

		Suggested Revision: Retain the old language for R 338.532 (2)(ii)(C)(b): "*Pass the MPJE as required under R 338.519.*"
Rules Committee Response	(2)(b): The Rules Committee does not agree with the comment to delete the requirement for an attestation that the applicant has sufficient knowledge of the code and the board's rules to competently practice pharmacy in this state as the Rules Committee does not agree to require the MPJE for the reasons stated in R 338.519, but also desires an applicant from another state to attest that they have knowledge of this state's laws and rules. The intent of the Rules Committee would be to delete the attestation requirement in the future and instead require additional CE hours regarding this state's laws and rules.	

Board Response	

R 338.523 Pharmacist license by endorsement; requirements.

Rule 23. (1) An applicant **that has never held a pharmacist license in this state and is licensed in another state or Canada, may apply** for licensure as a pharmacist by endorsement ~~shall submit~~ **by submitting** to the department a completed application on a form provided by the department with the requisite fee. An applicant **that** ~~who~~ meets the requirements of this rule**, R 338.7001 to R 338.7005, and any other rules promulgated under the code** 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 1 of the following:

(i) ~~He or she~~ **The applicant** holds a license in good standing as a pharmacist in another state and submits the NABP licensure transfer report to the department.

(ii) ~~He or she~~ **The applicant** holds a pharmacy license in Canada that is in good standing and meets all of the following:

(A) ~~He or she~~ **The applicant** has passed the NAPLEX or both part I and part II of the Pharmacy Examining Board of Canada ~~(PEBC)~~ Pharmacists Qualifying Examination.

(B) ~~He or she~~ **The applicant** completed educational requirements for a pharmacist license from a school of pharmacy accredited by the ACPE or accredited by the Canadian Council for Accreditation of Pharmacy Programs ~~(CCAPP)~~.

(C) If ~~he or she~~ **the applicant** held a pharmacist license for less than 1 year in Canada, ~~he or she~~ **the applicant** had acquired a minimum of 1,600 hours of pharmacy practice either through an approved internship or hours engaged in the practice as a pharmacist.

(b) ~~Pass the MPJE as required under R 338.519~~**Provide an attestation to the department that the applicant has sufficient knowledge of the code and the board's rules to competently practice pharmacy in this state.**

(c) An applicant **that** ~~who~~ is or has ever been licensed, registered, or certified in a health profession or specialty by ~~any other~~**another** state, the United States military, the federal government, or another country, shall do both of the following:

(i) Disclose each license, registration, or certification on the application form.

(ii) Satisfy the requirements of section 16174(2) of the code, MCL 333.16174, **including** ~~which include~~ verification from the issuing entity showing that disciplinary proceedings are not pending against the applicant and sanctions are not in force at the time of application.

(d) ~~He or she~~ **The applicant** meets section 16174 of the code, MCL 333.16174, and submits his or her fingerprints to the department of state police to have a criminal background check conducted by the state police and the ~~federal bureau of investigation~~**Federal Bureau of Investigation**.

(e) ~~He or she~~ **The applicant** completes a 1-time training identifying victims of human trafficking as required in R 338.511 and section 16148 of the code, MCL 333.16148.

(f) ~~He or she~~ **The applicant** completes a 1-time training in opioids and other controlled substances awareness as required in R 338.3135.

~~(g) He or she submits proof to the department of meeting the English language requirement under R 338.7002b and the implicit bias training required in R 338.7004.~~

~~(3)~~**(2)** An applicant **that** ~~who~~ has an FPGEC certification from NABP has met the English proficiency requirement. The applicant's credentials and English proficiency have been evaluated and determined to be equivalent to the credentials required in this state.

Rule 338.525 Relicensure of a pharmacist license; requirements.

Rule Numbers	Commenter	Comment
Section (1)(e) and (4)(f)	Morris	Delete MPJE requirement.
Section (1)(f) and (4)(g)	Young	Delete reference to English language requirement as this should only be required with initial licensure.
(4)(f)	Baran	A pharmacist needs knowledge of both state and federal regulations to competently practice in this state as identified in the competency statements of the MPJE exam. Add: *Must also attest to sufficient knowledge of the laws of the United States Code and Code of*

		Federal Regulations relevant to the practice of pharmacy.
Rules Committee Response	(1)(e) and (4)(f): The Rules Committee agrees with the comment to delete the MPJE requirement for the reasons stated in R 338.519. (1)(f) and (4)(g): The Rules Committee agrees to delete the English language requirement as it is only required for initial licensure. (4)(f):	

Board Response	

R 338.525 Relicensure of a pharmacist license; requirements.

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

For a pharmacist who has let his or her license lapse in this state and ~~who~~ is not currently licensed in another state or a province of Canada:	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~~ **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~~**Establish** that ~~he or she~~ **the applicant** is of good moral character as **that term is** defined **in, and determined** under**,** ~~sections 1 to 7 of~~ 1974 PA 381, MCL 338.41 to MCL 338.47.	X	X	X
(c) ~~Submit fingerprints: submit~~**Submit**		X	X

fingerprints as required under section 16174(3) of the code, MCL 333.16174.			
(d) ~~Continuing education: submit~~**Submit** proof of completing 30 hours of continuing education that satisfy R 338.3041 to R 338.3045 in the 2 years immediately ~~preceding~~ **before** the ~~date of~~ application for relicensure. However, if the continuing education hours submitted with the application are deficient, the applicant has 2 years ~~from~~**after** the date of the application to complete the deficient hours. The application ~~will~~ **must** be held and the license ~~will~~ **may** not be issued until the continuing education requirements **are** ~~have been~~ met.	X	X	X
~~(e) Pass MPJE: r~~**R**~~etake and pass the MPJE as provided in R 338.519.~~		~~X~~	~~X~~
~~**(f) Meet the English language requirement under R 338.7002b.**~~	~~X~~	~~X~~	~~X~~
(~~f~~**e**) ~~Submit~~**Submit** proof of completing a 1-time training in identifying victims of human trafficking as required in R 338.511, a 1-time training in opioids and other controlled substances awareness as required in R 338.3135, and implicit bias training as required in R 338.7004.	X	X	X
(~~g~~**f**) ~~Practical experience: complete~~**Complete** 200 hours of		X	

practical experience under the personal charge of a **pharmacist** currently licensed ~~Michigan~~ **in this state who is located** ~~pharmacist~~ in or outside of ~~Michigan~~ **this state**, within 6 months ~~of of~~ **after** being granted a limited license.			
(~~h~~**g**) ~~Practical experience: complete~~**Complete** 400 hours of practical experience under the personal charge of a **pharmacist** currently licensed ~~Michigan pharmacist~~**in this state who is located** in or outside of ~~Michigan~~ **this state**, within 6 months ~~of of~~**after** being granted a limited license.			X
(~~i~~**h**) ~~Examination:~~**Retake and pass** the NAPLEX within 2 years before applying for relicensure, as provided in R 338.519.			X
(~~j~~**i**) An applicant **that** ~~who~~ is or has ever been licensed, registered, or certified in a health profession or specialty by ~~any other~~**another** state, the United States military, the federal government, or another country, shall do both of the following: (i) Disclose each license, registration, or certification on the application form. (ii) Satisfy the requirements of section 16174(2) of the code, MCL 333.16174, ~~which includes~~ **including** verification from the issuing entity showing that	X	X	X

disciplinary proceedings are not pending against the applicant and sanctions are not in force at the time of application.			

(2) ~~For purposes of~~ **As used in** subrule (1)(~~g~~**f**) and (~~h~~**g**) of this rule, an applicant may be granted a non-renewable limited license to complete the practical experience.

(3) To demonstrate compliance with subrule (1)(~~g~~**f**) or (~~h~~**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 in this state, but who holds a current and valid pharmacist license in good standing in another state or a Canadian province:	License lapsed 0-3 ~~Years~~**years.**	License lapsed more than 3 years, but less than 8 years**.**	License lapsed 8 or more years**.**
(a) ~~Application and fee: submit~~**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~~**Establish** that ~~he or she~~ **the applicant** is of good moral character as **that term is** defined **in, and determined** under**,** ~~sections 1 to 7 of~~ 1974 PA 381, MCL 338.41 to MCL 338.47.	X	X	X
(c) ~~Submit fingerprints: submits~~**Submit** fingerprints as required under section 16174(3) of the code, MCL 333.16174.		X	X
(d) ~~Continuing education: submit~~ **Submit** proof of completing 30 hours of continuing education that satisfy	X	X	X

R 338.3041 to R 338.3045 in the 2 years immediately ~~preceding~~ **before** the ~~date of~~ application for relicensure. However, if the continuing education hours submitted with the application are deficient, the applicant has 2 years ~~from~~**after** the date of the application to complete the deficient hours. The application **must** ~~will~~ be held and the license ~~will~~ **may** not be issued until the continuing education requirements **are** ~~have been~~ met.			
(e) ~~Submit~~**Submit** proof of completing a 1-time training in identifying victims of human trafficking as required in R 338.511, a 1-time training in opioids and other controlled substances awareness as required in R 338.3135, and implicit bias training as required in R 338.7004.	X	X	X
~~(f) Examination: retake and pass the MPJE as provided in R 338.519519~~**~~Provide an attestation to the department that the applicant has sufficient knowledge of the code and the board's rules to competently practice pharmacy in this state.~~**		~~X~~	~~X~~
~~**(g) Meet the English language requirement under R 338.7002b.**~~	~~X~~	~~X~~	~~X~~
(g~~f~~) An applicant **that** ~~who~~ is or has ever been licensed, registered, or certified in a health profession or specialty by ~~any~~	X	X	X

~~other~~**another** state, the United States military, the federal government, or another country, shall do both of the following: (i) Disclose each license, registration, or certification on the application form. (ii) Satisfy the requirements of section 16174(2) of the code, MCL 333.16174, ~~which includes~~ **including** verification from the issuing entity showing that disciplinary proceedings are not pending against the applicant and sanctions are not in force at the time of application.			

(5) If relicensure is granted and it is determined that a sanction has been imposed by another state, the United States military, the federal government, or another country, the disciplinary subcommittee may impose appropriate sanctions under section 16174(5) of the code, MCL 333.16174.

Rule 338.531 Pharmacy license; remote pharmacy license; applications; requirements.

Rule Numbers	Commenter	Comment
Section (1)(d)	Foumia	We also require that a PIC works on average 8 hours a week in a pharmacy to be compliant as a PIC. Are we saying that if a pharmacist in charge goes on a leave of absence i.e., are we forgoing the requirement for them to maintain the 8 hours a week average?
Rules Committee Response	The Rules Committee does not agree with the comment that the provision is inconsistent with the Code requirement for a PIC to work an average of 8 hours a week in each pharmacy, and therefore, does not recommend a change to the rule.	

Board Response	

R 338.531 Pharmacy license; remote pharmacy license; applications; requirements.

Rule 31. (1) An applicant for a pharmacy license or a remote 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.

(c) A ~~federal employer identification number (~~FEIN~~)~~ certificate.

(d) The name and license number of the pharmacist in this state designated as the ~~pharmacist in charge (~~PIC~~)~~ ~~pursuant to~~**under** section 17748(2) of the code, MCL 333.17748, who must have a valid and unrestricted license. **If a PIC is unable to fulfill his or her duties for 120 consecutive days, the pharmacy shall appoint a new PIC and notify the department as required in section 17748(4) of the code, MCL 333.17748.**

(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 compounding services, proof of application with an entity that satisfies the requirements of R 338.532.~~

(~~h~~**g**) ~~An~~**If the applicant is an out-of-state pharmacy that will not provide sterile compounding services, an** inspection report that satisfies the requirements of R 338.534.

(~~i~~**h**) If the applicant is an in-state pharmacy that intends to compound **sterile** pharmaceutical products, the applicant shall submit to an inspection **under R 338.534a** ~~from an approved accrediting organization under R 338.532~~.

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

(~~k~~**j**) If the applicant is applying for a remote pharmacy license, the applicant shall submit the following:

(i) Ownership documents to demonstrate to the satisfaction of the department that the parent pharmacy and the proposed remote pharmacy share common ownership.

(ii) Copies of the policies and procedure manual required in section 17742b of the code, MCL 333.17742b.

(iii) A map showing all of the existing pharmacies within 10 miles of the proposed remote pharmacy if the remote pharmacy will not be located at a hospital or mental health facility.

(~~l~~**k**) If the applicant is or has ever been licensed, registered, or certified as a pharmacy by ~~any other~~**another** state, the United States military, the federal government, or another country, the applicant shall do both of the following:

(i) Disclose each license, registration, or certification on the application form.

(ii) Submit verification from the issuing entity showing that disciplinary proceedings are not pending against the applicant and sanctions are not in force at the time of application.

(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 must obtain a separate license.

Rule 338.532 Sterile compounding accrediting organizations; board.

Rule Numbers	Commenter	Comment
Section (5)	Baran	Need timely notice when the board the rescinds approval of a sterile compounding accrediting organization. This will give notice to the pharmacies involved so they may plan accordingly to obtain accreditation from an approved organization. Add: (a) *If the Board rescinds approval, the Board must indicate on the website that it has, with an effective date.* *(b) If the Board rescinds approval the accrediting organization or inspection entity must notify the pharmacies involved.*
Rules Committee Response	The Rules Committee does not agree with the comments to add information to the website because the only approved organizations will be those listed. Further, the Rules Committee does not agree with the comment to require an approved organization to notify pharmacies as enforcement of this requirement is not feasible.	

Board Response	

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-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 **is** 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~~**after** 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~~ **after** 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.

Rule 338.533 Compounding standards and requirements; outsourcing facilities; requirements.

Rule Numbers	Commenter	Comment
Section (1)	Apple, Belding, Bickel, Blake, Dehoorne, Foumia, Guzzardo, King, McCloskey, Medina, Miller, Roath, Smiddy, Thomas, Young, Whitefield	Opposes the addition of dates to this rule language. The proposed language creates a situation in which pharmacies are required to comply with outdated standards rather than the most current versions. Pharmacies may also be put in a situation where they might need to comply with the latest versions under federal law or for the purpose of accreditation by a non-governmental entity. This may not be possible as revised standards may conflict sufficiently with older versions that simultaneous compliance with both old and new versions is not feasible. Additionally, adding these dates punishes pharmacies that have sought to become compliant with upcoming versions of the standards in advance of official publication. It is anticipated that other regulatory and accrediting bodies (e.g. Joint Commission) will utilize the revised USP standards when evaluating Michigan pharmacies. This would result in state licensed pharmacies having to adopt the strict requirements in the updated chapters without realizing any of the corresponding benefits (e.g. extended BUDs) and leading to increased operational costs and waste. Also, the new standards are more in alignment with the FDA definition of compounding. For multi-state health-systems (like Ascension) attempting to standardize practice, state-specific compounding policies and metrics would need to be established for MI sites. Also, for MI

		pharmacies licensed outside of the state (e.g. home infusion), other states may not accept sterile products from MI pharmacies, which would result in a loss of business. Most recognized training programs (e.g. ASHP) will update their training and resources to reflect current USP standards, which will result in confusion for pharmacists licensed in the state of Michigan and both in-state and out-of-state pharmacy students/residents being trained at MI facilities. The current rule mandates compliance with United States Pharmacopeia (USP) 795 and 797 to versions revised in 2014 and 2008, respectively. We understand there is a new version of USP effective November 2023. USP needed to update the chapters because there are inconsistencies between the existing chapters and other chapters they have been updated. For example, we are required to follow USP to handle hazardous medications and several conflicts exist between chapters 800 and 797. The Joint Commission will require compliance with the new standards, and it will be impossible to be compliant with both the old and the new standards simultaneously. Comment: USP 795 and 797 (2022 revisions are set to be implemented on 11-1-23, has this been taken into account? Remove "not limited to." Suggested Revision: Do not specify the revision dates for USP 795 and 797 in R 338.533(1). Adopt "current compendial chapters of USP 795 and 797"
	Medina	**Adopt new USP standards not old standards**. Adopting old standards are putting your patient population, and even the livelihood of your Compounding pharmacists on the line. If you are specifically stating in law that your standards for compounding will be based on the old rules, as a Board of Pharmacy you are willfully stating that increased protection for the public as a whole is not a vital concern. For years now stakeholders have been meeting to discuss the revisions to USP 797. These revisions are now final and serve as the benchmark for any compounding pharmacist in the country as a gold

		standard. If you are going to hold your pharmacies to an outdated standard, what will happen to them when they pursue JCAHO, ACHC, or URAC accreditation? Failing those could mean loss of business. That aside, if you hold pharmacies to less than the standard, what will the board be saying to the public at large should harm come to them as a result of this? What would happen to the business or Pharmacist in charge if the FDA decides to come into a 503a pharmacy and sees way less than they should be seeing as a result of this law? I urge you as a Board of Pharmacy to reconsider your language on this. Remove your specificity to the old years and just state the Board will uphold the most current revisions to the USP standards as they come. Not doing this could have dramatic consequences for your pharmacists and your people.
Section (1)	Young	Adopt updated versions of USP with the exception of flavoring. Also address the range for monitoring relative humidity in cleanrooms.
Section (1)	Tharp, Herz	Suggest deleting the chapter version dates from USP 795 and 797 and add a statement to allow the Michigan Board of Pharmacy to adopt the revised versions of USP chapters, and to early adopt before the official date if so recommended by USP. Additionally, I recommend that revisions to cGMP standards be allowed for outsourcing facilities. Change as follows: 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, Maryland~~,~~ 20852-1790. This includes, but is not limited to, USP Chapters 795 and 797. *Revisions to USP chapters shall be adopted by the official date or earlier as encouraged by USP, unless otherwise stated by the Board.* The 2023 revisions to the Pharmacy-General Rules that restrict the applicable compounding standards to fixed version dates will result in o disparities with standards adherence for pharmacies and outsourcing facilities that are

		surveyed/inspected for out-of-state licenses, federal entities (FDA, CMS, etc) and other accrediting agencies who will update their evaluation criteria to be aligned with revised USP standards. o licensees will also find it difficult to obtain continuing education that aligns with past versions of USP and may become confused by learning opportunities that reflect the revised standards. USP chapters are periodically revised to reflect changing expert consensus and scientific advancements. The chapter revisions are led by expert committees made up of individuals with significant expertise in the field and also include FDA representatives. Revisions undergo public comment period review and subsequent revisions. Chapter revisions are generally released 6-12 months before their official dates. USP provides guidance about their recommendations if the revised chapters should be early adopted. In the case of the 2022 revisions of USP 797/795, USP encouraged compounders to early adopt the chapters.
Section (1)	Frank Young	Should USP 800 be mentioned to make it clear that it will be required noting that all the chapters referenced in 795 and 797 are not specifically listed in the rules. Should USP 800 be adopted for only pharmacies that are compounding or all pharmacies to protect pharmacy personnel? Should USP 800 be included?
Section (2)	Bickel, Foumia, Herz, Tharp, Young	USP no longer provides free copies of compounding chapters. Pharmacies and licensees must purchase or subscribe to USP to gain access the chapters. Modify: The standards adopted by reference in subrule (1) of this rule are available for purchase at http://www.usp.org/compounding, or at a cost of 10 cents per page 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, Michigan, 48909.
Section (3)	Herz, Tharp	The use of the phrase “current standards” is in conflict with the proposed fixed versions of USP being proposed in subrule (1) of this rule. I support leaving “current standards” in this sentence if my proposed changes to subrule (1) are adopted, or change to: (3) *A pharmacy that provides compounding services shall comply with all **applicable** current standards adopted in subrule (1) of this rule.*

Section (4)	Herz, Tharp	It may not be possible for an outsourcing facility to coordinate an FDA inspection before applying for a pharmacy license in the state if they are operating within the state of Michigan. Consider aligning this standard with the Sterile Compounding Pharmacy Licensing requirement in R 338.534a (2), An applicant for an in-state pharmacy license that intends to compound sterile pharmaceutical products shall complete both of the following: (a) Obtain an inspection from the department or its designee for the purpose of meeting R 338.536 and R 338.537 for initial licensure. (b) Within 6 months after initial licensure under this subrule, a pharmacy shall obtain, and provide to the department, a subsequent inspection to assess *adherence to cGMP*. Modify (4) An outsourcing facility located in this state or that dispenses, provides, distributes, or otherwise furnishes compounded pharmaceuticals in this state **shall** ~~must~~ be inspected and registered as an outsourcing facility by the ~~United States Food and Drug Administration (~~FDA~~)~~ ~~prior to~~ **before** applying for a pharmacy license in this state.
Section (6)(b)	Herz, Smiddy, Tharp	I recommend that revisions to cGMP standards be allowed for outsourcing facilities. Suggest deleting a fixed reference date (year) to cGMP standards: *(b) Compound drugs ~~pursuant to~~**under** current good manufacturing practices for finished pharmaceuticals set forth in 21 CFR 211.1 to 211.208.*
Rules Committee Response	(1): The Rules Committee agrees with the comments to adopt the updated USP versions of 795 and 797. The Code already includes a process for adopting modifications to the USP if the change occurs after rules are adopted, and the Administrative Code requires that a specific version of the standards be adopted in the rules. The Rules Committee recommends adopting the 2023 version of 795 and 797 with the exception of flavoring. The Rules Committee did not determine a specific range for monitoring relative humidity in cleanrooms. This range will be determined by the full Board. (1): The Rules Committee does not recommend that the Board separately adopt USP 800 before it is official. However, the provisions that are adopted in USP 795 and 797 are effective in November as they are part of the chapters that are being adopted by the Board. (2): The Rules Committee agrees that the rule should state that there is a cost associated with obtaining the USP and that the Department can't provide copies to the public as pharmacies and licensees must purchase or subscribe to USP to gain access the chapters.	

	(3): (4): The Rules Committee agrees with the comment that there is a need for a two-step process for licensing outsourcing facilities that practice in this state. (6)(b): The Rules Committee agrees with the comment to delete the year in the citation and simply adopt the current version and as amended.

Board Response	

R 338.533 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, Maryland~~,~~ 20852-1790. This includes, but is not limited to, USP Chapters 795 ~~**(revised 2014)**~~ and 797 ~~**(revised 2008)**~~**(revised 2023)**.

(2) The standards adopted by reference in subrule (1) of this rule are available at ~~no~~ **a** cost **of** _____ at http://www.usp.org/compounding~~, or at a cost of 10 cents per page 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, Michigan, 48909~~.

(3) A pharmacy that provides compounding services shall comply with all **applicable** 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 compounded pharmaceuticals in this state **shall** ~~must~~ be inspected and registered as an outsourcing facility by the ~~United States Food and Drug Administration (~~FDA.~~)~~ ~~prior to~~ **before** applying for a pharmacy license in this state.

(5) An applicant for an in-state pharmacy license that intends to compound sterile pharmaceutical products shall complete both of the following:

(a) Obtain an inspection from the department or its designee for the purpose of meeting R 338.536 and R 338.537 for initial licensure.

(b) Within 6 months after initial licensure under this subrule, a pharmacy shall obtain, and provide to the department, a subsequent inspection to assess adherence to the current and as amended good manufacturing practices for finished pharmaceuticals set forth in 21 CFR 211.1 to 211.208.

(~~5~~**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.

(~~6~~**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~~**under** current **and as amended** good manufacturing practices for finished pharmaceuticals set forth in 21 CFR 211.1 to 211.208 (~~2021~~**2022**).

(c) Ensure that a pharmacist who conducts or oversees compounding at an outsourcing facility is proficient in the practice of 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 **and compounded drugs that are patient specific in compliance with the requirements in R 338.582 and** ~~with all of the following and label compounded drugs that are patient specific with~~ **include** 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 compounding meet specified FDA criteria.

(~~7~~**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.

Rule 338.534a In-state initial pharmacy license inspections.

Rule Numbers	Commenter	Comment
Section (5)	King	An in-state pharmacy that will compound sterile pharmaceutical products will have a two-step inspection process that requires an inspection from the department and, within 6 months, an inspection to assess USP compliance or accreditation. - We all understand that there is not complete alignment in rules between the State of Michigan and USP compliance. In the many areas that rules are conflicting, which source would prevail? In any situation where the expectation that the State of Michigan rule were to be followed as opposed to USP, any Joint Commission accreditation would be in immediate noncompliance for not conforming with USP standards. - Additional burden of record keeping and standard compliance with having to maintain two

		separate sterile compounding surveys - From a safety perspective, I would suggest that compliance with the USP standards are sufficient to attain sterile compounding compliance. - A suggestion would be to consider the dual inspection for any site that previously failed inspection by the accrediting body as the first path back towards compliance with sterile compounding standards.
	Belding	We believe the second inspection is redundant as we are required to have all rooms and hoods certified semi-annually as well as conducting monthly testing for surface growth. The standards for an IV room are far stricter than other sterile areas, like surgery.
Rules Committee Response	The Rules Committee does not agree with the comments to modify the two-step process for an in-state initial pharmacy license as the change is being recommended because pharmacies stated they could not meet the requirements as written.	

Board Response	

R 338.534a In-state initial pharmacy license inspections.

Rule 34a. (1) An in-state pharmacy that will not compound sterile pharmaceutical products that is applying for initial licensure shall be inspected by the department or its designee before licensure.

(2) An applicant for an in-state pharmacy license that intends to compound sterile pharmaceutical products shall complete both of the following:

(a) Obtain an inspection from the department or its designee for the purpose of meeting R 338.536 and R 338.537 for initial licensure.

(b) Within 6 months after initial licensure under this subrule, a pharmacy shall obtain, and provide to the department, a subsequent inspection to assess USP compliance or achieve accreditation from 1 of the entities listed in R 338.534(2)(a) to (c).

(3) Approval to engage in sterile compounding will end 6 months after initial licensure if a subsequent inspection to assess USP compliance or accreditation is not successful.

Rule 338.537 Professional and technical equipment and supplies.

Rule Numbers	Commenter	Comment
Section (1)(b)	Young	Update (1)(b): *Most recent printed, and or unabridged computerized versions of the Michigan pharmacy laws and rules, plus at least 2 comprehensive pharmaceutical reference text(s). Which*

		will encompass the general practice of pharmacy that pertains to pharmacology, drug interactions, drug composition, or other information necessary for the delivery of safe and effective practice of pharmacy.
Section (5)	Baran	The rule needs clarification regarding the sink as proposed a bucket could be used to collect the effluent draining from the sink. Most pharmacies now have frozen vaccines in inventory as well as refrigerated pharmaceuticals, including both prescription and over the counter drugs. Vaccine storage practice standards are given by the Centers for Disease Control (CDC) as well as Michigan Department of Health and Human Service, Division of Immunization. Telephone needs further clarification. Is the phone requirement a separate land line with the capacity to accept fax prescriptions, or can it be a cell phone that is carried by the pharmacist? Should there be a requirement for a type of telephone system (VoIP system, PBX, or multi-line system). Change to: (2) In addition to subrule (1) of this rule, a pharmacy that dispenses drugs shall maintain, at a minimum, all of the following equipment: *(a) A functioning sink of adequate capacity, connected to running cold and hot water, with sanitary drainage.* *(b) A purpose-built or pharmaceutical-grade unit designed to either refrigerate or freeze, if frozen drugs are in the pharmacies inventory. Personal or food items must not be stored in the refrigerator or freezer. The units must be capable of maintaining temperature within a range compatible with the proper storage of drugs requiring refrigeration or freezing. Temperatures must be monitored at all times.* *(c) A telephone or telephone system that is HIPAA compliant for the exclusive use of the pharmacy.*
Rules Committee Response	(1)(b): The Rules Committee agrees that the language should be updated to include computerized versions. (5): The Rules Committee does not agree that the language in (5) needs further regulatory details as the regulations are sufficient to protect the public.	

Board Response	

R 338.537 Professional and technical equipment and supplies.

Rule 37. **(1)** A pharmacy ~~must~~ **shall** be equipped with both of the following:

(a) The necessary facilities, apparatus, utensils, and equipment to **allow** ~~permit~~ the pharmacy to provide prompt and efficient services.

(b) Current print, electronic, or ~~internet accessible~~**unabridged computerized versions**~~editions~~ of the ~~Michigan~~ pharmacy laws and rules **of this state**, and ~~at least~~**not less than** 2 current pharmacy reference texts that pertain to pharmacology, drug interactions, or drug composition**, or other information necessary for the delivery of safe and effective practice of pharmacy**.

(2) In addition to subrule (1) of this rule, a pharmacy that dispenses drugs shall maintain, at a minimum, all of the following equipment:

(a) A sink with running water.

(b) A refrigerator for the exclusive use of prescription drugs. Personal or food items must not be stored in the refrigerator. Refrigeration must be capable of maintaining temperature within a range compatible with the proper storage of drugs requiring refrigeration or freezing. Temperatures must be monitored at all times for out-of-range temperatures during business closure.

(c) A telephone.

Rule 338.538 Closing pharmacy.

Rule Numbers	Commenter	Comment
Section (1)	Foumia	Pharmacies are now allowed to print and download copies of their pharmacy licenses. I don't think it is necessary to have closed pharmacies return these licenses as many times they are not even originally printed by the department. Agree ask licensing.
Rules Committee Response	The Rules Committee agrees with the comment that the license does not need to be returned to the Department..	

Board Response	

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~~ provide the department with written notification of all of the following ~~at least~~**not less than** 15 days ~~prior to~~ **before** closing:

(a) The effective date of closing.

(b) How controlled substances will be disposed.

(c) How non-controlled substances will be disposed.

(d) The location where records and prescription files will be stored.

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

(3) Records must be maintained for the same amount of time that is required if the pharmacy remained open.

Rule 338.555 Federal regulation on good manufacturing practice for finished pharmaceuticals; adoption by reference; compliance.

Rule Numbers	Commenter	Comment
Section (1)	Roath, McCloskey, Whitefield,	Remove the 2021 revision date for cGMP in R 338.555 (1), but do not replace it with the 2022 date.
Section (1)	Tharp, Herz	Suggest deleting a fixed reference date (year) to cGMP standards:
Rules Committee Response	The Rules Committee agrees with the comment to delete the year in the citation and simply adopt the current version and as amended.	

Board Response	

R 338.555 Federal regulation on good manufacturing practice for finished pharmaceuticals; adoption by reference; compliance.

Rule 55. (1) The board approves and adopts by reference the current **and as amended** good manufacturing practice for finished pharmaceuticals regulations set forth in 21 CFR 211.1 to 211.208 ~~(2021~~**2022**~~)~~.

(2) A manufacturer shall comply with the standards adopted in subrule (1) of this rule.

(3) The standards adopted by reference in subrule (1) of this rule are available at no cost at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=211, or at 10 cents per page 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, Michigan~~,~~ 48909.

Rule 338.569 Wholesale distributor and wholesale distributor-broker recordkeeping and policy requirements.

Rule Numbers	Commenter	Comment
Section (1)(d)	Baran	Rule lacks the requirement to maintain information required by the drug supply chain security act. Add: *(d) All information required under the drug supply chain security act, Public Law 113-54.*
Rules Committee Response	The Rules Committee does not agree with the comment to reference the Drug Supply Chain Security Act, as federal law must be followed.	

Board Response	

R 338.569 Wholesale distributor and wholesale distributor-broker recordkeeping and policy requirements.

Rule 69. (1) A wholesale distributor shall establish and maintain inventories and records of transactions regarding the receipt, if applicable, and the distribution or other disposition of prescription drugs or devices. These records must include all of the following information:

(a) The source of the prescription drugs or devices, including the name and principal address of the seller or transferor and the address from which the prescription drugs or devices were shipped.

(b) The identity and quantity of the prescription drugs or devices received, if applicable, and distributed or disposed of.

(c) The dates of receipt, if applicable, and distribution of the prescription drugs or devices.

(2) A wholesale distributor shall establish and maintain a list of officers, directors, managers, and other **individuals** ~~persons~~ who are in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(3) A wholesale distributor shall have written policies and procedures that include all of the following:

(a) A procedure where~~by~~ the oldest stock of a prescription drug is distributed first. The procedure may ~~permit~~ **allow** deviation from this requirement if the deviation is temporary and appropriate.

(b) A procedure for handling recalls and withdrawals of the prescription drugs or devices. The procedure must deal with recalls and withdrawals due to any of the following:

(i) Any action initiated at the request of the FDA; other federal, state, or local law enforcement agency; or other governmental agency.

(ii) Any voluntary action by the manufacturer to remove defective or potentially defective prescription drugs or devices from the market.

(iii) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

(c) A procedure to ensure that a wholesale distributor prepares for, protects against, and handles~~,~~ any crises that affects security or operation of any facility**, including** ~~in the event of~~ employee strike, flood, fire, or other natural disaster, or other local, state, or national emergency.

(d) A procedure to ensure that any outdated prescription drugs or devices **are** ~~will be~~ segregated from other prescription drugs or devices and either returned to the manufacturer or destroyed. This procedure must include a provision for the written documentation of the disposition of outdated prescription drugs or devices that must be maintained for 2 years after the disposition of the outdated prescription drugs or devices.

(e) Procedures for identifying, recording, and reporting losses or thefts of prescription drugs or devices and for correcting errors and inaccuracies in inventory.

(4) A wholesale distributor-broker shall establish and maintain a list of officers, directors, managers, and other **individuals** ~~persons~~ who are in charge of wholesale drug delivery and trade, including a description of their duties and a summary of their qualifications.

(5) A wholesale distributor-broker shall maintain for ~~at least~~**not less than** 7 years the transaction history, transaction statements, and transaction information required by section 17748e of the code, MCL 333.17748e.

(6) The records described in subrules (1) to (5), and (8) of this rule and section of 17748e of the code, MCL 333.17748e, must be made available for inspection and photocopying by the department, board, authorized federal, state, or local law enforcement agency officials. The records that are **maintained** ~~kept~~ on-site or that are immediately retrievable by computer or other electronic means must be readily available for an authorized inspection during the retention period described in subrules (5) and (7) of this rule. Records that are **maintained** ~~kept~~ at a central location apart from the site must be made available for inspection within 2 working days ~~of~~**after** a request.

(7) A wholesale distributor shall retain the records described in this rule for a minimum of 2 years after the disposition of the prescription drugs or devices.

(8) A purchasing pharmacy using a wholesale distributor-broker to facilitate a transaction from a pharmacy that is not licensed in **this state** ~~Michigan~~ shall request the transaction history, transaction statement**,** or transaction information for the drugs supplied.

Rule 338.583a Pharmacy acquisition and distribution records.

Rule Numbers	Commenter	Comment
Section (1)	Baran	It places a burden on pharmacies that sell non-prescription drugs that it doesn't place on other retailers that sell non-prescription drugs that are not a pharmacy. It doesn't require the retailer to keep the records for non-prescription drugs as it does the pharmacy. This will increase cost for pharmacies. Delete "*and non-prescription*" from (1).
Section (1)	Baran	Also, rule 383.583a conflicts with the Pharmacy controlled substance rule 338.3153(k). The controlled substance rule states "Except for controlled substance prescriptions pursuant to subdivision (h) of this rule, a licensee shall maintain controlled substances records for 2 years." **(Note that the CS rule has been modified in the proposed rules;** **Sales receipts and dispensing records – 90 days** **Prescription record - 5 years, after 2 years may make an electronic duplicate** This rule also conflicts with Rule 338.3154(5) "If a controlled substance is dispensed from an automated device, then documentation of all of the following must be maintained on-site in the pharmacy responsible for the automated device for 2 years for review by the department, an agency, or the board:" So this would mean noncontrolled acquisition and distribution records would have to be kept for 5 years whereas controlled substance records, other than prescriptions need only be retained for 2 years." This will cause confusion and uncertainty. Change rule 338.583a(1) to: *Except for prescriptions, ~~a~~**A** pharmacy ~~must~~ **shall** keep and make available for inspection all acquisition and distribution records for prescription ~~and non-prescription~~ drugs and devices, ~~such as~~**including** invoices, packing slips or receipts, for **2** ~~5~~ years. All records, which may be electronic, must be readily retrievable within 48 hours.*
Rules Committee Response	(1): The Rules Committee agrees with the comment to delete non-prescription. (1): As R 383.3153(k) has been modified in the CS rules, no change is necessary. However, R 338.3154(5) in the CS rules is also inconsistent with these rules and should be modified.	

Board Response	

R 338.583a Pharmacy acquisition and distribution records.

Rule 83a. (1) A pharmacy ~~must~~ **shall** keep and make available for inspection all acquisition and distribution records for prescription ~~and non-prescription~~ drugs and devices, ~~such as~~**including** invoices, packing slips or receipts, for 5 years. All records, which may be electronic, must be readily retrievable within 48 hours.

(2) Acquisition and distribution records must include the following information:

(a) The source of the prescription drugs or devices, including the name and principal address of the seller or transferor and the address from which the prescription drugs or devices were shipped.

(b) The identity and quantity of the prescription drugs or devices received, if applicable, and distributed or disposed of.

(c) The dates of receipt, if applicable, and distribution of the prescription drugs or devices.

Rule 338.588 Automated devices.

Rule Numbers	Commenter	Comment
Modify CS rule for consistency with section (3)	Baran	This rule (3) requires records to be kept 5 years. Rule 338.3154 (CS) states "(5) If a controlled substance is dispensed from an automated device, then documentation of all of the following must be maintained on-site in the pharmacy responsible for the automated device for 2 years for review by the department, an agency, or the board:…." These two rules are inconsistent on how long to maintain the records. The CS rules, R 338.3154, is undergoing revision, recommend changing the time period in Rule 338.3154 to 5 years to maintain consistency.
Rules Committee Response	The Rules Committee agrees that the CS rules and General Rules should be consistent, however, the change should be made in the CS rules.	

Board Response	

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~~ **if** 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 **that term is** defined in section 20109~~(4)~~ of the code, MCL 333.20109.

(g) An office of a dispensing prescriber, **where the device is operated by the dispensing prescriber, not a pharmacy**.

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

(i) A location other than subdivisions (a) to (h) of this subrule, where the automated device acts as an extension of a pharmacy. In addition to the requirements in this rule, the automated device must meet the requirements in R 338.588a.

(~~7~~**3**) Records and electronic data ~~kept~~ **maintained** 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~~**4**) **Except for devices allowed under R 388.588a(2),** ~~Policy~~**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). **A pharmacist shall review the orders and authorize any further dispensing within 48 hours.**

(b) The system is being used in place of an emergency kit as provided in R 338.486(4)(c). **A pharmacist shall review the orders and authorize any further dispensing within 48 hours.**

(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. **A pharmacist shall review the orders and authorize any further dispensing within 48 hours.**

~~(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.~~

(~~c~~**d**) The automated device is located in a dispensing prescriber's office **to facilitate dispensing by the dispensing prescriber**.

(~~9~~**5**) 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.

Rule 338.588a Automated devices in non-inpatient settings.

Rule Numbers	Commenter	Comment
	Smiddy	Please define and clarify areas of impact. The MHA recommends using definitions such as, outpatient clinics, infusion centers, etc., rather than the term non-inpatient settings.
	Foumia	Does automated device need to be defined?
Section (1)(a)	Roath, Dehoorne	MPA advocates for removing the restriction that automated devices only be used to deliver non-controlled drugs in subsection (1)(a). Current technology allows for the capture of positive identification of a patient at the point of dispensing via an automated device. We suggest that rather than prohibit dispensing controlled medications via an automated device, the board introduces language requiring positive verification of a patient's ID at the point of delivery. Modify to: **The automated device may ~~only deliver non-controlled drugs~~ *not be used to deliver controlled substances.***
	Smiddy	The MHA recommends striking R 338.588a or updating to the suggested language above.
Section (1)(b)	Roath Dehoorne	Additionally, MPA advocates for removing the limitation prohibiting a remote pharmacy from operating an automated device in subsection (1)(b). If a pharmacist is available, as required by subsection (1)(c), and a pharmacist may be available for real-time consult in subsection (1)(f), then a remote pharmacy should be permitted to operate an automated device. Further, the added safety features implemented by an automated device stocked and maintained by a pharmacist will enhance the safe delivery of medications in a remote pharmacy.

	Dehoorne	Remove(b) the restriction that automated devices can only be used to deliver non-narcotics.
Section (1)(c)	Smiddy	The MHA has received direct feedback from hospitals that this section is unclear and they're not sure this would apply to their non-inpatient units. Would the pharmacist need to be onsite, available by phone or virtually?
Section (1)(d)	Smiddy	Please clarify 'privacy enabled', is the intent to ensure patient privacy? If patient privacy is the intent, the MHA recommends clarifying language that ensures the privacy of the end-user.
Section (1)(e)	Smiddy	Please clarify if this would be in-addition to the dispensing pharmacy. For non-inpatient settings within a hospital, would this be satisfied by a room number if the dispensing pharmacy and automated device share the same address.
Section (1)(f)	Smiddy	The MHA suggests combining (f) and (c) subsections.
Section (1)(g)	Smiddy	Please clarify who the department is?
Section (2)(b)	Smiddy	Please clarify if acute care hospitals, critical access hospitals, specialty hospitals, inpatient psychiatric facilities, etc. are excluded from R 338.588a 2(b).
Section (2)(b)	Eid	CVS Health supports the Board's efforts to simplify and create access to care for non-dispensing storage and pick up devices. These efforts will continue to allow Michigan patients to access medications and join along 29 other states that have had jurisdictional successes in allowing this type of access. Furthermore, we recommend simplifying (2) by adding the word "*inside of*" after "device" as shown below and deleting the word "on", along with letter (b) for clarity and simplification. **(2) A pharmacy licensee may locate a non-dispensing storage and pick up device *inside of* ~~on~~ the premises of the pharmacy that is used for a patient or agent of the patient to pick up prescription medication if the pharmacy meets both of the following:** **(a) The automated device is secured, lockable, and privacy enabled.** **~~(b) The automated device is located on the inside of the premises of the licensed pharmacy.~~**
Section (3)	Roath	MPA advocates for parity in the requirements for automated devices operated by pharmacies and automated devices managed by dispensing prescribers. In addition to the recommended revisions noted below, if the Board believes it necessary to continue the prohibition of dispensing controlled substances from an automated device controlled by a pharmacy, a similar prohibition should be put in place for the offices of a dispensing prescriber.

		Suggested Revision: MPA recommends adding the following language: *(3)(d) The dispensing prescriber shall be available for the automated device to be operable.* *(e) The automated device is secured, lockable, and privacy enabled.* *(f) Prescriptions must contain a label that identifies the automated device where the medication was dispensed.*
Rules Committee Response	Automated device is already defined in the Code. (1)(a): The Rules Committee does not agree with the comment to allow CS drugs in automated devices as the DEA will only approve of CS drugs in automated devices in very narrow circumstances.	

Board Response	

R 338.588a Automated devices in non-inpatient settings.

Rule 88a. (1) A pharmacy that operates an automated device to deliver prescription medication directly to an ultimate user that is not included in R 338.588(2)(a) to (h) shall comply with all of the following requirements:

(a) The automated device may only deliver non-controlled drugs.

(b) The automated device is operated as an extension of a pharmacy, under the control of a pharmacist, however, a remote pharmacy may not operate an automated device.

(c) A pharmacist shall be available for the automated device to be operable.

(d) The automated device is secured, lockable, and privacy enabled.

(e) Prescriptions must contain a label that identifies the automated device where the medication was dispensed.

(f) A pharmacist shall be available to provide patient consultation through real-time audio and visual communication. The pharmacist may provide consultation from a remote location.

(g) Before the automated device is put into service, the pharmacy shall notify the department of the location of the automated device on a form provided by the department.

(h) Dispensing activities through the automated device must comply with all recordkeeping, drug utilization review, and patient counseling requirements that are applicable to a pharmacy.

(2) A pharmacy licensee may locate a non-dispensing storage and pick up device on the premises of the pharmacy that is used for a patient or agent of the patient to pick up prescription medication if the pharmacy meets both of the following:

(a) The automated device is secured, lockable, and privacy enabled.

(b) The automated device is located on the inside of the premises of the licensed pharmacy.

(3) If an automated device is used in a dispensing prescriber's office, and the automated device is not affiliated with a pharmacy, the device must be used only to dispense medications to the dispensing prescriber's patients and only under the control of the dispensing prescriber. All of the following apply to the use of an automated device in a dispensing prescriber's office:

(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 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.

Rule 338.588b Automated devices in medical institutions.

Rule Numbers	Commenter	Comment
Section (1)(a) and	Smiddy	The suggested modifications attempt to reduce confusion related if the pharmacist is the default

(b)	Dehoorne	standard for stocking the automated device, since there is not an explicit language referencing stocking by a pharmacist. Above statements reference 'controlled by a pharmacy', not controlled by a pharmacist. Currently there is confusion as to who stocking may be delegated to. Modify to: (1) **An automated device used by staff to *~~administer~~* store medications *~~to registered patients~~* intended for patient administration in any hospital, county medical care facility, nursing home, hospice, or another skilled nursing facility, as defined in section 20109(4) of the code, MCL 333.20109, must comply with all of the following:** **(a) The automated device must be *~~supplied~~* stocked, maintained, and controlled by a pharmacy that is licensed in this state.** **(b) If *~~a pharmacist delegates~~* the stocking of the automated device is performed by non pharmacist personnel, 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.**
Rules Committee Response		

Board Response	

R 338.588b Automated devices in medical institutions.

Rule 88b. (1) An automated device used by staff to administer medications to registered patients in any hospital, county medical care facility, nursing home, hospice, or another skilled nursing facility, as that term is defined in section 20109 of the code, MCL 333.20109, must comply with all of the following:

(a) The automated device must be supplied and controlled by a pharmacy that is licensed in this state.

(b) If a pharmacist 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 bar-coding or another board-approved error-prevention technology that complies with R 338.3154.

(c) 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.

(d) 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 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.

(2) An automated device that is operated at a location affiliated with a hospital, but not at the same physical address as the pharmacy, which is owned and operated by the hospital, must comply with section 17760 of the code, MCL 333.17760.

Rule 338.589 Professional responsibility; patient counseling; "caregiver" defined.

Rule Numbers	Commenter	Comment
Section (5)	Baran	A technician at a remote pharmacy is not under the personal charge of a pharmacist. Add to (5) Pharmacist delegation of acts, tasks, or functions shall be in compliance must comply with section 16215 of the code, MCL 333.16215, and be under the personal charge of the delegating pharmacist, except as provided in R 338.486 *and 17742b of the code MCL 333.17742b*. A pharmacist who that delegates acts, tasks, or functions to a licensed or unlicensed individual person shall do all of the following:……..

Section (2)	Young	There is a line in the word “prescription.”
Section (5)	Young	Add the exception for pharmacy technicians doing remote work for performing certain prescription processing functions as allowed in the proposed Pharmacy Technician rules, if the pharmacy establishes controls to protect the privacy and security of confidential records.
Section (5)	Young	Add ability for the licensed Pharmacist to access pharmacy database from home or other remote location for remote order entry verification including performing a drug regimen review. If the pharmacy establishes controls to protect the privacy and security of confidential records.
Rules Committee Response		

Board Response	

R 338.589 Professional responsibility; **patient counseling;** “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~~ **may** 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~~**when** 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~~ **determines** 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~~ **must comply** with section 16215 of the code, MCL 333.16215, and **be** under the personal charge of the delegating pharmacist, except as provided in R 338.486. A pharmacist ~~who~~ **that** delegates acts, tasks, or functions to a licensed or unlicensed **individual** ~~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~~ **determine whether** ~~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**s** the ultimate responsibility for the performance of delegated acts, tasks, and functions performed by the delegatee within the scope of the delegation.

Rule 338.591 Dispensing emergency supply of insulin.

Rule Numbers	Commenter	Comment
Section (1)(c)	Baran	Remove typo at end of sentence.
Add Section (d)	Roath	MPA recommends the addition of language to clarify that although an emergency supply of insulin may only be dispensed once per qualified prescription, this does not change the ability of a pharmacy to issue three such emergency supplies per patient per year (MCL 333.17744f (2)). Add: *(d) A pharmacist may dispense an emergency supply of insulin for up to three qualified*

		prescriptions within a calendar year for an individual patient.
Section (1)	Apple, Blake, Dehoorne, Guzzardo, ThomasF	Change to also include insulin analogs Rationale: Since many patients are prescribed insulin analogs (e.g. lispro, aspart), adding this language would clarify that the emergency supply also pertains to these agents.
Rules Committee Response		

Board Response	

R 338.591 Dispensing emergency supply of insulin.

Rule 91. (1) A pharmacist may dispense an emergency supply of insulin to an individual if the pharmacist complies with all of the following:

(a) The requirements in section 17744f of the code, MCL 333.17744f.

(b) An emergency supply of insulin may only be dispensed from a pharmacy with real time access to the qualified prescription for insulin.

(c) Only 1 emergency supply, as that term is defined in MCL 333.17744f, may be dispensed per qualified prescription.~~0~~

(2) If the smallest single package of insulin available exceeds a 30-day supply, dispensing the package of insulin that is available complies with this rule and section 17744f of the code, MCL 333.17744f.